USA

Regulation for Food Additives and Contaminants & Residues

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농림축산식품부

한국농수산식품유통공사
Korea Agro-Fisheries & Food Trade Corporation

CONTENTS

I. FOOD ADDITIVES

CONTENTS

CONTENTS

II. Toxic Substance

Food Additives

Regulation

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SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 170—FOOD ADDITIVES

Subpart A—General Provisions

Subpart B—Food Additive Safety

Subpart C—Specific Administrative Rulings and Decisions

Subpart D—Premarket Notifications

Subpart E—Generally Recognized as Safe (GRAS) Notice

AUTHORITY: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

SOURCE: 42 FR 14483, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 170 appear at 66 FR 56035, Nov. 6, 2001, and 69 FR 13717, Mar. 24, 2004.

Subpart A—General Provisions

§ 170.3 Definitions.

For the purposes of this subchapter, the following definitions apply:

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 301–392).

(e)(1) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. ''Affecting the characteristics of food'' does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(2) *Uses of food additives not requiring a listing regulation.* Use of a substance in a food contact article (e.g., food-packaging or food-processing equipment) whereby the substance migrates, or may reasonably be expected to migrate, into food at such levels that the use has been exempted from regulation as a food additive under §170.39, and food contact substances used in accordance with a notification submitted under section 409(h) of the act that is effective.

(3) *A food contact substance* is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

(f) *Common use in food* means a substantial history of consumption of a substance for food use by a significant number of consumers.

(g) The word *substance* in the definition of the term ''food additive'' includes a food or food component consisting of one or more ingredients.

(h) *Scientific procedures* include the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

(2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

(j) The term *nonperishable processed food* means any processed food not subject to rapid decay or deterioration that would render it unfit for consumption. Examples are flour, sugar, cereals, packaged cookies, and crackers. Not included are hermetically sealed foods or manufactured dairy products and other processed foods requiring refrigeration.

(k) *General recognition of safety* shall be in accordance with §170.30.

(l) *Prior sanction* means an explicit approval granted with respect to use of a substance in food prior to September

6, 1958, by the Food and Drug Administration or the United States Department of Agriculture pursuant to the Federal Food, Drug, and Cosmetic Act, the Poultry Products Inspection Act, or the Meat Inspection Act.

(m) *Food* includes human food, substances migrating to food from food-contact articles, pet food, and animal feed.

(n) The following general food categories are established to group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients. Individual food products will be included within these categories according to the detailed classifications lists contained in Exhibit 33B of the report of the National Academy of Sciences/National Research Council report, ''A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe'' (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Baked goods and baking mixes, including all ready-to-eat and ready-to-bake products, flours, and mixes requiring preparation before serving.

(2) Beverages, alcoholic, including malt beverages, wines, distilled liquors, and cocktail mix.

(3) Beverages and beverage bases, nonalcoholic, including only special or spiced teas, soft drinks, coffee substitutes, and fruit and vegetable flavored gelatin drinks.

(4) Breakfast cereals, including ready-to-eat and instant and regular hot cereals.

(5) Cheeses, including curd and whey cheeses, cream, natural, grating, processed, spread, dip, and miscellaneous cheeses.

(6) Chewing gum, including all forms.

(7) Coffee and tea, including regular, decaffeinated, and instant types.

(8) Condiments and relishes, including plain seasoning sauces and spreads, olives, pickles, and relishes, but not spices or herbs.

(9) Confections and frostings, including candy and flavored frostings, marshmallows, baking chocolate, and brown, lump, rock, maple, powdered, and raw sugars.

(10) Dairy product analogs, including nondairy milk, frozen or liquid creamers, coffee whiteners, toppings, and other nondairy products.

(11) Egg products, including liquid, frozen, or dried eggs, and egg dishes made therefrom, i.e., egg roll, egg foo young, egg salad, and frozen multicourse egg meals, but not fresh eggs.

(12) Fats and oils, including margarine, dressings for salads, butter, salad oils, shortenings and cooking oils.

(13) Fish products, including all prepared main dishes, salads, appetizers, frozen multicourse meals, and spreads containing fish, shellfish, and other aquatic animals, but not fresh fish.

(14) Fresh eggs, including cooked eggs and egg dishes made only from fresh shell eggs.

(15) Fresh fish, including only fresh and frozen fish, shellfish, and other aquatic animals.

(16) Fresh fruits and fruit juices, including only raw fruits, citrus, melons, and berries, and home-prepared ''ades'' and punches made therefrom.

(17) Fresh meats, including only fresh or home-frozen beef or veal, pork, lamb or mutton and home-prepared fresh meat-containing dishes, salads, appetizers, or sandwich spreads made therefrom.

(18) Fresh poultry, including only fresh or home-frozen poultry and game birds and home-prepared fresh poultry-containing dishes, salads, appetizers, or sandwich spreads made therefrom.

(19) Fresh vegetables, tomatoes, and potatoes, including only fresh and home-prepared vegetables.

(20) Frozen dairy desserts and mixes, including ice cream, ice milks, sherbets, and other frozen dairy desserts and specialties.

(21) Fruit and water ices, including all frozen fruit and water ices.

(22) Gelatins, puddings, and fillings, including flavored gelatin desserts,

puddings, custards, parfaits, pie fillings, and gelatin base salads.

(23) Grain products and pastas, including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables.

(24) Gravies and sauces, including all meat sauces and gravies, and tomato, milk, buttery, and specialty sauces.

(25) Hard candy and cough drops, including all hard type candies.

(26) Herbs, seeds, spices, seasonings, blends, extracts, and flavorings, including all natural and artificial spices, blends, and flavors.

(27) Jams and jellies, home-prepared, including only home-prepared jams, jellies, fruit butters, preserves, and sweet spreads.

(28) Jams and jellies, commercial, including only commercially processed jams, jellies, fruit butters, preserves, and sweet spreads.

(29) Meat products, including all meats and meat containing dishes, salads, appetizers, frozen multicourse meat meals, and sandwich ingredients prepared by commercial processing or using commercially processed meats with home preparation.

(30) Milk, whole and skim, including only whole, lowfat, and skim fluid milks.

(31) Milk products, including flavored milks and milk drinks, dry milks, toppings, snack dips, spreads, weight control milk beverages, and other milk origin products.

(32) Nuts and nut products, including whole or shelled tree nuts, peanuts, coconut, and nut and peanut spreads.

(33) Plant protein products, including the National Academy of Sciences/National Research Council ''reconstituted vegetable protein'' category, and meat, poultry, and fish substitutes, analogs, and extender products made from plant proteins.

(34) Poultry products, including all poultry and poultry-containing dishes, salads, appetizers, frozen multicourse poultry meals, and sandwich ingredients prepared by commercial processing or using commercially processed poultry with home preparation.

(35) Processed fruits and fruit juices, including all commercially processed fruits, citrus, berries, and mixtures; salads, juices and juice punches, concentrates, dilutions, ''ades'', and drink substitutes made therefrom.

(36) Processed vegetables and vegetable juices, including all commercially processed vegetables, vegetable dishes, frozen multicourse vegetable meals, and vegetable juices and blends.

(37) Snack foods, including chips, pretzels, and other novelty snacks.

(38) Soft candy, including candy bars, chocolates, fudge, mints, and other chewy or nougat candies.

(39) Soups, home-prepared, including meat, fish, poultry, vegetable, and combination home-prepared soups.

(40) Soups and soup mixes, including commercially prepared meat, fish, poultry, vegetable, and combination soups and soup mixes.

(41) Sugar, white, granulated, including only white granulated sugar.

(42) Sugar substitutes, including granulated, liquid, and tablet sugar substitutes.

(43) Sweet sauces, toppings, and syrups, including chocolate, berry, fruit, corn syrup, and maple sweet sauces and toppings.

(o) The following terms describe the physical or technical functional effects for which direct human food ingredients may be added to foods. They are adopted from the National Academy of Sciences/National Research Council national survey of food industries, reported to the Food and Drug Administration under the contract title ''A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe'' (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(1) *Anticaking agents and free-flow agents*: Substances added to finely powdered or crystalline food products to prevent caking, lumping, or agglomeration.

(2) *Antimicrobial agents*: Substances used to preserve food by preventing

growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under ''preservatives.''

(3) *Antioxidants*: Substances used to preserve food by retarding deterioration, rancidity, or discoloration due to oxidation.

(4) *Colors and coloring adjuncts*: Substances used to impart, preserve, or enhance the color or shading of a food, including color stabilizers, color fixatives, color-retention agents, etc.

(5) *Curing and pickling agents*: Substances imparting a unique flavor and/or color to a food, usually producing an increase in shelf life stability.

(6) *Dough strengtheners*: Substances used to modify starch and gluten, thereby producing a more stable dough, including the applicable effects listed by the National Academy of Sciences/National Research Council under ''dough conditioner.''

(7) *Drying agents*: Substances with moisture-absorbing ability, used to maintain an environment of low moisture.

(8) *Emulsifiers and emulsifier salts*: Substances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.

(9) *Enzymes*: Enzymes used to improve food processing and the quality of the finished food.

(10) *Firming agents*: Substances added to precipitate residual pectin, thus strengthening the supporting tissue and preventing its collapse during processing.

(11) *Flavor enhancers*: Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.

(12) *Flavoring agents and adjuvants*: Substances added to impart or help impart a taste or aroma in food.

(13) *Flour treating agents*: Substances added to milled flour, at the mill, to improve its color and/or baking qualities, including bleaching and maturing agents.

(14) *Formulation aids*: Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.

(15) *Fumigants*: Volatile substances used for controlling insects or pests.

(16) *Humectants*: Hygroscopic substances incorporated in food to promote retention of moisture, including moisture-retention agents and antidusting agents.

(17) *Leavening agents*: Substances used to produce or stimulate production of carbon dioxide in baked goods to impart a light texture, including yeast, yeast foods, and calcium salts listed by the National Academy of Sciences/National Research Council under ''dough conditioners.''

(18) *Lubricants and release agents*: Substances added to food contact surfaces to prevent ingredients and finished products from sticking to them.

(19) *Non-nutritive sweeteners*: Substances having less than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

(20) *Nutrient supplements*: Substances which are necessary for the body's nutritional and metabolic processes.

(21) *Nutritive sweeteners*: Substances having greater than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

(22) *Oxidizing and reducing agents*: Substances which chemically oxidize or reduce another food ingredient, thereby producing a more stable product, including the applicable effect listed by the National Academy of Sciences/National Research Council under ''dough conditioners.''

(23) *pH control agents*: Substances added to change or maintain active acidity or basicity, including buffers, acids, alkalies, and neutralizing agents.

(24) *Processing aids*: Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculents, filter aids, and crystallization inhibitors, etc.

(25) *Propellants, aerating agents, and gases*: Gases used to supply force to expel a product or used to reduce the amount of oxygen in contact with the food in packaging.

(26) *Sequestrants*: Substances which combine with polyvalent metal ions to

form a soluble metal complex, to improve the quality and stability of products.

(27) *Solvents and vehicles*: Substances used to extract or dissolve another substance.

(28) *Stabilizers and thickeners*: Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.

(29) *Surface-active agents*: Substances used to modify surface properties of liquid food components for a variety of effects, other than emulsifiers, but including solubilizing agents, dispersants, detergents, wetting agents, rehydration enhancers, whipping agents, foaming agents, and defoaming agents, etc.

(30) *Surface-finishing agents*: Substances used to increase palatability, preserve gloss, and inhibit discoloration of foods, including glazes, polishes, waxes, and protective coatings.

(31) *Synergists*: Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.

(32) *Texturizers*: Substances which affect the appearance or feel of the food.

[42 FR 14483, Mar. 15, 1977, as amended at 47 FR 11835, Mar. 19, 1982; 53 FR 16546, May 10, 1988; 54 FR 24896, June 12, 1989; 60 FR 36595, July 17, 1995; 67 FR 35729, May 21, 2002; 81 FR 55047, Aug. 17, 2016]

AUTHORITY: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

SOURCE: 42 FR 14491, Mar. 15, 1977, unless otherwise noted.

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Subpart A—General Provisions

§ 172.5 General provisions for direct food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purposes of this part, good manufacturing practice shall be defined to include the following restrictions.

(1) The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food.

(2) Any substance intended for use in or on food is of appropriate food grade and is prepared and handled as a food ingredient.

(b) The existence of a regulation prescribing safe conditions of use for a food additive shall not be construed to relieve the use of the substance from compliance with any other provision of the Act.

(c) The existence of any regulation prescribing safe conditions of use for a nutrient substance does not constitute a finding that the substance is useful or required as a supplement to the diet of humans.

Subpart B—Food Preservatives

§ 172.105 Anoxomer.

Anoxomer as identified in this section may be safely used in accordance with the following conditions:

(a) Anoxomer is 1,4-benzenediol, 2-(1,1-dimethylethyl)-polymer with diethenylbenzene, 4-(1,1-dimethylethyl)phenol, 4- methoxyphenol, 4,4′-(1-methylethylidene)bis(phenol) and 4-methylphenol (CAS Reg. No. 60837–57–2) prepared by condensation polymerization of divinylbenzene (*m*- and *p*-) with *tert*-butylhydroquinone, *tert*-butylphenol, hydroxyanisole, *p*-cresol and 4,4′-isopropylidenediphenol.

(b) The polymeric antioxidant meets the following specifications:

(1) Polymer, not less than 98.0 percent as determined by an ultraviolet method entitled ''Ultraviolet Assay, ''1982, which is incorporated by reference. Copies are available from the

Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(2) Molecular weight: Total monomers, dimers and trimers below 500 not more than 1 percent as determined by a method entitled ''Low Molecular Weight Anoxomer Analysis,'' 1982, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(3) Phenol content: Not less than 3.2 milliequivalent/gram and not more than 3.8 milliequivalent/gram as determined by a method entitled ''Total Phenols,'' 1982, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(4) Heavy metals as lead (as Pb), not more than 10 parts per million. Arsenic (as As), not more than 3 parts per million. Mercury (as Hg), not more than 1 part per million.

(c) Anoxomer may be safely used as an antioxidant in food at a level of not more than 5,000 parts per million based on fat and oil content of the food.

[48 FR 18798, Apr. 26, 1983, as amended at 54 FR 24896, June 12, 1989]

§ 172.110 BHA.

The food additive BHA (butylated hydroxyanisole) alone or in combination with other antioxidants permitted in food for human consumption in this subpart B may be safely used in or on specified foods, as follows:

(a) The BHA meets the following specification:

Assay (total BHA), 98.5 percent minimum. Melting point 48 °C minimum.

(b) The BHA is used alone or in combination with BHT, as an antioxidant in foods, as follows:

Food	Limitations (total BHA and BHT) parts per million
Dehydrated potato shreds	50
Active dry yeast	[1] 1,000
Beverages and desserts prepared from dry mixes	[1] 2
Dry breakfast cereals	50
Dry diced glazed fruit	[1] 32
Dry mixes for beverages and desserts	[1] 90
Emulsion stabilizers for shortenings	200
Potato flakes	50
Potato granules	10
Sweet potato flakes	50

[1] BHA only.

(c) To assure safe use of the additive:

(1) The label of any market package of the additive shall bear, in addition to the other information required by the Act, the name of the additive.

(2) When the additive is marketed in a suitable carrier, in addition to meeting the requirement of paragraph (c)(1) of this section, the label shall declare the percentage of the additive in the mixture.

(3) The label or labeling of dry mixes for beverages and desserts shall bear adequate directions for use to provide that beverages and desserts prepared from the dry mixes contain no more than 2 parts per million BHA.

§ 172.115 BHT.

The food additive BHT (butylated hydroxytoluene), alone or in combination with other antioxidants permitted in this subpart B may be safely used in or on specified foods, as follows:

(a) The BHT meets the following specification: Assay (total BHT) 99 percent minimum.

(b) The BHT is used alone or in combination with BHA, as an antioxidant in foods, as follows:

Food	Limitations (total BHA and BHT) parts per million
Dehydrated potato shreds	50
Dry breakfast cereals	50
Emulsion stabilizers for shortenings	200
Potato flakes	50
Potato granules	10
Sweetpotato flakes	50

(c) To assure safe use of the additive:

(1) The label of any market package of the additive shall bear, in addition to the other information required by the Act, the name of the additive.

(2) When the additive is marketed in a suitable carrier, in addition to meeting the requirement of paragraph (c)(1) of this section, the label shall declare the percentage of the additive in the mixture.

§ 172.120 Calcium disodium EDTA.

The food additive calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the conditions prescribed, as follows:

(a) The additive contains a minimum of 99 percent by weight of either the dihydrate $C_{10}H_{12}O_8N_2CaNa_2 \cdot 2H_2O$ or the trihydrate $C_{10}H_{12}O_8N_2CaNa_2 \cdot 3H_2O$, or any mixture of the two.

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as the anhydrous compound:

Food	Limitation (parts per million)	Use
Cabbage, pickled	220	Promote color, flavor, and texture retention.
Canned carbonated soft drinks.	33	Promote flavor retention.
Canned white potatoes	110	Promote color retention.
Clams (cooked canned)	340	Promote color retention.
Crabmeat (cooked canned).	275	Retard struvite formation; promote color retention.
Cucumbers pickled	220	Promote color, flavor, and texture retention.
Distilled alcoholic beverages.	25	Promote stability of color, flavor, and/or product clarity.
Dressings, nonstandardized.	75	Preservative.
Dried lima beans (cooked canned).	310	Promote color retention.
Egg product that is hard-cooked and consists, in a cylindrical shape, of egg white with an inner core of egg yolk.	[1] 200	Preservative.
Fermented malt beverages.	25	Antigushing agent.
French dressing	75	Preservative.
Legumes (all cooked canned, other than dried lima beans, pink beans, and red beans).	365	Promote color retention.
Mayonnaise	75	Do.
Mushrooms (cooked canned).	200	Promote color retention.
Oleomargarine	75	Preservative.
Pecan pie filling	100	Promote color retention.
Pink beans (cooked canned).	165	Promote color retention.
Potato salad	100	Preservative.
Processed dry pinto beans.	800	Promote color retention.
Red beans (cooked canned).	165	Promote color retention.
Salad dressing	75	Preservative.
Sandwich spread	100	Do.
Sauces	75	Do.
Shrimp (cooked canned).	250	Retard struvite formation; promote color retention.
Spice extractives in soluble carriers.	60	Promote color and flavor retention.
Spreads, artificially colored and lemon-flavored or orange-flavored.	100	Promote color retention.

[1] By weight of egg yolk portion.

(2) With disodium EDTA (disodium ethylenediaminetetraacetate) in the following foods at not to exceed, in combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

Food	Limitation (parts per million)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

(c) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraph (b) of this section, the additives are used only in compliance with the applicable standards of identity for such foods.

[42 FR 14491, Mar. 15, 1977, as amended at 48 FR 10815, Mar. 15, 1983; 58 FR 52222, Oct. 7, 1993; 60 FR 33710, June 29, 1995; 65 FR 48379, Aug. 8, 2000]

§ 172.130 Dehydroacetic acid.

The food additive dehydroacetic acid and/or its sodium salt may be safely used in accordance with the following prescribed conditions:

(a) The food additive meets the following specifications:

Dehydroacetic acid: Melting point, 109 °C–111 °C; assay, minimum 98 percent (dry basis).
Sodium salt of dehydroacetic acid: Assay, minimum 98 percent (dry basis).

(b) It is used or intended for use as a preservative for cut or peeled squash, and is so used that no more than 65 parts per million expressed as dehydroacetic acid remains in or on the prepared squash.

(c) The label or labeling of any package of the additive intended for use in food shall bear adequate directions for use to insure compliance with this section.

§ 172.133 Dimethyl dicarbonate.

Dimethyl dicarbonate (CAS Reg. No. 4525–33–1) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive meets the following specifications:

(1) The additive has a purity of not less than 99.8 percent as determined by the following titration method:

PRINCIPLES OF METHOD

Dimethyl dicarbonate (DMDC) is mixed with excess diisobutylamine with which it reacts quantitatively. The excess amine is backtitrated with acid.

APPARATUS

250-milliliter (mL) Beaker
100-mL Graduate cylinder
25-mL Pipette
10-mL Burette (automatic, eg., Metrohm burette)
Stirrer
Device for potentiometric titration
Reference electrode
Glass electrode

REAGENTS

Acetone, analytical-grade
Solution of 1 *N* diisobutylamine in chlorobenzene, distilled
1 *N* Acetic Acid

PROCEDURE

Accurately weigh in about 2 grams of the sample (W) and dissolve in 100 mL acetone. Add accurately 25 mL of the 1 *N* diisobutylamine solution by pipette and allow to stand for 5 minutes. Subsequently, titrate the reaction mixture potentiometrically with 1 *N* hydrochloric acid (consumption=*a* mL) while stirring. For determining the blank consumption, carry out the analysis without a sample (consumption=*b* mL).

CALCULATION

$$\frac{(b-a)\times 13.4}{W} = \%\ \text{DMDC}$$

NOTE: For adding the diisobutylamine solution, always use the same pipette and wait for a further three drops to fall when the flow has stopped.

(2) The additive contains not more than 2,000 ppm (0.2 percent) dimethyl carbonate as determined by a method entitled ''Gas Chromatography Method for Dimethyl Carbonate Impurity in Dimethyl Dicarbonate,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) The additive is used or intended for use as a microbial control agent in the following beverages under normal circumstances of bottling, canning, or other forms of final packaging, where

the viable microbial load has been reduced to 500 microorganisms per milliliter or less by current good manufacturing practices such as heat treatment, filtration, or other technologies prior to the use of dimethyl dicarbonate:

(1) In wine, dealcoholized wine, and low alcohol wine in an amount not to exceed 200 parts per million.

(2) In ready-to-drink teas in an amount not to exceed 250 parts per million.

(3) In carbonated or noncarbonated, nonjuice-containing (less than or equal to 1 percent juice), flavored or unflavored beverages containing added electrolytes (5–20 milliequivalents/liter sodium ion (Na +) and 3–7 milliequivalents/liter potassium ion (K +)) in an amount not to exceed 250 parts per million.

(4) In carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent, in an amount not to exceed 250 parts per million.

(c) To ensure the safe use of the food additive, the label of the package containing the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The name of the additive ''dimethyl dicarbonate.''

(2) The intended use of the additive.

(3) Adequate directions for use to ensure compliance with this section.

[53 FR 41329, Oct. 21, 1988, as amended at 58 FR 6091, Jan. 26, 1993; 59 FR 5319, Feb. 4, 1994; 61 FR 14245, Apr. 1, 1996; 61 FR 26788, May 29, 1996; 66 FR 13653, Mar. 7, 2001]

§ 172.135 Disodium EDTA.

The food additive disodium EDTA (disodium ethylenediaminetetraacetate) may be safely used in designated foods for the purposes and in accordance with the following prescribed conditions:

(a) The additive contains a minimum of 99 percent disodium ethylenediaminetetraacetate dihydrate ($C_{10}H_{14}O_8N_2Na_2{\cdot}2H_2O$).

(b) It is used or intended for use as follows:

(1) Alone, in the following foods at not to exceed the levels prescribed, calculated as anhydrous calcium disodium EDTA:

Food	Limitation (parts per million)	Use
Aqueous multivitamin preparations.	150	With iron salts as a stabilizer for vitamin B[12] in liquid multivitamin preparations.
Canned black-eyed peas	145	Promote color retention.
Canned kidney beans	165	Preservative.
Canned strawberry pie filling	500	Promote color retention.
Cooked sausage	36	As a cure accelerator with sodium ascorbate or ascorbic acid.
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Frozen white potatoes including cut potatoes.	100	Promote color retention.
Gefilte fish balls or patties in packing medium.	[1] 50	Inhibit discoloration.
Legumes (all cooked canned, other than black-eyed peas).	165	Promote color retention.
Mayonnaise	75	Preservative.
Ready-to-eat cereal products containing dried bananas.	[2] 315	Promote color retention.
Salad dressing	75	Preservative.
Sandwich spread	100	Do.
Sauces	75	Do.

[1] Based on total weight of finished product including packing medium.
[2] In dried banana component of cereal product.

(2) With calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate; calcium disodium (ethylenedinitrilo) tetraacetate), in the following foods at not to exceed, in combination, the levels prescribed, calculated as anhydrous $C_{10}H_{12}O_8N_2CaNa_2$:

Food	Limitation (parts per million)	Use
Dressings, nonstandardized	75	Preservative.
French dressing	75	Do.
Mayonnaise	75	Do.
Salad dressing	75	Do.
Sandwich spread	100	Do.
Sauces	75	Do.

(3) Alone, as a sequestrant in the nonnutritive sweeteners that are listed in § 180.37 of this chapter and that, in addition, are designed for aqueous solution: *Provided,* That the amount of the additive, calculated as anhydrous calcium disodium EDTA, does not exceed

0.1 percent by weight of the dry nonnutritive sweetener.

(c) To assure the safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate use directions to provide a final food product that complies with the limitations provided in paragraph (b) of this section.

(d) In the standardized foods listed in paragraphs (b)(1) and (2) of this section the additives are used only in compliance with the applicable standards of identity for such foods.

[42 FR 14491, Mar. 15, 1977, as amended at 65 FR 48379, Aug. 8, 2000]

§ 172.140 Ethoxyquin.

(a) Ethoxyquin (1,2-dihydro-6-ethoxy-2,2,4-trimethylquinoline) may be safely used as an antioxidant for preservation of color in the production of chili powder, paprika, and ground chili at levels not in excess of 100 parts per million.

(b) In order to provide for the safe use of the additive in feed prepared in accordance with §§ 573.380 and 573.400 of this chapter, tolerances are established for residues of ethoxyquin in or on edible products of animals as follows:

5 parts per million in or on the uncooked fat of meat from animals except poultry.
3 parts per million in or on the uncooked liver and fat of poultry.
0.5 part per million in or on the uncooked muscle meat of animals.
0.5 part per million in poultry eggs.
Zero in milk.

§ 172.145 Heptylparaben.

(a) The food additive heptylparaben is the chemical *n*-heptyl *p*-hydroxybenzoate.

(b) It may be safely used to inhibit microbiological spoilage in accordance with the following prescribed conditions:

(1) In fermented malt beverages in amounts not to exceed 12 parts per million.

(2) In noncarbonated soft drinks and fruit-based beverages in amounts not to exceed 20 parts per million, when standards of identity established under section 401 of the Act (21 U.S.C. 341) do not preclude such use.

§ 172.150 4-Hydroxymethyl-2,6-di-*tert*-butylphenol.

The food additive 4-hydroxymethyl-2,6-di-*tert*-butylphenol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a solidification point of 140 °C–141 °C.

(b) The additive is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total amount of all antioxidants added to such food shall not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

§ 172.155 Natamycin (pimaricin).

(a) Natamycin (CAS Reg. No. 7681–93–8), also known as pimaricin, is a polyene macrolide antimycotic substance possessing an empirical formula of $C_{33}H_{47}NO_{13}$ and a molecular weight of 665.7.

(b) The additive shall conform to the following specifications:

Purity: 97 percent ±2 percent on an anhydrous basis.
Arsenic: Not more than 1 part per million.
Heavy metals (as Pb): Not more than 20 parts per million.

(c) The additive may be applied on cheese, as an antimycotic, in amounts not to exceed 20 milligrams per kilogram (20 parts per million) in the finished product as determined by International Dairy Federation (IDF) Standard 140A:1992, ''Cheese and Cheese Rind-Determination of Natamycin Content-Method by Molecular Absorption Spectrometry and by High-Performance Liquid Chromatography,'' which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Product Policy (HFS–206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or

at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

[47 FR 26823, June 22, 1982, as amended at 50 FR 49536, Dec. 3, 1985; 63 FR 66015, Dec. 1, 1998; 66 FR 13847, Mar. 8, 2001; 81 FR 5591, Feb. 3, 2016]

§ 172.160 Potassium nitrate.

The food additive potassium nitrate may be safely used as a curing agent in the processing of cod roe, in an amount not to exceed 200 parts per million of the finished roe.

§ 172.165 Quaternary ammonium chloride combination.

The food additive, quaternary ammonium chloride combination, may be safely used in food in accordance with the following conditions:

(a) The additive contains the following compounds: *n*-dodecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139–07–1); *n*-dodecyl dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 27479–28–3); *n*-hexadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122–18–9); *n*-octadecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 122–19–0); *n*-tetradecyl dimethyl benzyl ammonium chloride (CAS Reg. No. 139–08–2); *n*-tetradecyl dimethyl ethylbenzyl ammonium chloride (CAS Reg. No. 27479–29–4).

(b) The additive meets the following specifications: pH (5 percent active solution) 7.0–8.0; total amines, maximum 1 percent as combined free amines and amine hydrochlorides.

(c) The additive is used as an antimicrobial agent, as defined in § 170.3(o)(2) of this chapter, in raw sugar cane juice. It is added prior to clarification when further processing of the sugar cane juice must be delayed.

(d) The additive is applied to the sugar juice in the following quantities, based on the weight of the raw cane:

Component	Parts per million
n-Dodecyl dimethyl benzyl ammonium chloride	0.25–1.0
n-Dodecyl dimethyl ethylbenzyl ammonium chloride	3.4–13.5
n-Hexadecyl dimethyl benzyl ammonium chloride	1.5–6.0
n-Octadecyl dimethyl benzyl ammonium chloride	0.25–1.0
n-Tetradecyl dimethyl benzyl ammonium chloride	3.0–12.0
n-Tetradecyl dimethyl ethylbenzyl ammonium chloride	1.6–6.5

[50 FR 3890, Jan. 29, 1985]

§ 172.167 Silver nitrate and hydrogen peroxide solution.

An aqueous solution containing a mixture of silver nitrate and hydrogen peroxide may be safely used in accordance with the following prescribed conditions:

(a) The additive is used as an antimicrobial agent in bottled water.

(b) Hydrogen peroxide meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 496–497, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(c) The amount of silver added will not exceed 17 micrograms per kilogram in the treated bottled water, and the amount of hydrogen peroxide will not exceed 23 milligrams per kilogram in the treated bottled water. Analyses for silver and hydrogen peroxide shall be conducted on samples of treated bottled water at the site of bottling, using samples of the water intended for treatment for the blank determination.

(d)(1) The amount of silver in the treated bottled water is determined using the method for silver designated in 21 CFR 165.110(b)(4)(iii)(G)(*2*)(*i*).

(2) The amount of hydrogen peroxide in the treated bottled water is determined using a Hydrogen Peroxide Test Kit from the HACH Co., or equivalent. The manual from the Hydrogen Peroxide Test Kit, Model HYP–1, Catalog Number 22917–00, 1991, is incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the test kit manual from the HACH Co., P.O. Box 389, Loveland CO, 80359 (1–800–227–4224), Model HYP–1, Catalog Number 22917–00. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, 301–436–2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(e) Substances generally recognized as safe in or on food may be used to stabilize the additive to ensure that the additive will perform its intended technical effect.

(f) The additive may not be added to bottled water that has been filtered or is intended to be filtered through a silver-containing water filter.

(g) Bottled water must meet the quality standards for bottled water in §165.110(b)(2) through (b)(5) of this chapter, including the limits specified for total silver and nitrate, unless the water bears a label statement of substandard quality, as provided for under §165.110(c) of this chapter.

[74 FR 11478, Mar. 18, 2009, as amended at 78 FR 71461, Nov. 29, 2013; 81 FR 5591, Feb. 3, 2016]

§ 172.170 Sodium nitrate.

The food additive sodium nitrate may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a preservative and color fixative, with or without sodium nitrite, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad, so that the level of sodium nitrate does not exceed 500 parts per million and the level of sodium nitrite does not exceed 200 parts per million in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrite, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrate to not more than 500 parts per million in the finished meat product and the amount of sodium nitrite to not more than 200 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive or of a mixture containing the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraph (a) of this section.

(3) If in a retail package intended for household use, the label of the additive or of a mixture containing the additive, shall bear the statement ''Keep out of the reach of children''.

§ 172.175 Sodium nitrite.

The food additive sodium nitrite may be safely used in or on specified foods in accordance with the following prescribed conditions:

(a) It is used or intended for use as follows:

(1) As a color fixative in smoked cured tunafish products so that the level of sodium nitrite does not exceed 10 parts per million (0.001 percent) in the finished product.

(2) As a preservative and color fixative, with or without sodium nitrate, in smoked, cured sablefish, smoked, cured salmon, and smoked, cured shad so that the level of sodium nitrite does not exceed 200 parts per million and the level of sodium nitrate does not exceed

500 parts per million in the finished product.

(3) As a preservative and color fixative, with sodium nitrate, in meat-curing preparations for the home curing of meat and meat products (including poultry and wild game), with directions for use which limit the amount of sodium nitrite to not more than 200 parts per million in the finished meat product, and the amount of sodium nitrate to not more than 500 parts per million in the finished meat product.

(b) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive or of a mixture containing the additive shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive in any mixture.

(2) If in a retail package intended for household use, the label and labeling of the additive, or of a mixture containing the additive, shall bear adequate directions for use to provide a final food product which complies with the limitations prescribed in paragraph (a) of this section.

(3) If in a retail package intended for household use, the label of the additive, or of a mixture containing the additive, shall bear the statement ''Keep out of the reach of children''.

§ 172.177 Sodium nitrite used in processing smoked chub.

The food additive sodium nitrite may be safely used in combination with salt (NaCl) to aid in inhibiting the outgrowth and toxin formation from *Clostridium botulinum* type E in the commercial processing of smoked chub in accordance with the following prescribed conditions:

(a) All fish in smoking establishments shall be clean and wholesome and shall be expeditiously processed, packed, and stored under adequate sanitary conditions in accordance with good manufacturing practice.

(b) The brining procedure is controlled in such a manner that the water phase portion of the edible portion of the finished smoked product has a salt (NaCl) content of not less than 3.5 percent, as measured in the loin muscle, and the sodium nitrite content of the edible portion of the finished smoked product is not less than 100 parts per million and not greater than 200 parts per million, as measured in the loin muscle.

(c) Smoked chub shall be heated by a controlled heat process which provides a monitoring system positioned in as many strategic locations in the smokehouse as necessary to assure a continuous temperature throughout each fish of at least 160 °F for a minimum of 30 minutes.

(d) The finished product shall be cooled to a temperature of 50 °F or below within 3 hours after smoking and further cooled to a temperature of 38 °F or below within 12 hours after smoking. A temperature of 38 °F or below shall be maintained during all subsequent storage and distribution. All shipping containers, retail packages, and shipping records shall indicate with appropriate notice the perishable nature of the product and specify that the product shall be held under refrigeration (38 °F or below) until consumed.

(e) To assure safe use of the additive:

(1) The label and labeling of the additive container shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or labeling of the additive container shall bear adequate directions to assure use in compliance with the provisions of this section.

§ 172.180 Stannous chloride.

The food additive stannous chloride may be safely used for color retention in asparagus packed in glass, with lids lined with an inert material, in an amount not to exceed 20 parts per million calculated as tin (Sn).

§ 172.185 TBHQ.

The food additive TBHQ, which is the chemical 2-(1,1-dimethylethyl)-1,4-benzenediol (Chemical Abstracts Service Registry Number 1948–33–0), also known as tertiary butylhydroquinone, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of not less than 126.5 °C.

(b) The percentage of TBHQ in the food additive is not less than 99.0 percent when tested by the assay described in the Food Chemicals Codex,

9th ed. (2014), pp. 1192–1194, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) It is used as an antioxidant alone or in combination with BHA and/or BHT.

(d) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

[42 FR 14491, Mar. 15, 1977, as amended at 80 FR 34276, June 16, 2015]

§ 172.190 THBP.

The food additive THBP (2,4,5-trihydroxybutyrophenone) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a melting point of 149 °C–153 °C.

(b) It is used as an antioxidant alone or in combination with other permitted antioxidants.

(c) The total antioxidant content of a food containing the additive will not exceed 0.02 percent of the oil or fat content of the food, including the essential (volatile) oil content of the food.

Subpart C—Coatings, Films and Related Substances

§ 172.210 Coatings on fresh citrus fruit.

Coatings may be applied to fresh citrus fruit for protection of the fruit in accordance with the following conditions:

(a) The coating is applied in the minimum amount required to accomplish the intended effect.

(b) The coating may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

(1) Substances generally recognized as safe for the purpose or previously sanctioned for the purpose.

(2) One or more of the following:

Component	Limitations
Fatty acids	Complying with § 172.860.
Oleic acid derived from tall oil fatty acids	Complying with § 172.862.
Partially hydrogenated rosin	Catalytically hydrogenated to a maximum refractive index of 1.5012 at 100 °C. Color of WG or paler.
Pentaerythritol ester of maleic anhydride-modified wood rosin.	Acid number of 134–145; drop-softening point of 127 °C–173 °C; saponification number of less than 280; and a color of M or paler.
Do	Acid number of 176–186; drop-softening point of 110 °C–118 °C; saponification number of less than 280; and a color of M or paler.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyhydric alcohol diesters of oxidatively refined (Gersthofen process) montan wax acids.	Complying with § 178.3770 of this chapter and having a dropping point of 77 to 83 °C (170.6 to 181.4 °F), as determined by ASTM Method D566–76 (Reapproved 1982), ''Standard Test Method for Dropping Point of Lubricating Grease,'' which is incorporated by reference (Copies are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*) using as a solvent xylene-ethyl alcohol in a 2:1 ratio instead of toluene-ethyl alcohol in a 2:1 ratio.
Sodium lauryl sulfate	Complying with § 172.822. As a film former.
Wood rosin	Color of K or paler.

(3) In lieu of the components listed in paragraph (b)(2) and (4) of this section, the following copolymer and one or more of the listed adjuvants.

Component	Limitations
Vinyl chloride-vinylidene chloride copolymer	As an aqueous dispersion containing a minimum of 75 percent water when applied.
Polyethylene glycol	Complying with § 172.820. As a defoamer and dispersing adjuvant.
Polyvinylpyrrolidone	As an adjuvant.
Potassium persulfate	Do.
Propylene glycol alginate	Do.
Sodium decylbenzenesulfonate	Do.

(4) In lieu of the components listed in paragraph (b)(2) and (3) of this section, the following rosin derivative and either or both of the listed adjuvants:

Component	Limitations
Calcium salt of partially dimerized rosin	Having a maximum drop-softening point of 197 °C and a color of H or paler. It is prepared by reaction with not more than 7 parts hydrated lime per 100 parts of partially dimerized rosin. The partially dimerized rosin is rosin that has been dimerized by sulfuric acid catalyst to a drop-softening point of 95 °C to 105 °C and a color of WG or paler.
Petroleum naphtha	As adjuvant. Complying with § 172.250.
Sperm oil	As adjuvant.

[42 FR 14491, Mar. 15, 1977; 49 FR 5747, Feb. 15, 1984, as amended at 51 FR 2693, Jan. 21, 1986; 52 FR 18911, May 20, 1987; 61 FR 14245, Apr. 1, 1996]

§ 172.215 Coumarone-indene resin.

The food additive coumarone-indene resin may be safely used on grapefruit, lemons, limes, oranges, tangelos, and tangerines in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the polymerization of a crude, heavy coal-tar solvent naphtha meeting the following specifications:

(1) It is a mixture of indene, indan (hydrindene), substituted benzenes, and related compounds.

(2) It contains no more than 0.25 percent tar bases.

(3) 95 percent distills in the range 167 °C–184 °C.

(b) The food additive meets the following specifications:

(1) Softening point, ring and ball: 126 °C minimum as determined by ASTM method E28–67 (Reapproved 1982), ''Standard Test Method for Softening Point by Ring-and-Ball Apparatus,'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(2) Refractive index (n^{25}/D) 1.63–1.64.

(c) It is used or intended for use as a protective coating for grapefruit, lemons, limes, oranges, tangelos, and tangerines whereby the maximum amount of the resin remaining on the fruit does not exceed 200 parts per million on a fresh-weight basis.

(d) To assure safe use of the additive:

(1) The label of the market package or any intermediate premix of the additive shall bear, in addition to the other information required by the act:

(i) The name of the additive, coumarone-indene resin.

(ii) A statement of the concentration of the additive therein.

(2) The label or accompanying labeling shall bear adequate directions that, if followed, will result in a finished food not in conflict with the requirements of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10103, Mar. 19, 1984]

§ 172.225 Methyl and ethyl esters of fatty acids produced from edible fats and oils.

Methyl esters and ethyl esters of fatty acids produced from edible fats and oils may be safely used in food,

subject to the following prescribed conditions:

(a) The additive consists of a mixture of either methyl or ethyl esters of fatty acids produced from edible fats and oils and meets the following specifications:

(1) Not less than 90 percent methyl or ethyl esters of fatty acids.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at the level not to exceed 3 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 200 parts per million.

[57 FR 12711, Apr. 13, 1992]

§ 172.230 Microcapsules for flavoring substances.

Microcapsules may be safely used for encapsulating discrete particles of flavoring substances that are generally recognized as safe for their intended use or are regulated under this part, in accordance with the following conditions:

(a) The microcapsules may be formulated from the following components, each used in the minimum quantity required to accomplish the intended effect:

(1) Substances generally recognized as safe for the purpose.

(2) One or more of the following components:

COMPONENT AND LIMITATIONS
Succinylated gelatin—Not to exceed 15 percent by combined weight of the microcapsule and flavoring oil. Succinic acid content of the gelatin is 4.5 to 5.5 percent.
Arabinogalactan—Complying with §172.610; as adjuvant.
Silicon dioxide—Complying with §172.480; as adjuvant.

(3) In lieu of the components listed in paragraph (a)(2) of this section, the following components:

COMPONENT AND LIMITATIONS
Glutaraldehyde—As cross-linking agent for insolubilizing a coacervate of gum arabic and gelatin.
n-Octyl alcohol—As a defoamer.

(4) In lieu of the components listed in paragraphs (a)(2) and (3) of this section, the following component:

COMPONENT AND LIMITATIONS
Petroleum wax—Complying with §172.886. Not to exceed 50 percent by combined weight of the microcapsule and spice-flavoring substance.

(b) The microcapsules produced from the components listed in paragraphs (a)(1), (2), and (3) of this section may be used for encapsulating authorized flavoring oils for use, in accordance with good manufacturing practice, in foods for which standards of identity established under section 401 of the Act do not preclude such use, except that microcapsules formulated from components listed in paragraph (a)(2) of this section may be used only for encapsulating lemon oil, distilled lime oil, orange oil, peppermint oil, and spearmint oil for use in dry mixes for puddings and gelatin desserts.

(c) The microcapsules produced from the components listed in paragraphs (a)(1) and (4) of this section may be used only for encapsulating authorized spice-flavoring substances for use, in accordance with good manufacturing practice, in frozen pizzas which are to be further processed by heat. Such pizzas shall bear labels or labeling including adequate directions for use to ensure heating to temperatures which will melt the wax to release the spice-flavoring substances.

[45 FR 48123, July 18, 1980]

§ 172.235 Morpholine.

Morpholine may be safely used as a component of food, subject to the following restrictions.

(a) It is used as the salt(s) of one or more of the fatty acids meeting the requirements of §172.860, as a component of protective coatings applied to fresh fruits and vegetables.

(b) It is used at a level not in excess of that reasonably required to produce its intended effect.

§ 172.250 Petroleum naphtha.

Petroleum naphtha may be safely used in food in accordance with the following conditions:

(a) The additive is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum,

(b) The additive is refined to meet the following specifications when subjected to the procedures described in this paragraph.

(1) Boiling-point range: 175 °F–300 °F.

(2) Nonvolatile residue: 0.002 gram per 100 milliliters maximum.

(3) Ultraviolet absorbance limits, as follows:

Wavelength (milli-microns)	Maximum absorbance per centimeter optical pathlength
280–289	0.15
290–299	.13
300–359	.08
360–400	.02

ANALYTICAL SPECIFICATION FOR PETROLEUM NAPHTHA

GENERAL INSTRUCTIONS

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of petroleum naphtha samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250-milliliter, and 2,000-milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Erlenmeyer flask. 125-milliliter with 24/40 standard taper neck.

Evaporation flask. 250-milliliter capacity all-glass flask equipped with 24/40 standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of the container liquid to be evaporated.

Condenser. 24/40 joints, fitted with drying tube, length optional.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5,000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1,000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250–400 mμ with spectral slit width of 2 mμ or less; under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Ultraviolet lamp. Long wavelength (3400–3800A°).

REAGENTS

Isooctane (*2,2,4-trimethylpentane*). Use 180 milliliters in a 250-milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane, insert the head assembly, allow nitrogen gas to flow into the inlet tube and connect the outlet tube to a solvent trap and vacuum line in such a way as to prevent any back flow of condensate into the flask. The contents of the flask are evaporated on a steam bath until 1 milliliter of residue remains. Dissolve the 1 milliliter of hexadecane residue in isooctane and make up to 25 milliliters. Determine the absorbance in a 5-centimeter path length cell compared to isooctane as reference. The absorbance should not exceed 0.01 per centimeter path length between 280–400 mμ. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davidson Chemical Co., Baltimore, Md., or equivalent) or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10 milliliters and proceed as with isooctane. The absorbance per centimeter of path length should be 0.00 between 280–400 mμ. Methyl alcohol may be purified by simple

[1] As determined by procedure using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. The procedure is incorporated by reference. Copies of the material incorporated by reference are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

distillation or by refluxing in the presence of potassium hydroxide (10 grams/2 liters) and zinc dust (25 grams/2 liters) for 3 hours followed by distillation.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5-centimeter cell compared to isooctane as reference between 280–400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Sodium borohydride. 98 percent.

Water. All distilled water must be extracted with isooctane before use. A series of three successive extracts of 1.5 liters of distilled water with 100-milliliter portions of isooctane is satisfactory.

PROCEDURE

Determination of ultraviolet absorbance. Add a 25-milliliter aliquot of the hydrocarbon solvent together with 1 milliliter of hexadecane to the 125-milliliter Erlenmeyer flask. While flushing with nitrogen, evaporate to 1 milliliter on a steam bath. Nitrogen is admitted through a 8±1-milliliter outer-diameter tube, drawn out into a 2±1-centimeter long and 1±0.5-millimeter inner-diameter capillary tip. This is positioned so that the capillary tip extends 4 centimeters into the flask. The nitrogen flow rate is such that the surface of the liquid is barely disturbed. After the volume is reduced to that of the 1 milliliter of hexadecane, the flask is left on the steam bath for 10 more minutes before removing. Add 10 milliliters of purified isooctane to the flask and reevaporate the solution to a 1-milliliter volume in the same manner as described above, except do not heat for an added 10 minutes. Repeat this operation twice more. Let the flask cool.

Add 10 milliliters of methyl alcohol and about 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere; a measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the sodium borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this time, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until sodium borohydride begins to drop out of solution. Remove the flask and let it cool.

Add 6 milliliters of isooctane to the flask and swirl to wash the crystalline slurry. Carefully transfer the isooctane extract to a 250-milliliter separatory funnel. Dissolve the crystals in the flask with about 25 milliliters of distilled water and pour this also into the separatory funnel. Adjust the water volume in the separatory funnel to about 100 milliliters and shake for 1 minute. After separation of the layers, draw off the aqueous layer into a second 250-milliliter separatory funnel. Transfer the hydrocarbon layer in the first funnel to a 25-milliliter volumetric flask.

Carefully wash the Erlenmeyer flask with an additional 6 milliliters of isooctane, swirl, and transfer to the second separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer into the first separatory funnel. Transfer the isooctane in the second funnel to the volumetric flask. Again wash the Erlenmeyer flask with an additional 6 milliliters of isooctane, swirl, and transfer to the first separatory funnel. Shake the funnel for 1 minute. After separation of the layers, draw off the aqueous layer and discard. Transfer the isooctane layer to the volumetric flask and adjust the volume to 25 milliliters of isooctane. Mix the contents well, then transfer to the first separatory funnel and wash twice with 50-milliliter portions of distilled water. Discard the aqueous layers after each wash.

Determine the ultraviolet absorbance of the isooctane extract in 5-centimeter path length cells compared to isooctane as reference between 280–400 mμ. Determine a reagent blank concurrently with the sample, using 25 milliliters of purified isooctane instead of a solvent sample and measuring the ultraviolet absorbance of the blank between 280–400mμ.

The reagent blank absorbance should not exceed 0.04 per centimeter path length between 280–289 mμ; 0.020 between 290–359 mμ; and 0.010 between 360–400 mμ.

Determination of boiling-point range. Use ASTM method D86–82, ''Standard Method for Distillation of Petroleum Products,'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

Determination of nonvolatile residue. For hydrocarbons boiling below 121 °C, determine the nonvolatile residue by ASTM method D1353–78, ''Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products;'' for those boiling above 121 °C, use ASTM method D381–80, ''Standard Test Method for Existent Gum in Fuels by Jet Evaporation,'' which methods are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) Petroleum naphtha containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. Petroleum naphtha may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended effect or to exceed any prescribed limitations.

(d) Petroleum naphtha is used or intended for use as a solvent in protective coatings on fresh citrus fruit in compliance with § 172.210.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11835, Mar. 19, 1982; 49 FR 10104, Mar. 19, 1984; 54 FR 24896, June 12, 1989]

§ 172.255 Polyacrylamide.

Polyacrylamide containing not more than 0.2 percent of acrylamide monomer may be safely used as a film former in the imprinting of soft-shell gelatin capsules when the amount used is not in excess of the minimum required to produce the intended effect.

§ 172.260 Oxidized polyethylene.

Oxidized polyethylene may be safely used as a component of food, subject to the following restrictions:

(a) Oxidized polyethylene is the basic resin produced by the mild air oxidation of polyethylene. The polyethylene used in the oxidation process conforms to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed in item 2.3 of the table in § 177.1520(c) of this chapter. The oxidized polyethylene has a minimum number average molecular weight of 1,200, as determined by high temperature vapor pressure osmometry; contains a maximum of 5 percent by weight of total oxygen; and has an acid value of 9 to 19.

(b) The additive is used or intended for use as a protective coating or component of protective coatings for fresh avocados, bananas, beets, coconuts, eggplant, garlic, grapefruit, lemons, limes, mango, muskmelons, onions, oranges, papaya, peas (in pods), pineapple, plantain, pumpkin, rutabaga, squash (acorn), sweetpotatoes, tangerines, turnips, watermelon, Brazil nuts, chestnuts, filberts, hazelnuts, pecans, and walnuts (all nuts in shells).

(c) The additive is used in accordance with good manufacturing practice and in an amount not to exceed that required to produce the intended effect.

§ 172.270 Sulfated butyl oleate.

Sulfate butyl oleate may be safely used in food, subject to the following prescribed conditions:

(a) The additive is prepared by sulfation, using concentrated sulfuric acid, of a mixture of butyl esters produced by transesterification of an edible vegetable oil using 1-butanol. Following sulfation, the reaction mixture is washed with water and neutralized with aqueous sodium or potassium hydroxide. Prior to sulfation, the butyl oleate reaction mixture meets the following specifications:

(1) Not less than 90 percent butyl oleate.

(2) Not more than 1.5 percent unsaponifiable matter.

(b) The additive is used or intended for use at a level not to exceed 2 percent by weight in an aqueous emulsion in dehydrating grapes to produce raisins, whereby the residue of the additive on the raisins does not exceed 100 parts per million.

[57 FR 12711, Apr. 13, 1992]

§ 172.275 Synthetic paraffin and succinic derivatives.

Synthetic paraffin and succinic derivatives identified in this section may be safely used as a component of food, subject to the following restrictions:

(a) The additive is prepared with 50 percent Fischer-Tropsch process synthetic paraffin, meeting the definition and specifications of § 172.615, and 50 percent of such synthetic paraffin to which is bonded succinic anhydride and succinic acid derivatives of isopropyl alcohol, polyethylene glycol, and polypropylene glycol. It consists of a mixture of the Fischer-Tropsch process paraffin (alkane), alkyl succinic anhydride, alkyl succinic anhydride isopropyl half ester, dialkyl succinic anhydride polyethylene glycol half ester,

and dialkyl succinic anhydride polypropylene glycol half ester, where the alkane (alkyl) has a chain length of 30–70 carbon atoms and the polyethylene and polypropylene glycols have molecular weights of 600 and 260, respectively.

(b) The additive meets the following specifications: Molecular weight, 880–930; melting point, 215°–217 °F; acid number, 43–47; and saponification number, 75–78.

(c) It is used or intended for use as a protective coating or component of protective coatings for fresh grapefruit, lemons, limes, muskmelons, oranges, sweetpotatoes, and tangerines.

(d) It is used in an amount not to exceed that required to produce the intended effect.

§ 172.280 Terpene resin.

The food additive terpene resin may be safely used in accordance with the following prescribed conditions:

(a) The food additive is the beta-pinene polymer obtained by polymerizing terpene hydrocarbons derived from wood. It has a softening point of 112 °C–118 °C, as determined by ASTM method E28–67 (Reapproved 1982), ''Standard Test Method for Softening Point By Ring-and-Ball Apparatus,'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(b) It is used or intended for use as follows:

(1) As a moisture barrier on soft gelatin capsules in an amount not to exceed 0.07 percent of the weight of the capsule.

(2) As a moisture barrier on powders of ascorbic acid or its salts in an amount not to exceed 7 percent of the weight of the powder.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10104, Mar. 19, 1984]

Subpart D—Special Dietary and Nutritional Additives

§ 172.310 Aluminum nicotinate.

Aluminum nicotinate may be safely used as a source of niacin in foods for special dietary use. A statement of the concentration of the additive, expressed as niacin, shall appear on the label of the food additive container or on that of any intermediate premix prepared therefrom.

§ 172.315 Nicotinamide-ascorbic acid complex.

Nicotinamide-ascorbic acid complex may be safely used in accordance with the following prescribed conditions:

(a) The additive is the product of the controlled reaction between ascorbic acid and nicotinamide, melting in the range 141 °C to 145 °C.

(b) It is used as a source of ascorbic acid and nicotinamide in multivitamin preparations.

§ 172.320 Amino acids.

The food additive amino acids may be safely used as nutrients added to foods in accordance with the following conditions:

(a) The food additive consists of one or more of the following individual amino acids in the free, hydrated, or anhydrous form, or as the hydrochloride, sodium, or potassium salts:

(1) L-Alanine
(2) L-Arginine
(3) L-Asparagine
(4) L-Aspartic acid
(5) L-Cysteine
(6) L-Cystine
(7) L-Glutamic acid
(8) L-Glutamine
(9) Aminoacetic acid (glycine)
(10) L-Histidine
(11) L-Isoleucine
(12) L-Leucine
(13) L-Lysine
(14) DL-Methionine (not for infant foods)
(15) L-Methionine
(16) L-Phenylalanine
(17) L-Proline
(18) L-Serine
(19) L-Threonine
(20) L-Tryptophan
(21) L-Tyrosine
(22) L-Valine

(b) The food additive meets the following specifications:

(1) As found in Food Chemicals Codex:

(i) L-Alanine, pages 28 and 29.

(ii) L-Arginine, pages 69 and 70.

(iii) L-Arginine Monohydrochloride, pages 70 and 71.

(iv) L-Cysteine Monohydrochloride, pages 269 and 270.

(v) L-Cystine, pages 270 and 271.

(vi) Aminoacetic acid (glycine), pages 457 and 458.

(vii) L-Leucine, pages 577 and 578.

(viii) DL-Methionine, pages 641 and 642.

(ix) L-Methionine, pages 642 and 643.

(x) L-Tryptophan, pages 1060 and 1061.

(xi) L-Phenylalanine, pages 794 and 795.

(xii) L-Proline, pages 864 and 865.

(xiii) L-Serine, pages 915 and 916.

(xiv) L-Threonine, pages 1031 and 1032.

(xv) L-Glutamic Acid Hydrochloride, page 440.

(xvi) L-Isoleucine, pages 544 and 545.

(xvii) L-Lysine Monohydrochloride, pages 598 and 599.

(xviii) Monopotassium *L*-glutamate, pages 697 and 698.

(xix) L-Tyrosine, page 1061.

(xx) L-Valine, pages 1072.

(2) As found in ''Specifications and Criteria for Biochemical Compounds,'' NAS/NRC Publication, for the following:

(i) L-Asparagine

(ii) L-Aspartic acid

(iii) L-Glutamine

(iv) L-Histidine

(c) The additive(s) is used or intended for use to significantly improve the biological quality of the total protein in a food containing naturally occurring primarily intact protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact protein (based upon 10 percent of the daily allowance for the ''reference'' adult male recommended by the National Academy of Sciences in ''Recommended Dietary Allowances,'' NAS Publication No. 1694.

(2) The additive(s) results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) Each amino acid (or combination of the minimum number necessary to achieve a statistically significant increase) added results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the amino acid(s) to achieve the desired effect must be used and the increase in PER over the primarily intact naturally occurring protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

	Percent by weight of total protein (expressed as free amino acid)
L-Alanine	6.1
L-Arginine	6.6
L-Aspartic acid (including L-asparagine)	7.0
L-Cystine (including L-cysteine)	2.3
L-Glutamic acid (including L-glutamine)	12.4
Aminoacetic acid (glycine)	3.5
L-Histidine	2.4
L-Isoleucine	6.6
L-Leucine	8.8
L-Lysine	6.4
L- and DL-Methionine	3.1
L-Phenylalanine	5.8
L-Proline	4.2
L-Serine	8.4
L-Threonine	5.0
L-Tryptophan	1.6
L-Tyrosine	4.3
L-Valine	7.4

(d) Compliance with the limitations concerning PER under paragraph (c) of this section shall be determined by the method described in sections 43.212–43.216, ''Official Methods of Analysis of the Association of Official Analytical Chemists.'' Each manufacturer or person employing the additive(s) under the provisions of this section shall keep and maintain throughout the period of his use of the additive(s) and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation and shall make

such records available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration, or any other officer or employee acting on behalf of the Secretary of Health and Human Services and shall permit such officer or employee to conduct such inventories of raw and finished materials on hand as he deems necessary and otherwise to check the correctness of such records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the amino acid(s) contained therein including the specific optical and chemical form.

(2) The amounts of each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) The food additive amino acids added as nutrients to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and comply with the requirements of part 105 of this chapter are exempt from the limitations in paragraphs (c) and (d) of this section and may be used in such foods at levels not to exceed good manufacturing practices.

(g) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(1) AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877:

(i) Sections 43.212–43.216, ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980).

(ii) [Reserved]

(2) National Academy of Sciences, available from the FDA Main Library, 10903 New Hampshire Ave., Silver Spring, MD 20993:

(i) ''Recommended Dietary Allowances,'' NAS Publication No. 1694, 7th Ed. (1968).

(ii) ''Specifications and Criteria for Biochemical Compounds,'' NAS/NRC Publication, 3rd Ed. (1972).

(3) United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*):

(i) Food Chemicals Codex, 7th ed. (2010), pages 28, 29, 69, 70, 71, 269, 270, 271, 440, 457, 458, 544, 545, 577, 578, 598, 599, 641, 642, 643, 697, 698, 794, 795, 864, 865, 915, 916, 1031, 1032, 1060, 1061, and 1072.

(ii) [Reserved]

[78 FR 71461, Nov. 29, 2013]

§ 172.325 Bakers yeast protein.

Bakers yeast protein may be safely used in food in accordance with the following conditions:

(a) Bakers yeast protein is the insoluble proteinaceous material remaining after the mechanical rupture of yeast cells of *Saccharomyces cerevisiae* and removal of whole cell walls by centrifugation and separation of soluble cellular materials.

(b) The additive meets the following specifications on a dry weight basis:

(1) Zinc salts less than 500 parts per million (ppm) as zinc.

(2) Nucleic acid less than 2 percent.

(3) Less than 0.3 ppm arsenic, 0.1 ppm cadmium, 0.4 ppm lead, 0.05 ppm mercury, and 0.3 ppm selenium.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

§ 172.330 Calcium pantothenate, calcium chloride double salt.

The food additive calcium chloride double salt of calcium pantothenate may be safely used in foods for special dietary uses in accordance with good manufacturing practice and under the following prescribed conditions:

(a) The food additive is of the *d* (dextrorotatory) or the *dl* (racemic) form.

(b) To assure safe use of the additive, the label and labeling of the food additive container, or that of any intermediate premixes prepared therefrom, shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive ''calcium chloride double salt of *d*-calcium pantothenate'' or ''calcium chloride double salt of *dl*-calcium pantothenate'', whichever is appropriate.

(2) A statement of the appropriate concentration of the additive, expressed as pantothenic acid.

§ 172.335 D-Pantothenamide.

The food additive D-pantothenamide as a source of pantothenic acid activity, may be safely used in foods for special dietary use in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.340 Fish protein isolate.

(a) The food additive fish protein isolate may be safely used as a food supplement in accordance with the following prescribed conditions:

(1) The additive shall consist principally of dried fish protein prepared from the edible portions of fish after removal of the heads, fins, tails, bones, scales, viscera, and intestinal contents.

(2) The additive shall be derived only from species of bony fish that are generally recognized by qualified scientists as safe for human consumption and that can be processed as prescribed to meet the required specifications.

(3) Only wholesome fresh fish otherwise suitable for human consumption may be used. The fish shall be handled expeditiously under sanitary conditions. These conditions shall be in accordance with recognized good manufacturing practice for fish to be used as human food.

(4) The additive shall be prepared by extraction with hexane and food-grade ethanol to remove fat and moisture. Solvent residues shall be reduced by drying.

(b) The food additive meets the following specifications: (Where methods of determination are specified, they are Association of Official Analytical Chemists Methods, 13th ed., 1980, which are incorporated by reference).[1]

(1) Protein content, as N × 6.25, shall not be less than 90 percent by weight of the final product, as determined by the method described in section 2.057, Improved Kjeldahl Method for Nitrate-Free Samples (20)—Official Final Action.

(2) Moisture content shall not be more than 10 percent by weight of the final product, as determined by the method described in section 24.003, Air Drying (1)—Official First Action.

(3) Fat content shall not be more than 0.5 percent by weight of the final product, as determined by the method described in section 24.005, Crude Fat or Ether Extract—Official Final Action.

(4) Solvent residues in the final product shall not be more than 5 parts per million of hexane and 3.5 percent ethanol by weight.

[46 FR 38072, July 24, 1981, as amended at 47 FR 53344, Nov. 26, 1982; 54 FR 24897, June 12, 1989]

§ 172.345 Folic acid (folacin).

Folic acid (CAS Reg. No. 59–30–3), also known as folacin or folate, may be safely used in food as a nutrient in accordance with the following prescribed conditions:

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[1] Copies are available from: AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(a) Folic acid is the chemical *N*-[4-[[(2-amino-1,4-dihydro-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-*L*-glutamic acid.

(b) Folic acid meets the specifications of the Food Chemicals Codex, 9th ed., updated through Third Supplement, effective December 1, 2015, pp. 495–496, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) Folic acid may be added to foods subject to a standard of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act (the act) when the standard of identity specifically provides for the addition of folic acid.

(d) Folic acid may be added, at levels not to exceed 400 micrograms (µg) per serving, to breakfast cereals, as defined under §170.3(n)(4) of this chapter, and to corn grits at a level such that each pound of corn grits contains not more than 1.0 milligram of folic acid.

(e) Folic acid may be added to infant formula in accordance with section 412(i)(1) of the act or with regulations issued under section 412(i)(2) of the act which are codified in §107.100 of this chapter.

(f) Folic acid may be added to a medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), at levels not to exceed the amount necessary to meet the distinctive nutritional requirements of the disease or condition for which the food is formulated.

(g) Folic acid may be added to food for special dietary use at levels not to exceed the amount necessary to meet the special dietary needs for which the food is formulated.

(h) Folic acid may be added to foods represented as meal-replacement products, in amounts not to exceed:

(1) Four hundred µg per serving if the food is a meal-replacement that is represented for use once per day; or

(2) Two hundred µg per serving if the food is a meal-replacement that is represented for use more than once per day.

(i) Folic acid may be added to corn masa flour at a level not to exceed 0.7 milligrams of folic acid per pound of corn masa flour.

[61 FR 8807, Mar. 5, 1996, as amended at 61 FR 27779, June 3, 1996; 64 FR 1758, Jan. 12, 1999; 78 FR 71463, Nov. 29, 2013; 81 FR 22183, Apr. 15, 2016]

§ 172.350 Fumaric acid and salts of fumaric acid.

Fumaric acid and its calcium, ferrous, magnesium, potassium, and sodium salts may be safely used in food in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) Fumaric acid contains a minimum of 99.5 percent by weight of fumaric acid, calculated on the anhydrous basis.

(2) The calcium, magnesium, potassium, and sodium salts contain a minimum of 99 percent by weight of the respective salt, calculated on the anhydrous basis. Ferrous fumarate contains a minimum of 31.3 percent total iron and not more than 2 percent ferric iron.

(b) With the exception of ferrous fumarate, fumaric acid and the named salts are used singly or in combination in food at a level not in excess of the amount reasonably required to accomplish the intended effect.

(c) Ferrous fumarate is used as a source of iron in foods for special dietary use, when the use is consistent with good nutrition practice.

§ 172.365 Kelp.

Kelp may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use

in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women. The food additive kelp is the dehydrated, ground product prepared from *Macrocystis pyrifera*, *Laminaria digitata*, *Laminaria saccharina*, and *Laminaria cloustoni*.

§ 172.370 Iron-choline citrate complex.

Iron-choline citrate complex made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in foods for special dietary use.

§ 172.372 *N*-Acetyl-L-methionine.

The food additive *N*-acetyl-L-methionine may be safely added to food (except infant foods and foods containing added nitrites/nitrates) as a source of L-methionine for use as a nutrient in accordance with the following conditions:

(a) *N*-Acetyl-L-methionine (Chemical Abstracts Service Registry No. 65–82–7) is the derivative of the amino acid methionine formed by addition of an acetyl group to the *alpha*-amino group of methionine. It may be in the free, hydrated or anhydrous form, or as the sodium or potassium salts.

(b) The additive meets the following specifications:

(1) Purity assay, on a dry basis: Minimum 99 percent.

(2) Residue on ignition: Maximum 0.1 percent.

(3) Specific optical rotation $[alpha]^{20}_{D}$: Between $-19°$ and $-23°$.

(4) The additive may contain residues of not more than 500 ppm ethyl acetate; 50 ppm ethyl alcohol; 10 ppm methyl alcohol; and 10 ppm acetone, when used as processing solvents.

(c) The additive is used or intended for use as a source of L-methionine to improve significantly the biological quality of the total protein in a food containing naturally occurring primarily intact vegetable protein that is considered a significant dietary protein source, provided that:

(1) A reasonable daily adult intake of the finished food furnishes at least 6.5 grams of naturally occurring primarily intact vegetable protein.

(2) The additive results in a protein efficiency ratio (PER) of protein in the finished ready-to-eat food equivalent to casein as determined by the method specified in paragraph (d) of this section.

(3) The use of the additive results in a statistically significant increase in the PER as determined by the method described in paragraph (d) of this section. The minimum amount of the additive to achieve the desired effect must be used, and the increase in PER over the primarily intact naturally occurring vegetable protein in the food must be substantiated as a statistically significant difference with at least a probability (P) value of less than 0.05.

(4) The amount of the additive added for nutritive purpose shall not exceed the level that will provide a total of 3.1 percent L- and DL-methionine (expressed as the free amino acid) by weight of the total protein of the finished food, including the amount naturally present in free and combined (as protein) form.

(5) The additive shall not be added to infant foods or to foods containing added nitrites/nitrates.

(d) Compliance with the limitations concerning PER under paragraph (c) of the section shall be determined by the method described in sections 43.212–43.216, ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Each manufacturer

or person employing the additive under the provisions of this section shall keep and maintain throughout the period of use of the additive and for a minimum of 3 years thereafter, records of the tests required by this paragraph and other records required to assure effectiveness and compliance with this regulation. Those records shall be made available upon request at all reasonable hours by any officer or employee acting on behalf of the Secretary of Health and Human Services. Those officers or employees shall be permitted to conduct inventories of raw and finished materials on hand as are deemed necessary to verify the records.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive contained therein.

(2) The amounts of additive and each amino acid contained in any mixture.

(3) Adequate directions for use to provide a finished food meeting the limitations prescribed by paragraph (c) of this section.

(f) When the food additive is added as a nutrient to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and these foods comply with the requirements of part 105 of this chapter, the food additive is exempt from the limitations in paragraphs (c)(1) through (4) and (d) of this section and may be used in those foods at levels not to exceed good manufacturing practices.

[43 FR 27784, June 27, 1978, as amended at 46 FR 59968, Dec. 8, 1981; 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 172.375 Potassium iodide.

The food additive potassium iodide may be safely used in accordance with the following prescribed conditions:

(a) Potassium iodide may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women.

(b) To assure safe use of the additive, in addition to the other information required by the Act, the label of the additive shall bear:

(1) The name of the additive.

(2) A statement of the concentration of the additive in any mixture.

§ 172.379 Vitamin D_2.

Vitamin D_2 may be used safely in foods as a nutrient supplement defined under §170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D_2, also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. Vitamin D_2 is produced by ultraviolet irradiation of ergosterol isolated from yeast and is purified by crystallization.

(b) Vitamin D_2 meets the specifications of the 2015 Food Chemical Codex, 9th edition (through Third Supplement), effective December 1, 2015, pp. 1260–1261, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) The additive may be used as follows:

Category of Food	Maximum Levels in Food (as Served)
Edible plant-based beverages intended as milk alternatives	84 IU/100 g.
Edible plant-based yogurt alternatives	89 IU/100 g.
Soy beverage products	89 IU/100 g
Soy-based butter substitute spreads	330 IU/100 g
Soy-based cheese substitutes and soy-based cheese substitute products	270 IU/100 g

[74 FR 11022, Mar. 16, 2009, as amended at 78 FR 71463, Nov. 29, 2013; 81 FR 46581, July 18, 2016]

§ 172.380 Vitamin D_3.

Vitamin D_3 may be used safely in foods as a nutrient supplement defined under § 170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D_3, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D_3 occurs in and is isolated from fish liver oils. It also is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization.

(b) Vitamin D_3 meets the specifications of ''Vitamin D_3,'', Food Chemicals Codex, 11th ed., copyright 2018, pp. 1243–1244, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) The additive may be used as follows:

(1) At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 330 milligrams (mg) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

(2) At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 100 mg of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

(3) At levels not to exceed 140 IU per 240 mL (prepared beverage) in soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight in accordance with § 105.66 of this chapter.

(4) At levels not to exceed 100 IU per 40 grams in meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight in accordance with § 105.66 of this chapter.

(5) At levels not to exceed 81 IU per 30 grams in cheese and cheese products as defined under § 170.3(n)(5) of this chapter, excluding cottage cheese, ricotta cheese, and hard grating cheeses such as Parmesan and Romano as defined in §§ 133.165 and 133.183 of this chapter, and those defined by standard of identity in § 133.148 of this chapter.

(6) At levels not to exceed 500 IU per 240 mL (prepared beverage) in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that the total amount of Vitamin D_3 provided by the product does not exceed 1,000 IU per day.

(7) At levels not to exceed 1.0 IU per kilocalorie in foods represented for use as a sole source of nutrition for enteral feeding.

(8) At levels not to exceed 84 IU per 100 g (800 IU/quart) in milk that contains more than 42 IU vitamin D per 100 g (400 IU/quart) and that meets the requirements for foods named by use of a nutrient content claim and a standardized term in accordance with §130.10 of this chapter.

[68 FR 9003, Feb. 27, 2003, as amended at 70 FR 36025, June 22, 2005; 70 FR 37257, June 29, 2005; 70 FR 69438, Nov. 16, 2005; 78 FR 71463, Nov. 29, 2013; 79 FR 46996, Aug. 12, 2014; 81 FR 46582, July 18, 2016; 83 FR 47559, Sept. 20, 2018]

§ 172.381 Vitamin D_2.

Vitamin D_2 bakers yeast may be used safely in foods as a source of vitamin D_2 and as a leavening agent in accordance with the following prescribed conditions:

(a) Vitamin D_2 bakers yeast is the substance produced by exposing bakers yeast (*Saccharomyces cerevisiae*) to ultraviolet light, resulting in the photochemical conversion of endogenous ergosterol in bakers yeast to vitamin D_2 (also known as ergocalciferol or (9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol)).

(b) Vitamin D_2 bakers yeast may be used alone as an active dry yeast concentrate or in combination with conventional bakers yeast.

(c) The additive may be used in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods at levels not to exceed 400 International Units of vitamin D_2 per 100 grams in the finished food.

(d) To assure safe use of the additive, the label or labeling of the food additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

(e) Labels of manufactured food products containing the additive shall bear, in the ingredient statement, the name of the additive, ''vitamin D_2 bakers yeast,'' in the proper order of decreasing predominance in the finished food.

[77 FR 52231, Aug. 29, 2012]

§ 172.382 Vitamin D_2 mushroom powder.

Vitamin D_2 mushroom powder may be used safely in foods as a source of vitamin D_2 in accordance with the following prescribed conditions:

(a) Vitamin D_2 mushroom powder is the substance produced by exposing an aqueous homogenate of edible cultivars of *Agaricus bisporus* mushrooms to ultraviolet (UV) light, resulting in the photochemical conversion of endogenous ergosterol in the mushrooms to vitamin D_2 (also known as ergocalciferol or [9,10-Seco(5Z,7E,22E)-5,7,10(19),22- ergostatetraen-3-ol]).

(b) The total dose of UV light applied to the mushroom homogenate shall not exceed 12 Joules/square centimeter (J/cm^2).

(c) Vitamin D_2 mushroom powder meets the following specifications:

(1) Moisture, not more than 10 percent.

(2) Negative for *Salmonella*, *Staphylococcus aureus*, and *Listeria monocytogenes*, and any other recognized microbial pathogen or any harmful microbial toxin.

(3) Standard plate count, not more than 5,000 colony forming units per gram (CFU/g).

(4) Yeasts and molds, not more than 100 CFU/g.

(5) Lead, not more than 0.5 milligrams per kilogram (mg/kg).

(6) Arsenic, not more than 0.3 mg/kg.

(d) To assure safe use of the additive, the label or labeling of the food additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (f) of this section.

(e) Labels of manufactured food products containing the additive shall bear, in the ingredient statement, the name of the additive ''vitamin D_2 mushroom powder,'' in the proper order of decreasing predominance in the finished food.

(f) Vitamin D_2 mushroom powder may be used as a source of vitamin D_2 in food as follows:

TABLE 1 TO PARAGRAPH (f)

Category of food	Maximum level of vitamin D_2
Breakfast cereals	350 IU/100 g.
Edible plant-based beverages marketed as milk alternatives	84 IU/100 g.
Edible plant-based products marketed as yogurt alternatives	89 IU/100 g.
Extruded vegetable snacks	80 IU/28 g.
Fruit smoothies	100 IU/240 mL.
100% fruit juices that are fortified with greater than or equal to 330 mg of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.	100 IU/240 mL.
Fruit juice drinks that are fortified with greater than or equal to 100 mg of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.	100 IU/240 mL.
Grain products and pastas	90 IU/100 g.
Meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight.	100 IU/40 g.
Meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that the total amount of Vitamin D provided by the product does not exceed 1,000 IU per day.	500 IU/240 mL.
Plant protein products	80 IU/85 g.
Soups and soup mixes, except for soup and soup mixes containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act.	100 IU/245 mL.
Soy-based spreads marketed as butter alternatives	330 IU/100 g.
Soy-based products marketed as cheese and cheese-product alternatives	270 IU/100 g.
Soy beverage products	89 IU/100 g.
Soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight.	140 IU/240 mL.
Vegetable juices	100 IU/240 mL.
Yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods.	400 IU/100 g.

[85 FR 41920, July 13, 2020]

§ 172.385 Whole fish protein concentrate.

The food additive whole fish protein concentrate may be safely used as a food supplement in accordance with the following prescribed conditions:

(a) The additive is derived from whole, wholesome hake and hakelike fish, herring of the genera *Clupea*, menhaden, and anchovy of the species *Engraulis mordax*, handled expeditiously and under sanitary conditions in accordance with good manufacturing practices recognized as proper for fish that are used in other forms for human food.

(b) The additive consists essentially of a dried fish protein processed from the whole fish without removal of heads, fins, tails, viscera, or intestinal contents. It is prepared by solvent extraction of fat and moisture with isopropyl alcohol or with ethylene dichloride followed by isopropyl alcohol, except that the additive derived from herring, menhaden and anchovy is prepared by solvent extraction with isopropyl alcohol alone. Solvent residues are reduced by conventional heat drying and/or microwave radiation and there is a partial removal of bone.

(c) The food additive meets the following specifications:

(1) Protein content (N × 6.25) shall not be less than 75 percent by weight of the final product, as determined by the method described in section 2.057 in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980). Protein quality shall not be less than 100, as determined by the method described in sections 43.212–43.216 of the AOAC. The 13th Ed. is incorporated by reference, and copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(2) Moisture content shall not exceed 10 percent by weight of the final product, as determined by the method described in section 24.003 of the AOAC.

See paragraph (c)(1) of this section for availability of the material incorporated by reference.

(3) Fat content shall not exceed 0.5 percent by weight of the final product, as determined by the method described in section 24.005 of the AOAC. See paragraph (c)(1) of the this section for availability of the material incorporated by reference.

(4) The additive may contain residues of isopropyl alcohol and ethylene dichloride not in excess of 250 parts per million and 5 parts per million, respectively, when used as solvents in the extraction process.

(5) Microwave radiation meeting the requirements of §179.30 of this chapter may be used to reduce residues of the solvents used in the extraction process.

(6) The additive shall contain not in excess of 100 parts per million fluorides (expressed as F).

(7) The additive shall be free of *Escherichia coli* and pathogenic organisms, including *Salmonella*, and shall have a total bacterial plate count of not more than 10,000 per gram.

(8) The additive shall have no more than a faint characteristic fish odor and taste.

(d) When the additive is used or intended for use in the household as a protein supplement in food for regular consumption by children up to 8 years of age, the amount of the additive from this source shall not exceed 20 grams per day (about one heaping tablespoon).

(e) When the additive is used as a protein supplement in manufactured food, the total fluoride content (expressed as F) of the finished food shall not exceed 8 ppm based on the dry weight of the food product.

(f) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of consumer-sized or bulk containers of the additive shall bear the name ''whole fish protein concentrate''.

(2) The label or labeling of containers of the additive shall bear adequate directions for use to comply with the limitations prescribed by paragraphs (d) and (e) of this section.

(3) Labels of manufactured foods containing the additive shall bear, in the ingredient statement, the name of the additive, ''whole fish protein concentrate'' in the proper order of decreasing predominance in the finished food.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 172.395 Xylitol.

Xylitol may be safely used in foods for special dietary uses, provided the amount used is not greater than that required to produce its intended effect.

§ 172.399 Zinc methionine sulfate.

Zinc methionine sulfate, CAS Reg. No. 56329–42–1, may be safely used in accordance with the following prescribed conditions:

(a) The additive is the product of the reaction between equimolar amounts of zinc sulfate and DL-methionine in purified water.

(b) The additive meets the following specifications:

Zinc content—19 to 22 percent.
$C_5H_{11}NO_2S$ ''DL-methionine''—46 to 50 percent.
Cadmium—not more than 0.05 part per million.

(c) The additive is used in tablet form as a source of dietary zinc.

[46 FR 58297, Dec. 1, 1981]

Subpart E—Anticaking Agents

§ 172.410 Calcium silicate.

Calcium silicate, including synthetic calcium silicate, may be safely used in food in accordance with the following prescribed conditions:

(a) It is used as an anticaking agent in food in an amount not in excess of that reasonably required to produce its intended effect.

(b) It will not exceed 2 percent by weight of the food, except that it may be present up to 5 percent by weight of baking powder.

§ 172.430 Iron ammonium citrate.

Iron ammonium citrate may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the chemical green ferric ammonium citrate.

(b) The additive is used, or intended for use as an anticaking agent in salt for human consumption so that the level of iron ammonium citrate does not exceed 25 parts per million (0.0025 percent) in the finished salt.

(c) To assure safe use of the additive the label or labeling of the additive shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.480 Silicon dioxide.

The food additive silicon dioxide may be safely used in food in accordance with the following conditions:

(a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.

(b) It is used as an anticaking agent, subject to the following conditions:

(1) It is used in only those foods in which the additive has been demonstrated to have an anticaking effect.

(2) It is used in an amount not in excess of that reasonably required to produce its intended effect.

(3) [Reserved]

(4) It is used in an amount not to exceed 2 percent by weight of the food.

(c) It is used or intended for use as a stabilizer in the production of beer, and is removed from the beer by filtration prior to final processing.

(d) It is used or intended for use as an adsorbent for *dl-α*-tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use, in an amount not greater than that required to accomplish the intended physical or technical effect.

§ 172.490 Yellow prussiate of soda.

(a) The food additive yellow prussiate of soda (sodium ferrocyanide decahydrate; $Na_4Fe(CN)_6 \cdot 10H_2O$ contains a minimum of 99 percent by weight of sodium ferrocyanide decahydrate.

(b) The additive is used or intended for use as an anticaking agent in salt and as an adjuvant in the production of dendritic crystals of salt in an amount needed to produce its intended effect but not in excess of 13 parts per million calculated as anhydrous sodium ferrocyanide.

[42 FR 14491, Mar. 15, 1977, as amended at 58 FR 17098, Apr. 1, 1993]

Subpart F—Flavoring Agents and Related Substances

§ 172.510 Natural flavoring substances and natural substances used in conjunction with flavors.

Natural flavoring substances and natural adjuvants may be safely used in food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended physical or technical effect and in accordance with all the principles of good manufacturing practice.

(b) In the appropriate forms (plant parts, fluid and solid extracts, concentrates, absolutes, oils, gums, balsams, resins, oleoresins, waxes, and distillates) they consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, previously sanctioned for such use, or regulated in any section of this part.

Common name	Scientific name	Limitations
Aloe	*Aloe perryi* Baker, *A. barbadensis* Mill., *A. ferox* Mill., and hybrids of this sp. with *A. africana* Mill. and *A. spicata* Baker.	
Althea root and flowers	*Althea officinalis* L.	
Amyris (West Indian sandalwood)	*Amyris balsamifera* L.	
Angola weed	*Roccella fuciformis* Ach	In alcoholic beverages only
Arnica flowers	*Arnica montana* L., *A. fulgens* Pursh, *A. sororia* Greene, or *A. cordifolia* Hooker.	Do.
Artemisia (wormwood)	*Artemisia* spp	Finished food thujone free [1]
Artichoke leaves	*Cynara scolymus* L	In alcoholic beverages only

Common name	Scientific name	Limitations
Benzoin resin	*Styrax benzoin* Dryander, *S. paralleloneurus* Perkins, *S. tonkinensis* (Pierre) Craib ex Hartwich, or other spp. of the Section *Anthostyrax* of the genus *Styrax*.	
Blackberry bark	*Rubus,* Section *Eubatus*.	
Boldus (boldo) leaves	*Peumus boldus* Mol	Do.
Boronia flowers	*Boronia megastigma* Nees.	
Bryonia root	*Bryonia alba* L., or *B. diocia* Jacq	Do.
Buchu leaves	*Barosma betulina* Bartl. et Wendl., *B. crenulata* (L.) Hook. or *B. serratifolia* Willd.	
Buckbean leaves	*Menyanthes trifoliata* L	Do.
Cajeput	*Melaleuca leucadendron* L. and other *Melaleuca* spp.	
Calumba root	*Jateorhiza palmata* (Lam.) Miers	Do.
Camphor tree	*Cinnamomum camphora* (L.) Nees et Eberm	Safrole free
Cascara sagrada	*Rhamnus purshiana* DC.	
Cassie flowers	*Acacia farnesiana* (L.) Willd.	
Castor oil	*Ricinus communis* L.	
Catechu, black	*Acacia catechu* Willd.	
Cedar, white (aborvitae), leaves and twigs	*Thuja occidentalis* L	Finished food thujone free [1]
Centuary	*Centaurium umbellatum* Gilib	In alcoholic beverages only
Cherry pits	*Prunus avium* L. or *P. cerasus* L	Not to exceed 25 p.p.m. prussic acid
Cherry-laurel leaves	*Prunus laurocerasus* L	Do.
Chestnut leaves	*Castanea dentata* (Marsh.) Borkh.	
Chirata	*Swertia chirata* Buch.-Ham	In alcoholic beverages only
Cinchona, red, bark	*Cinchona succirubra* Pav. or its hybrids	In beverages only; not more than 83 p.p.m. total cinchona alkaloids in finished beverage
Cinchona, yellow, bark	*Cinchona ledgeriana* Moens, *C. calisaya* Wedd., or hybrids of these with other spp. of *Cinchona*..	Do.
Copaiba	South American spp. of *Copaifera* L.	
Cork, oak	*Quercus suber* L., or *Q. occidentalis* F. Gay	In alcoholic beverages only
Costmary	*Chrysanthemum balsamita* L	Do.
Costus root	*Saussurea lappa* Clarke.	
Cubeb	*Piper cubeba* L. f.	
Currant, black, buds and leaves	*Ribes nigrum* L.	
Damiana leaves	*Turnera diffusa* Willd.	
Davana	*Artemisia pallens* Wall.	
Dill, Indian	*Anethum sowa* Roxb. (*Peucedanum graveolens* Benth et Hook., *Anethum graveolens* L.).	
Dittany (fraxinella) roots	*Dictamnus albus* L	Do.
Dittany of Crete	*Origanum dictamnus* L.	
Dragon's blood (dracorubin)	*Daemonorops* spp.	
Elder tree leaves	*Sambucus nigra* L	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor
Elecampane rhizome and roots	*Inula helenium* L	In alcoholic beverages only
Elemi	*Canarium commune* L. or *C. luzonicum* Miq.	
Erigeron	*Erigeron canadensis* L.	
Eucalyptus globulus leaves	*Eucalyptus globulus* Labill.	
Fir (''pine'') needles and twigs	*Abies sibirica* Ledeb., *A. alba* Mill., *A. sachalinesis* Masters or *A. mayriana* Miyabe et Kudo.	
Fir, balsam, needles and twigs	*Abies balsamea* (L.) Mill.	
Galanga, greater	*Alpinia galanga* Willd	Do.
Galbanum	*Ferula galbaniflua* Boiss. et Buhse and other *Ferula* spp.	
Gambir (catechu, pale)	*Uncaria gambir* Roxb.	
Genet flowers	*Spartium junceum* L.	
Gentian rhizome and roots	*Gentiana lutea* L.	
Gentian, stemless	*Gentiana acaulis* L	Do.
Germander, chamaedrys	*Teucrium chamaedrys* L	Do.
Germander, golden	*Teucrium polium* L	Do.
Guaiac	*Guaiacum officinale* L., *G. santum* L., *Bulnesia sarmienti* Lor.	
Guarana	*Paullinia cupana* HBK.	
Haw, black, bark	*Viburnum prunifolium* L.	
Hemlock needles and twigs	*Tsuga canadensis* (L.) Carr. or *T. heterophylla* (Raf.) Sarg.	

Common name	Scientific name	Limitations
Hyacinth flowers	*Hyacinthus orientalis* L.	
Iceland moss	*Cetraria islandica* Ach	Do.
Imperatoria	*Peucedanum ostruthium* (L.). Koch (*Imperatoria ostruthium* L.).	
Iva	*Achillea moschata* Jacq	Do.
Labdanum	*Cistus* spp.	
Lemon-verbena	*Lippia citriodora* HBK	Do.
Linaloe wood	*Bursera delpechiana* Poiss. and other *Bursera* spp.	
Linden leaves	*Tillia* spp	Do.
Lovage	*Levisticum officinale* Koch.	
Lungmoss (lungwort)	*Sticta pulmonacea* Ach.	
Maidenhair fern	*Adiantum capillus-veneris* L	Do.
Maple, mountain	*Acer spicatum* Lam.	
Mimosa (black wattle) flowers	*Acacia decurrens* Willd. var. *dealbata.*	
Mullein flowers	*Verbascum phlomoides* L. or *V. thapsiforme* Schrad	Do.
Myrrh	*Commiphora molmol* Engl., *C. abyssinica* (Berg) Engl., or other *Commiphora* spp.	
Myrtle leaves	*Myrtus communis* L	Do.
Oak, English, wood	*Quercus robur* L	Do.
Oak, white, chips	*Quercus alba* L.	
Oak moss	*Evernia prunastri* (L.) Ach., *E. furfuracea* (L.) Mann, and other lichens.	Finished food thujone free [1]
Olibanum	*Boswellia carteri* Birdw. and other *Boswellia* spp.	
Opopanax (bisabolmyrrh)	*Opopanax chironium* Koch (true opopanax) of *Commiphora erythraea* Engl. var. *Llabrescens.*	
Orris root	*Iris germanica* L. (including its variety *florentina* Dykes) and *I. pallida* Lam.	
Pansy	*Viola tricolor* L	In alcoholic beverages only
Passion flower	*Passiflora incarnata* L.	
Patchouly	*Pogostemon cablin* Benth. and *P. heyneanus* Benth.	
Peach leaves	*Prunus persica* (L.) Batsch	In alcoholic beverages only; not to exceed 25 p.p.m. prussic acid in the flavor
Pennyroyal, American	*Hedeoma pulegioides* (L.) Pers.	
Pennyroyal, European	*Mentha pulegium* L.	
Pine, dwarf, needles and twigs	*Pinus mugo* Turra var. *pumilio* (Haenke) Zenari.	
Pine, Scotch, needles and twigs	*Pinus sylvestris* L.	
Pine, white, bark	*Pinus strobus* L	In alcoholic beverages only
Pine, white oil	*Pinus palustris* Mill., and other *Pinus* spp.	
Poplar buds	*Populus balsamifera* L. (*P. tacamahacca* Mill.), *P. candicans* Ait., or *P. nigra* L.	Do.
Quassia	*Picrasma excelsa* (Sw.) Planch, or *Quassia amara* L.	
Quebracho bark	*Aspidosperma quebracho-blanco* Schlecht, or (*Quebrachia lorentzii* (Griseb)).	*Schinopsis lorentzii* (Griseb.) Engl.
Quillaia (soapbark)	*Quillaja saponaria* Mol.	
Red saunders (red sandalwood)	*Pterocarpus san alinus* L	In alcoholic beverages only
Rhatany root	*Krameria triandra* Ruiz et Pav. or *K. argentea* Mart.	
Rhubarb, garden root	*Rheum rhaponticum* L	Do.
Rhubarb root	*Rheum officinale* Baill., *R. palmatum* L., or other spp. (excepting *R. rhaponticum* L.) or hybrids of *Rheum* grown in China.	
Roselle	*Hibiscus sabdariffa* L	Do.
Rosin (colophony)	*Pinus palustris* Mill., and other *Pinus* spp	Do.
St. Johnswort leaves, flowers, and caulis	*Hypericum perforatum* L	Hypericin-free alcohol distillate form only; in alcoholic beverages only
Sandalwood, white (yellow, or East Indian)	*Santalum album* L.	
Sandarac	*Tetraclinis articulata* (Vahl.), Mast	In alcoholic beverages only
Sarsaparilla	*Smilax aristolochiaefolia* Mill., (Mexican sarsaparilla), *S. regelii* Killip et Morton (Honduras sarsaparilla), *S. febrifuga* Kunth (Ecuadorean sarsaparilla), or undetermined *Smilax* spp. (Ecuadorean or Central American sarsaparilla).	
Sassafras leaves	*Sassafras albidum* (Nutt.) Nees	Safrole free
Senna, Alexandria	*Cassia acutifolia* Delile.	
Serpentaria (Virginia snakeroot)	*Aristolochia serpentaria* L	In alcoholic beverages only
Simaruba bark	*Simaruba amara* Aubl	Do.
Snakeroot, Canadian (wild ginger)	*Asarum canadense* L.	

Common name	Scientific name	Limitations
Spruce needles and twigs	*Picea glauca* (Moench) Voss or *P. mariana* (Mill.) BSP.	
Storax (styrax)	*Liquidambar orientalis* Mill. or *L. styraciflua* L.	
Tagetes (marigold)	*Tagetes patula* L., *T. erecta* L., or *T. minuta* L. (*T. glandulifera* Schrank).	As oil only
Tansy	*Tanacetum vulgare* L	In alcoholic beverages only; finished alcoholic beverage thujone free [1]
Thistle, blessed (holy thistle)	*Onicus benedictus* L	In alcoholic beverages only
Thymus capitatus (Spanish ''origanum'')	*Thymus capitatus* Hoffmg. et Link.	
Tolu	*Myroxylon balsamum* (L.) Harms.	
Turpentine	*Pinus palustris* Mill. and other *Pinus* spp. which yield terpene oils exclusively.	
Valerian rhizome and roots	*Valeriana officinalis* L.	
Veronica	*Veronica officinalis* L	Do.
Vervain, European	*Verbena officinalis* L	Do.
Vetiver	*Vetiveria zizanioides* Stapf	Do.
Violet, Swiss	*Viola calcarata* L.	
Walnut husks (hulls), leaves, and green nuts	*Juglans nigra* L. or *J. regia* L.	
Woodruff, sweet	*Asperula odorata* L	In alcoholic beverages only
Yarrow	*Achillea millefolium* L	In beverages only; finished beverage thujone free [1]
Yerba santa	*Eriodictyon californicum* (Hook, et Arn.) Torr.	
Yucca, Joshua-tree	*Yucca brevifolia* Engelm.	
Yucca, Mohave	*Yucca schidigera* Roezl ex Ortgies (*Y. mohavensis* Sarg.).	

[1] As determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in section 9.129 of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/ code__of__federal__regulations/ ibr__locations.html.*

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 14644, Apr. 7, 1978; 49 FR 10104, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 69 FR 24511, May 4, 2004; 72 FR 10357, Mar. 8, 2007]

§ 172.515 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants may be safely used in food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended effect, and otherwise in accordance with all the principles of good manufacturing practice.

(b) They consist of one or more of the following, used alone or in combination with flavoring substances and adjuvants generally recognized as safe in food, prior-sanctioned for such use, or regulated by an appropriate section in this part.

Acetal; acetaldehyde diethyl acetal.
Acetaldehyde phenethyl propyl acetal.
Acetanisole; 4′-methoxyacetophenone.
Acetophenone; methyl phenyl ketone.
Allyl anthranilate.
Allyl butyrate.
Allyl cinnamate.
Allyl cyclohexaneacetate.
Allyl cyclohexanebutyrate.
Allyl cyclohexanehexanoate.
Allyl cyclohexaneproprionate.
Allyl cyclohexanevalerate.
Allyl disulfide.
Allyl 2-ethylbutyrate.
Allyl hexanoate; allyl caproate.
Allyl α-ionone; 1-(2,6,6-trimethyl-2-cyclo-hexene-1-yl)-1,6-heptadiene-3-one.
Allyl isothiocyanate; mustard oil.
Allyl isovalerate.
Allyl mercaptan; 2-propene-1-thiol.
Allyl nonanoate.
Allyl octanoate.
Allyl phenoxyacetate.
Allyl phenylacetate.
Allyl propionate.
Allyl sorbate; allyl 2,4-hexadienoate.
Allyl sulfide.
Allyl tiglate; allyl *trans*-2-methyl-2-butenoate.
Allyl 10-undecenoate.
Ammonium isovalerate.
Ammonium sulfide.
Amyl alcohol; pentyl alcohol.
Amyl butyrate.
α-Amylcinnamaldehyde.
α-Amylcinnamaldehyde dimethyl acetal.

α-Amylcinnamyl acetate.
α-Amylcinnamyl alcohol.
α-Amylcinnamyl formate.
α-Amylcinnamyl isovalerate.
Amyl formate.
Amyl heptanoate.
Amyl hexanoate.
Amyl octanoate.
Anisole; methoxybenzene.
Anisyl acetate.
Anisyl alcohol; *p*-methoxybenzyl alcohol.
Anisyl butyrate
Anisyl formate.
Anisyl phenylacetate.
Anisyl propionate.
Beechwood creosote.
Benzaldehyde dimethyl acetal.
Benzaldehyde glyceryl acetal; 2-phenyl-*m*-dioxan-5-ol.
Benzaldehyde propylene glycol acetal; 4-methyl-2-phenyl-*m*-dioxolane.
Benzenethiol; thiophenol.
Benzoin; 2-hydroxy-2-phenylacetophenone.
Benzyl acetate.
Benzyl acetoacetate.
Benzyl alcohol.
Benzyl benzoate.
Benzyl butyl ether.
Benzyl butyrate.
Benzyl cinnamate.
Benzyl 2,3–dimethylcrotonate; benzyl methyl tiglate.
Benzyl disulfide; dibenzyl disulfide.
Benzyl ethyl ether.
Benzyl formate.
3-Benzyl-4-heptanone; benzyl dipropyl ketone.
Benzyl isobutyrate.
Benzyl isovalerate.
Benzyl mercaptan; α-toluenethiol.
Benzyl methoxyethyl acetal; acetaldehyde benzyl β-methoxyethyl acetal.
Benzyl phenylacetate.
Benzyl propionate.
Benzyl salicylate.
Birch tar oil.
Borneol; *d*-camphanol.
Bornyl acetate.
Bornyl formate.
Bornyl isovalerate.
Bornyl valerate.
β-Bourbonene; 1,2,3,3a,3bβ,4,5,6,6aβ,6bα-decahydro-lα-isopropyl-3a$_a$-methyl-6-methylene-cyclobuta [1,2:3,4] dicyclopentene.
2-Butanol.
2-Butanone; methyl ethyl ketone.
Butter acids.
Butter esters.
Butyl acetate.
Butyl acetoacetate.
Butyl alcohol; 1-butanol.
Butyl anthranilate.
Butyl butyrate.
Butyl butyryllactate; lactic acid, butyl ester, butyrate.
α-Butylcinnamaldehyde.
Butyl cinnamate.
Butyl 2-decenoate.
Butyl ethyl malonate.
Butyl formate.
Butyl heptanoate.
Butyl hexanoate.
Butyl *p*-hydroxybenzoate.
Butyl isobutyrate.
Butyl isovalerate.
Butyl lactate.
Butyl laurate.
Butyl levulinate.
Butyl phenylacetate.
Butyl propionate.
Butyl stearate.
Butyl sulfide.
Butyl 10-undecenoate.
Butyl valerate.
Butyraldehyde.
Cadinene.
Camphene; 2,2-dimethyl-3-methylene-norbornane.
d-Camphor.
Carvacrol; 2-*p*-cymenol.
Carvacryl ethyl ether; 2-ethoxy-*p*-cymene.
Carveol; *p*-mentha-6,8-dien-2-ol.
4-Carvomenthenol; 1-*p*-menthen-4-ol; 4-terpinenol.
cis Carvone oxide; 1,6-epoxy-*p*-menth-8-en-2-one.
Carvyl acetate.
Carvyl propionate.
β-Caryophyllene.
Caryophyllene alcohol.
Caryophyllene alcohol acetate.
β-Caryophyllene oxide; 4-12,12-trimethyl-9-methylene-5-oxatricylo [8.2.0.0$^{4\,6}$] dodecane.
Cedarwood oil alcohols.
Cedarwood oil terpenes.
1,4-Cineole.
Cinnamaldehyde ethylene glycol acetal.
Cinnamic acid.
Cinnamyl acetate.
Cinnamyl alcohol; 3-phenyl-2-propen-1-ol.
Cinnamyl benzoate.
Cinnamyl butyrate.
Cinnamyl cinnamate.
Cinnamyl formate.
Cinnamyl isobutyrate.
Cinnamyl isovalerate.
Cinnamyl phenylacetate.
Cinnamyl propionate.
Citral diethyl acetal; 3,7-dimethyl-2,6-octadienal diethyl acetal.
Citral dimethyl acetal; 3,7-dimethyl-2,6-octadienal dimethyl acetal.
Citral propylene glycol acetal.
Citronellal; 3,7-dimethyl-6-octenal; rhodinal.
Citronellol; 3,7-dimethyl-6-octen-1-ol; *d*-citronellol.
Citronelloxyacetaldehyde.
Citronellyl acetate.
Citronellyl butyrate.
Citronellyl formate.
Citronellyl isobutyrate.
Citronellyl phenylacetate.
Citronellyl propionate.

Citronellyl valerate.
p-Cresol.
Cuminaldehyde; cuminal; *p*-isopropyl benzaldehyde.
Cyclohexaneacetic acid.
Cyclohexaneethyl acetate.
Cyclohexyl acetate.
Cyclohexyl anthranilate.
Cyclohexyl butyrate.
Cyclohexyl cinnamate.
Cyclohexyl formate.
Cyclohexyl isovalerate.
Cyclohexyl propionate.
p-Cymene.
γ-Decalactone; 4-hydroxy-decanoic acid, γ-lactone.
γ-Decalactone; 5-hydroxy-decanoic acid, δ-lactone.
Decanal dimethyl acetal.
1-Decanol; decylic alcohol.
2-Decenal.
3-Decen-2-one; heptylidene acetone.
Decyl actate.
Decyl butyrate.
Decyl propionate.
Dibenzyl ether.
4,4-Dibutyl-γ-butyrolactone; 4,4-dibutyl-4-hydroxy-butyric acid, γ-lactone.
Dibutyl sebacate.
Diethyl malate.
Diethyl malonate; ethyl malonate.
Diethyl sebacate.
Diethyl succinate.
Diethyl tartrate.
2,5-Diethyltetrahydrofuran.
Dihydrocarveol; 8-*p*-menthen-2-ol; 6-methyl-3-isopropenylcyclohexanol.
Dihydrocarvone.
Dihydrocarvyl acetate.
m-Dimethoxybenzene.
p-Dimethoxybenzene; dimethyl hydroquinone.
2,4-Dimethylacetophenone.
α,α-Dimethylbenzyl isobutyrate; phenyldimethylcarbinyl isobutyrate.
2,6-Dimethyl-5-heptenal.
2,6-Dimethyl octanal; isodecylaldehyde.
3,7-Dimethyl-1-octanol; tetrahydrogeraniol.
α,α-Dimethylphenethyl acetate; benzylpropyl acetate; benzyldimethylcarbinyl acetate.
α,α-Dimethylphenethyl alcohol; dimethylbenzyl carbinol.
α,α-Dimethylphenethyl butyrate; benzyldimethylcarbinyl butyrate.
α,α-Dimethylphenethyl formate; benzyldimethylcarbinyl formate.
Dimethyl succinate.
1,3-Diphenyl-2-propanone; dibenzyl ketone.
delta-Dodecalactone; 5-hydroxydodecanoic acid, deltalactone.
γ-Dodecalactone; 4-hydroxydodecanoic acid γ-lactone.
2-Dodecenal.
Estragole.
ρ-Ethoxybenzaldehyde.
Ethyl acetoacetate.
Ethyl 2-acetyl-3-phenylpropionate; ethylbenzyl acetoacetate.
Ethyl aconitate, mixed esters.
Ethyl ρ-anisate.
Ethyl anthranilate.
Ethyl benzoate.
Ethyl benzoylacetate.
α-Ethylbenzyl butyrate; α-phenylpropyl butyrate.
Ethyl brassylate; tridecanedioic acid cyclic ethylene glycol diester; cyclo 1,13-ethylenedioxytridecan-1,13-dione.
2-Ethylbutyl acetate.
2-Ethylbutyraldehyde.
2-Ethylbutyric acid.
Ethyl cinnamate.
Ethyl crotonate; *trans*-2-butenoic acid ethyl ester.
Ethyl cyclohexanepropionate.
Ethyl decanoate.
2-Ethylfuran.
Ethyl 2-furanpropionate.
4-Ethylguaiacol; 4-ethyl-2-methoxyphenol.
Ethyl heptanoate.
2-Ethyl-2-heptenal; 2-ethyl-3-butylacrolein.
Ethyl hexanoate.
Ethyl isobutyrate.
Ethyl isovalerate.
Ethyl lactate.
Ethyl laurate.
Ethyl levulinate.
Ethyl maltol; 2-ethyl-3-hydroxy-4H-pyran-4-one.
Ethyl 2-methylbutyrate.
Ethyl myristate.
Ethyl nitrite.
Ethyl nonanoate.
Ethyl 2-nonynoate; ethyl octyne carbonate.
Ethyl octanoate.
Ethyl oleate.
Ethyl phenylacetate.
Ethyl 4-phenylbutyrate.
Ethyl 3-phenylglycidate.
Ethyl 3-phenylpropionate; ethyl hydrocinnamate.
Ethyl propionate.
Ethyl pyruvate.
Ethyl salicylate.
Ethyl sorbate; ethyl 2,4-hexadienoate.
Ethyl tiglate; ethyl *trans*-2-methyl-2-butenoate.
Ethyl undecanoate.
Ethyl 10-undecenoate.
Ethyl valerate.
Eucalyptol; 1,8-epoxy-*p*-menthane; cineole.
Eugenyl acetate.
Eugenyl benzoate.
Eugenyl formate.
Farnesol; 3,7,11-trimethyl-2,6,10-dodecatrien-1-ol.
d-Fenchone; *d*-1,3,3-trimethyl-2-norbornanone.
Fenchyl alcohol; 1,3,3-trimethyl-2-norbornanol.
Formic acid
(2-Furyl)-2-propanone; furyl acetone.
1-Furyl-2-propanone; furyl acetone.

Fusel oil, refined (mixed amyl alcohols).
Geranyl acetoacetate; *trans*-3,7-dimethyl-2, 6-octadien-1-yl acetoacetate.
Geranyl acetone; 6,10-dimethyl-5,9-undecadien-2-one.
Geranyl benzoate.
Geranyl butyrate.
Geranyl formate.
Geranyl hexanoate
Geranyl isobutyrate.
Geranyl isovalerate.
Geranyl phenylacetate.
Geranyl propionate.
Glucose pentaacetate.
Guaiacol; μ-methoxyphenol.
Guaiacyl acetate; μ-methoxyphenyl acetate.
Guaiacyl phenylacetate.
Guaiene; 1,4-dimethyl-7-isopropenyl-Δ9,10-octahydroazulene.
Guaiol acetate; 1,4-dimethyl-7-(α-hydroxyisopropyl)-δ9,10-octahydroazulene acetate.
γ-Heptalactone; 4-hydroxyheptanoic acid, γ-lactone.
Heptanal; enanthaldehyde.
Heptanal dimethyl acetal.
Heptanal 1,2-glyceryl acetal.
2,3-Heptanedione; acetyl valeryl.
3-Heptanol.
2-Heptanone; methyl amyl ketone.
3-Heptanone; ethyl butyl ketone.
4-Heptanone; dipropyl ketone.
cis-4-Heptenal; *cis*-4-hepten-1-al.
Heptyl acetate.
Heptyl alcohol; enanthic alcohol.
Heptyl butyrate.
Heptyl cinnamate.
Heptyl formate.
Heptyl isobutyrate.
Heptyl octanoate.
1-Hexadecanol; cetyl alcohol.
ω-6-Hexadecenlactone; 16-hydroxy-6-hexadecenoic acid, ω-lactone; ambrettolide.
γ-Hexalactone; 4-hydroxyhexanoic acid, γ-lactone; tonkalide.
Hexanal; caproic aldehyde.
2,3-Hexanedione; acetyl butyryl.
Hexanoic acid; caproic acid.
2-Hexenal.
2-Hexen-1-ol.
3-Hexen-1-ol; leaf alcohol.
2-Hexen-1-yl acetate.
3-Hexenyl isovalerate.
3-Hexenyl 2-methylbutyrate.
3-Hexenyl phenylacetate; *cis*-3-hexenyl phenylacetate.
Hexyl acetate.
2-Hexyl-4-acetoxytetrahydrofuran.
Hexyl alcohol.
Hexyl butyrate.
α-Hexylcinnamaldehyde.
Hexyl formate.
Hexyl hexanoate.
2-Hexylidene cyclopentanone.
Hexyl isovalerate.
Hexyl 2-methylbutyrate.
Hexyl octanoate.
Hexyl phenylacetate; *n*-hexyl phenylacetate.
Hexyl propionate.
Hydroxycitronellal; 3,7-dimethyl-7-hydroxyoctanal.
Hydroxycitronellal diethyl acetal.
Hydroxycitronellal dimethyl acetal.
Hydroxycitronellol; 3,7-dimethyl-1,7-octanediol.
N-(4-Hydroxy-3-methoxybenzyl)-nonanamide; pelargonyl vanillylamide.
5-Hydroxy-4-octanone; butyroin.
4-(*p*-Hydroxyphenyl)-2-butanone; *p*-hydroxybenzyl acetone.
Indole.
α-Ionone; 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one.
β-Ionone; 4-(2,6,6-trimethyl-1-cyclohexen-1-yl)-3-buten-2-one.
α-Irone; 4-(2,5,6,6-tetramethyl-2-cyclohexene-1-yl)-3-buten-2-one; 6-methylionone.
Isoamyl acetate.
Isoamyl acetoacetate.
Isoamyl alcohol; isopentyl alcohol; 3-methyl-1-butanol.
Isoamyl benzoate.
Isoamyl butyrate.
Isoamyl cinnamate.
Isoamyl formate.
Isoamyl 2-furanbutyrate; α-isoamyl furfurylpropionate.
Isoamyl 2-furanpropionate; α-isoamyl furfurylacetate.
Isoamyl hexanoate.
Isoamyl isobutyrate.
Isoamyl isovalerate.
Isoamyl laurate.
Isoamyl-2-methylbutyrate; isopentyl-2-methylbutyrate.
Isoamyl nonanoate.
Isoamyl octanoate.
Isoamyl phenylacetate.
Isoamyl propionate.
Isoamyl pyruvate.
Isoamyl salicylate.
Isoborneol.
Isobornyl acetate.
Isobornyl formate.
Isobornyl isovalerate.
Isobornyl propionate.
Isobutyl acetate.
Isobutyl acetoacetate.
Isobutyl alcohol.
Isobutyl angelate; isobutyl *cis*-2-methyl-2-butenoate.
Isobutyl anthranilate.
Isobutyl benzoate.
Isobutyl butyrate.
Isobutyl cinnamate.
Isobutyl formate.
Isobutyl 2-furanpropionate.
Isobutyl heptanoate.
Isobutyl hexanoate.
Isobutyl isobutyrate.
α-Isobutylphenethyl alcohol; isobutyl benzyl carbinol; 4-methyl-1-phenyl-2-pentanol.
Isobutyl phenylacetate.
Isobutyl propionate.

Isobutyl salicylate.
2-Isobutylthiazole.
Isobutyraldehyde.
Isobutyric acid.
Isoeugenol; 2-methoxy-4-propenylphenol.
Isoeugenyl acetate.
Isoeugenyl benzyl ether; benzyl isoeugenol.
Isoeugenyl ethyl ether; 2-ethoxy-5-propenylanisole; ethyl isoeugenol.
Isoeugenyl formate.
Isoeugenyl methyl ether; 4-propenylveratrole; methyl isoeugenol.
Isoeugenyl phenylacetate.
Isojasmone; mixture of 2-hexylidenecyclopentanone and 2-hexyl-2-cyclopenten-1-one.
α-Isomethylionone; 4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-methyl-3-buten-2-one; methyl γ-ionone.
Isopropyl acetate.
ρ-Isopropylacetophenone.
Isopropyl alcohol; isopropanol.
Isopropyl benzoate.
ρ-Isopropylbenzyl alcohol; cuminic alcohol; ρ-cymen-7-ol.
Isopropyl butyrate.
Isopropyl cinnamate.
Isopropyl formate.
Isopropyl hexanoate.
Isopropyl isobutyrate.
Isopropyl isovalerate.
ρ-Isopropylphenylacetaldehyde; ρ-cymen-7-carboxaldehyde.
Isopropyl phenylacetate.
3-(ρ-Isopropylphenyl)-propionaldehyde; ρ-isopropylhydrocinnamaldehyde; cuminyl acetaldehyde.
Isopropyl propionate.
Isopulegol; *p*-menth-8-en-3-ol.
Isopulegone; *p*-menth-8-en-3-one.
Isopulegyl acetate.
Isoquinoline.
Isovaleric acid.
cis-Jasmone; 3-methyl-2-(2-pentenyl)-2-cyclopenten-1-one.
Lauric aldehyde; dodecanal.
Lauryl acetate.
Lauryl alcohol; 1-dodecanol.
Lepidine; 4-methylquinoline.
Levulinic acid.
Linalool oxide; *cis*- and *trans*-2-vinyl-2-methyl-5-(1′-hydroxy-1′-methylethyl) tetrahydrofuran.
Linalyl anthranilate; 3,7-dimethyl-1,6-octadien-3-yl anthranilate.
Linalyl benzoate.
Linalyl butyrate.
Linalyl cinnamate.
Linalyl formate.
Linalyl hexanoate.
Linalyl isobutyrate.
Linalyl isovalerate.
Linalyl octanoate.
Linalyl propionate.
Maltol; 3-hydroxy-2-methyl-4H-pyran-4-one.
Menthadienol; *p*-mentha-1,8(10)-dien-9-ol.
p-Mentha-1,8-dien-7-ol; perillyl alcohol.
Menthadienyl acetate; *p*-mentha-1,8(10)-dien-9-yl acetate.
p-Menth-3-en-1-ol.
1-*p*-Menthen–9-yl acetate; *p*-menth-1-en-9-yl acetate.
Menthol; 2-isopropyl-5-methylcyclohexanol.
Menthone; *p*-menthan-3-one.
Menthyl acetate; *p*-menth-3-yl acetate.
Menthyl isovalerate; *p*-menth-3-yl isovalerate.
o-Methoxybenzaldehyde.
p-Methoxybenzaldehyde; *p*-anisaldehyde.
o-Methoxycinnamaldehyde.
2-Methoxy-4-methylphenol; 4-methylguaiacol; 2-methoxy-*p*-cresol.
4-(*p*-Methoxyphenyl)-2-butanone; anisyl acetone.
1-(4-Methoxyphenyl)-4-methyl-1-penten-3-one; methoxystyryl isopropyl ketone.
1-(*p*-Methoxyphenyl)-1-penten-3-one; α-methylanisylidene acetone; ethone.
1-(*p*-Methoxyphenyl)-2-propanone; anisylmethyl ketone; anisic ketone.
2-Methoxy-4-vinylphenol; *p*-vinylguaiacol.
Methyl acetate.
4′-Methylacetophenone; *p*-methylacetophenone; methyl *p*-tolyl ketone.
2-Methylallyl butyrate; 2-methyl-2-propenlyl butyrate.
Methyl anisate.
o-Methylanisole; *o*-cresyl methyl ether.
p-Methylanisole; *p*-cresyl methyl ether; *p*-methoxytoluene.
Methyl benzoate.
Methylbenzyl acetate, mixed *o*-,*m*-,*p*-.
α-Methylbenzyl acetate; styralyl acetate.
α-Methylbenzyl alcohol; styralyl alcohol.
α-Methylbenzyl butyrate; styralyl butyrate.
α-Methylbenzyl isobutyrate; styralyl isobutyrate.
α-Methylbenzyl formate; styralyl formate.
α-Methylbenzyl propionate; styralyl propionate.
2-Methyl-3-buten-2-ol.
2-Methylbutyl isovalerate.
Methyl *p*-*tert*-butylphenylacetate.
2-Methylbutyraldehyde; methyl ethyl acetaldehyde.
3-Methylbutyraldehyde; isovaleraldehyde.
Methyl butyrate.
2-Methylbutyric acid.
α-Methylcinnamaldehyde.
p-Methylcinnamaldehyde.
Methyl cinnamate.
2-Methyl-1,3-cyclohexadiene.
Methylcyclopentenolone; 3-methylcyclopentane-1,2-dione.
Methyl disulfide; dimethyl disulfide.
Methyl ester of rosin, partially hydrogenated (as defined in §172.615); methyl dihydroabietate.
Methyl heptanoate.
2-Methylheptanoic acid.
6-Methyl-3,5-heptadien-2-one.
Methyl-5-hepten-2-ol.
6-Methyl-5-hepten-2-one.
Methyl hexanoate.

Methyl 2-hexanoate.
Methyl *p*-hydroxybenzoate; methylparaben.
Methyl α-ionone; 5-(2,6,6-trimethyl-2-cyclohexen-1-yl)-4-penten-3-one.
Methyl β-ionone; 5-(2,6,6-trimethyl-1-cyclohexen-1-yl)-4-penten-3-one.
Methyl Δ-ionone; 5-(2,6,6-trimethyl-3-cyclohexen-1-yl-)-4-penten-3-one.
Methyl isobutyrate.
2-Methyl-3-(*p*-isopropylphenyl)-propionaldehyde; α-methyl-*p*-isopropylhydrocinnamal- dehyde; cyclamen aldehyde.
Methyl isovalerate.
Methyl laurate.
Methyl mercaptan; methanethiol.
Methyl *o*-methoxybenzoate.
Methyl *N*-methylanthranilate; dimethyl anthranilate.
Methyl 2-methylbutyrate.
Methyl-3-methylthiopropionate.
Methyl 4-methylvalerate.
Methyl myristate.
Methyl β-naphthyl ketone; 2′-acetonaphthone.
Methyl nonanoate.
Methyl 2-nonenoate.
Methyl 2-nonynoate; methyloctyne carbonate.
2-Methyloctanal; methyl hexyl acetaldehyde.
Methyl octanoate.
Methyl 2-octynoate; methyl heptine carbonate.
4-Methyl-2,3-pentanedione; acetyl isobutyryl.
4-Methyl-2-pentanone; methyl isobutyl ketone.
β-Methylphenethyl alcohol; hydratropyl alcohol.
Methyl phenylacetate.
3-Methyl-4-phenyl-3-butene-2-one.
2-Methyl-4-phenyl-2-butyl acetate; dimethylphenylethyl carbinyl acetate.
2-Methyl-4-phenyl-2-butyl isobutyrate; dimethylphenyl ethylcarbinyl isobutyrate.
3-Methyl-2-phenylbutyraldehyde; α-isopropyl phenylacetaldehyde.
Methyl 4-phenylbutyrate.
4-Methyl-1-phenyl-2-pentanone; benzyl isobutyl ketone.
Methyl 3-phenylpropionate; methyl hydrocinnamate.
Methyl propionate.
3-Methyl-5-propyl-2-cyclohexen-1-one.
Methyl sulfide.
3-Methylthiopropionaldehyde; methional.
2-Methyl-3-tolylpropionaldehyde, mixed *o*-, *m*-, *p*-.
2-Methylundecanal; methyl nonyl acetaldehyde.
Methyl 9-undecenoate.
Methyl 2-undecynoate; methyl decyne carbonate.
Methyl valerate.
2-Methylvaleric acid.
Myristaldehyde; tetradecanal.
d-Neomenthol; 2-isopropyl-5-methylcyclohexanol.
Nerol; *cis*-3,7-dimethyl-2,6-octadien-1-ol.
Nerolidol; 3,7,11-trimethyl-1,6,10-dodecatrien-3-ol.
Neryl acetate.
Neryl butyrate.
Neryl formate.
Neryl isobutyrate.
Neryl isovalerate.
Neryl propionate.
2,6-Nonadien-1-ol.
γ-Nonalactone; 4-hydroxynonanoic acid, γ-lactone; aldehyde C–18.
Nonanal; pelargonic aldehyde.
1,3-Nonanediol acetate, mixed esters.
Nonanoic acid; pelargonic acid.
2-Nonanone; methylheptyl ketone.
3-Nonanon-1-yl acetate; 1-hydroxy-3-nonanone acetate.
Nonyl acetate.
Nonyl alcohol; 1-nonanol.
Nonyl octanoate.
Nonyl isovalerate.
Nootkatone; 5,6-dimethyl-8-isopropenylbicyclo[4,4,0]-dec-1-en-3-one.
Ocimene; *trans*-β-ocimene; 3,7-dimethyl-1,3,6-octatriene.
γ-Octalactone; 4-hydroxyoctanoic acid, γ-lactone.
Octanal; caprylaldehyde.
Octanal dimethyl acetal.
1-Octanol; octyl alcohol.
2-Octanol.
3-Octanol.
2-Octanone; methyl hexyl ketone.
3-Octanone; ethyl amyl ketone.
3-Octanon-1-ol.
1-Octen-3-ol; amyl vinyl carbinol.
1-Octen-3-yl acetate.
Octyl acetate.
3-Octyl acetate.
Octyl butyrate.
Octyl formate.
Octyl heptanoate.
Octyl isobutyrate.
Octyl isovalerate.
Octyl octanoate.
Octyl phenylacetate.
Octyl propionate.
ω-Pentadecalactone; 15-hydroxypentadecanoic acid, ω-lactone; pentadecanolide; angelica lactone.
2,3-Pentanedione; acetyl propionyl.
2-Pentanone; methyl propyl ketone.
4-Pentenoic acid.
1-Penten-3-ol.
Perillaldehyde; 4-isopropenyl-1-cyclohexene-1-carboxaldehyde;*p*-mentha-1,8-dien-7-al.
Perillyl acetate; *p*-mentha-1,8-dien-7-yl acetate.
α-Phellandrene; ρ-mentha-1,5-diene.
Phenethyl acetate.
Phenethyl alcohol; β-phenylethyl alcohol.
Phenethyl anthranilate.
Phenethyl benzoate.
Phenethyl butyrate.
Phenethyl cinnamate.
Phenethyl formate.

Phenethyl isobutyrate.
Phenethyl isovalerate.
Phenethyl 2-methylbutyrate.
Phenethyl phenylacetate.
Phenethyl propionate.
Phenethyl salicylate.
Phenethyl senecioate; phenethyl 3,3-dimethylacrylate.
Phenethyl tiglate.
Phenoxyacetic acid.
2-Phenoxyethyl isobutyrate.
Phenylacetaldehyde; α-toluic aldehyde.
Phenylacetaldehyde 2,3-butylene glycol acetal.
Phenylacetaldehyde dimethyl acetal.
Phenylacetaldehyde glyceryl acetal.
Phenylacetic acid; α-toluic acid.
4-Phenyl-2-butanol; phenylethyl methyl carbinol.
4-Phenyl-3-buten-2-ol; methyl styryl carbinol.
4-Phenyl-3-buten-2-one.
4-Phenyl-2-butyl acetate; phenylethyl methyl carbinyl acetate.
1-Phenyl-3-methyl-3-pentanol; phenylethyl methyl ethyl carbinol.
1-Phenyl-1-propanol; phenylethyl carbinol.
3-Phenyl-1-propanol; hydrocinnamyl alcohol.
2-Phenylpropionaldehyde; hydratropaldehyde.
3-Phenylpropionaldehyde; hydrocinnamaldehyde.
2-Phenylpropionalde-hyde dimethyl acetal; hydratropic aldehyde dimethyl acetal.
3-Phenylpropionic acid; hydrocinnamic acid.
3-Phenylpropyl acetate.
2-Phenylpropyl butyrate.
3-Phenylpropyl cinnamate.
3-Phenylpropyl formate.
3-Phenylpropyl hexanoate.
2-Phenylpropyl isobutyrate.
3-Phenylpropyl isobutyrate.
3-Phenylpropyl isovalerate.
3-Phenylpropyl propionate.
2-(3-Phenylpropyl)-tetrahydrofuran.
α-Pinene; 2-pinene.
β-Pinene; 2(10)-pinene.
Pine tar oil.
Pinocarveol; 2(10)-pinen-3-ol.
Piperidine.
Piperine.
d-Piperitone; *p*-menth-1-en-3-one.
Piperitenone; *p*-mentha-1,4(8)-dien-3-one.
Piperitenone oxide; 1,2-epoxy-*p*-menth-4-(8)-en-3-one.
Piperonyl acetate; heliotropyl acetate.
Piperonyl isobutyrate.
Polylimonene.
Polysorbate 20; polyoxyethylene (20) sorbitan monolaurate.
Polysorbate 60; polyoxyethylene (20) sorbitan monostereate.
Polysorbate 80; polyoxyethylene (20) sorbitan monooleate.
Potassium acetate.
Propenylguaethol; 6-ethoxy-*m*-anol.
Propionaldehyde.
Propyl acetate.
Propyl alcohol; 1-propanol.
p-Propyl anisole; dihydroanethole.
Propyl benzoate.
Propyl butyrate.
Propyl cinnamate.
Propyl disulfide.
Propyl formate.
Propyl 2-furanacrylate.
Propyl heptanoate.
Propyl hexanoate.
Propyl *p*-hydroxybenzoate; propylparaben.
3-Propylidenephthalide.
Propyl isobutyrate.
Propyl isovalerate.
Propyl mercaptan.
α-Propylphenethyl alcohol.
Propyl phenylacetate.
Propyl propionate.
Pyroligneous acid extract.
Pyruvaldehyde.
Pyruvic acid.
Rhodinol; 3,7-dimethyl-7-octen-1-ol; *l*-citronellol.
Rhodinyl acetate.
Rhodinyl butyrate.
Rhodinyl formate.
Rhodinyl isobutyrate.
Rhodinyl isovalerate.
Rhodinyl phenylacetate.
Rhodinyl propionate.
Rum ether; ethyl oxyhydrate.
Salicylaldehyde.
Santalol, α and β.
Santalyl acetate.
Santalyl phenylacetate.
Skatole.
Sorbitan monostearate.
Sucrose octaacetate.
α-Terpinene.
γ-Terpinene.
α-Terpineol; *p*-menth-1-en-8-ol.
β-Terpineol.
Terpinolene; *p*-menth-1,4(8)-diene.
Terpinyl acetate.
Terpinyl anthranilate.
Terpinyl butyrate.
Terpinyl cinnamate.
Terpinyl formate.
Terpinyl isobutyrate.
Terpinyl isovalerate.
Terpinyl propionate.
Tetrahydrofurfuryl acetate.
Tetrahydrofurfuryl alcohol.
Tetrahydrofurfuryl butyrate.
Tetrahydrofurfuryl propionate.
Tetrahydro-pseudo-ionone; 6,10-dimethyl-9-undecen-2-one.
Tetrahydrolinalool; 3,7-dimethyloctan-3-ol.
Tetramethyl ethylcyclohexenone; mixture of 5-ethyl-2,3,4,5-tetramethyl-2-cyclohexen-1-one and 5-ethyl-3,4,5,6-tetramethyl-2-cyclohexen-1-one.
2-Thienyl mercaptan; 2-thienylthiol.
Thymol.
Tolualdehyde glyceryl acetal, mixed *o*, *m*, *p*.
Tolualdehydes, mixed *o*, *m*, *p*.

p-Tolylacetaldehyde.
o-Tolyl acetate; *o*-cresyl acetate.
p-Tolyl acetate; *p*-cresyl acetate.
4-(*p*-Tolyl)-2-butanone; *p*-methylbenzylacetone.
p-Tolyl isobutyrate.
p-Tolyl laurate.
p-Tolyl phenylacetate.
2-(*p*-Tolyl)-propionaldehyde; *p*-methylhydratropic aldehyde.
Tributyl acetylcitrate.
2-Tridecenal.
2,3-Undecadione; acetyl nonyryl.
γ-Undecalactone; 4-hydroxyundecanoic acid γ-lactone; peach aldehyde; aldehyde C–14.
Undecenal.
2-Undecanone; methyl nonyl ketone.
9-Undecenal; undecenoic aldehyde.
10-Undecenal.
Undecen-1-ol; undecylenic alcohol.
10-Undecen-1-yl acetate.
Undecyl alcohol.
Valeraldehyde; pentanal.
Valeric acid; pentanoic acid.
Vanillin acetate; acetyl vanillin.
Veratraldehyde.
Verbenol; 2-pinen-4-ol.
Zingerone; 4-(4-hydroxy-3-methoxyphenyl)-2-butanone.

(c) Δ-Decalactone and Δ-dodecalactone when used separately or in combination in oleomargarine are used at levels not to exceed 10 parts per million and 20 parts per million, respectively, in accordance with § 166.110 of this chapter.

(d) BHA (butylated hydroxyanisole) may be used as an antioxidant in flavoring substances whereby the additive does not exceed 0.5 percent of the essential (volatile) oil content of the flavoring substance.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 23148, May 6, 1977; 43 FR 19843, May 9, 1978; 45 FR 22915, Apr. 4, 1980; 47 FR 27810, June 25, 1982; 48 FR 10812, Mar. 15, 1983; 48 FR 51907, Nov. 15, 1983; 49 FR 5747, Feb. 15, 1984; 50 FR 42932, Oct. 23, 1985; 54 FR 7402, Feb. 21, 1989; 61 FR 14245, Apr. 1, 1996; 69 FR 24511, May 4, 2004; 83 FR 50490, 50503, Oct. 9, 2018]

§ 172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

The food additive ''cocoa with dioctyl sodium sulfosuccinate for manufacturing,'' conforming to § 163.117 of this chapter and § 172.810, is used or intended for use as a flavoring substance in dry beverage mixes whereby the amount of dioctyl sodium sulfosuccinate does not exceed 75 parts per million of the finished beverage. The labeling of the dry beverage mix shall bear adequate directions to assure use in compliance with this section.

§ 172.530 Disodium guanylate.

Disodium guanylate may be safely used as a flavor enhancer in foods, at a level not in excess of that reasonably required to produce the intended effect.

§ 172.535 Disodium inosinate.

The food additive disodium inosinate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the disodium salt of inosinic acid, manufactured and purified so as to contain no more than 150 parts per million of soluble barium in the compound disodium inosinate with seven and one-half molecules of water of crystallization.

(b) The food additive is used as a flavoring adjuvant in food.

§ 172.540 DL-Alanine.

DL-Alanine (a racemic mixture of D- and L-alanine; CAS Reg. No. 302–72–7) may be safely used as a flavor enhancer for sweeteners in pickling mixtures at a level not to exceed 1 percent of the pickling spice that is added to the pickling brine.

[56 FR 6968, Feb. 21, 1991]

§ 172.560 Modified hop extract.

The food additive modified hop extract may be safely used in beer in accordance with the following prescribed conditions:

(a) The food additive is used or intended for use as a flavoring agent in the brewing of beer.

(b) The food additive is manufactured by one of the following processes:

(1) The additive is manufactured from a hexane extract of hops by simultaneous isomerization and selective reduction in an alkaline aqueous medium with sodium borohydride, whereby the additive meets the following specifications:

(i) A solution of the food additive solids is made up in approximately 0.012 *n* alkaline methyl alcohol (6 milliliters of 1 *n* sodium hydroxide diluted to 500 milliliters with methyl alcohol) to show an absorbance at 253 millimicrons

of 0.6 to 0.9 per centimeter. (This absorbance is obtained by approximately 0.03 milligram solids permilliliter.) The ultraviolet absorption spectrum of this solution exhibits the following characteristics: An absorption peak at 253 millimicrons; no absorption peak at 325 to 330 millimicrons; the absorbance at 268 millimicrons does not exceed the absorbance at 272 millimicrons.

(ii) The boron content of the food additive does not exceed 310 parts per million (0.0310 percent), calculated as boron.

(2) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, and methyl alcohol as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, and 250 parts per million of methyl alcohol. The light petroleum spirits and benzene solvents shall comply with the specifications in §172.250 except that the boiling point range for light petroleum spirits is 150 °F–300 °F.

(3) The additive is manufactured from hops by a sequence of extractions and fractionations, using methylene chloride, hexane, and methyl alcohol as solvents, followed by isomerization by sodium hydroxide treatment. Residues of the solvents in the modified hop extract shall not exceed 5 parts per million of methylene chloride, 25 parts per million of hexane, and 100 parts per million of methyl alcohol.

(4) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, methyl alcohol, *n*-butyl alcohol, and ethyl acetate as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, 50 parts per million of methyl alcohol, 50 parts per million of *n*-butyl alcohol, and 1 part per million of ethyl acetate. The light petroleum spirits and benzene solvents shall comply with the specifications in §172.250 except that the boiling point range for light petroleum spirits is 150 °F to 300 °F.

(5) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the following solvents: Ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene, and water; followed by isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene and a further sequence of extractions and fractionations using one or more of the solvents set forth in this paragraph. Residues of the solvents in the modified hop extract shall not exceed 125 parts per million of hexane; 150 parts per million of ethylene dichloride, methylene chloride, or trichloroethylene; or 250 parts per million of isopropyl alcohol or methyl alcohol.

(6) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by: Hydrogenation using palladium as a catalyst in methyl alcohol, ethyl alcohol, or isopropyl alcohol acidified with hydrochloric or sulfuric acid; oxidation with peracetic acid; isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene (alternatively, the hydrogenation and isomerization steps may be performed in reverse order); and a further sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section.

(7) The additive is manufactured from hops as set forth in paragraph (b)(6) of this section followed by reduction with sodium borohydride in aqueous alkaline methyl alcohol, and a sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section, and a boron content level not in excess of 300 parts per million (0.0300 percent), calculated as boron.

(8) The additive is manufactured from hops as a nonisomerizable nonvolatile hop resin by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by a sequence of aqueous extractions and removal of nonaqueous solvents to less than 0.5 percent. The additive is added to the wort before or during cooking in the manufacture of beer.

§ 172.575 Quinine.

Quinine, as the hydrochloride salt or sulfate salt, may be safely used in food in accordance with the following conditions:

Uses	Limitations
In carbonated beverages as a flavor.	Not to exceed 83 parts per million, as quinine. Label shall bear a prominent declaration of the presence of quinine either by the use of the word "quinine" in the name of the article or through a separate declaration.

§ 172.580 Safrole-free extract of sassafras.

The food additive safrole-free extract of sassafras may be safely used in accordance with the following prescribed conditions:

(a) The additive is the aqueous extract obtained from the root bark of the plant *Sassafras albidum* (Nuttall) Nees (Fam. Lauraceae).

(b) It is obtained by extracting the bark with dilute alcohol, first concentrating the alcoholic solution by vacuum distillation, then diluting the concentrate with water and discarding the oily fraction.

(c) The purified aqueous extract is safrole-free.

(d) It is used as a flavoring in food.

§ 172.585 Sugar beet extract flavor base.

Sugar beet extract flavor base may be safely used in food in accordance with the provisions of this section.

(a) Sugar beet extract flavor base is the concentrated residue of soluble sugar beet extractives from which sugar and glutamic acid have been recovered, and which has been subjected to ion exchange to minimize the concentration of naturally occurring trace minerals.

(b) It is used as a flavor in food.

§ 172.590 Yeast-malt sprout extract.

Yeast-malt sprout extract, as described in this section, may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by partial hydrolysis of yeast extract (derived from *Saccharomyces cereviseae*, *Saccharomyces fragilis*, or *Candida utilis*) using the sprout portion of malt barley as the source of enzymes. The additive contains a maximum of 6 percent 5′ nucleotides by weight.

(b) The additive may be used as a flavor enhancer in food at a level not in excess of that reasonably required to produce the intended effect.

Subpart G—Gums, Chewing Gum Bases and Related Substances

§ 172.610 Arabinogalactan.

Arabinogalactan may be safely used in food in accordance with the following conditions:

(a) Arabinogalactan is a polysaccharide extracted by water from Western larch wood, having galactose units and arabinose units in the approximate ratio of six to one.

(b) It is used in the following foods in the minimum quantity required to produce its intended effect as an emulsifier, stabilizer, binder, or bodying agent: Essential oils, nonnutritive sweeteners, flavor bases, nonstandardized dressings, and pudding mixes.

§ 172.615 Chewing gum base.

The food additive chewing gum base may be safely used in the manufacture of chewing gum in accordance with the following prescribed conditions:

(a) The food additive consists of one or more of the following substances that meet the specifications and limitations prescribed in this paragraph, used in amounts not to exceed those required to produce the intended physical or other technical effect.

MASTICATORY SUBSTANCES

NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	Genus and species
Sapotaceae:	
Chicle	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Chiquibul	Manilkara zapotilla Gilly.
Crown gum	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Gutta hang kang	Palaquium leiocarpum Boerl. and Palaquium oblongifolium Burck.
Massaranduba balata (and the solvent-free resin extract of Massaranduba balata).	Manilkara huberi (Ducke) Chevalier.
Massaranduba chocolate	Manilkara solimoesensis Gilly.
Nispero	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Rosidinha (rosadinha)	Micropholis (also known as Sideroxylon) spp.
Venezuelan chicle	Manilkara williamsii Standley and related spp.
Apocynaceae:	
Jelutong	Dyera costulata Hook, F. and Dyera lowii Hook, F.
Leche caspi (sorva)	Couma macrocarpa Barb. Rodr.
Pendare	Couma macrocarpa Barb. Rodr. and Couma utilis (Mart.) Muell. Arg.
Perillo	Couma macrocarpa Barb. Rodr. and Couma utilis (Mart.) Muell. Arg.
Moraceae:	
Leche de vaca	Brosimum utile (H.B.K.) Pittier and Poulsenia spp.; also Lacmellea standleyi (Woodson), Monachino (Apocynaceae).
Niger gutta	Ficus platyphylla Del.
Tunu (tuno)	Castilla fallax Cook.
Euphorbiaceae:	
Chilte	Cnidoscolus (also known as Jatropha) elasticus Lundell and Cnidoscolus tepiquensis (Cost. and Gall.) McVaugh.
Natural rubber (smoked sheet and latex solids).	Hevea brasiliensis.

Synthetic	Specifications
Butadiene-styrene rubber	Basic polymer.
Isobutylene-isoprene copolymer (butyl rubber).	Do.
Paraffin	Synthesized by Fischer-Tropsch process from carbon monoxide and hydrogen which are catalytically converted to a mixture of paraffin hydrocarbon. Lower molecular weight fractions are removed by distillation. The residue is hydrogenated and further treated by percolation through activated charcoal. The product has a congealing point of 93°–99 °C as determined by ASTM method D938–71 (Reapproved 1981), ''Standard Test Method for Congealing Point of Petroleum Waxes, Including Petrolatum,'' a maximum oil content of 0.5 percent as determined by ASTM method D721–56T, ''Tentative Method of Test for Oil Content of Petroleum Waxes,'' and an absorptivity of less than 0.01 at 290 millimicrons in decahydronaphthalene at 88 °C as determined by ASTM method D2008–80, ''Standard Test Method for Ultraviolet Absorbance and Absorptivity of Petroleum Products,'' which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*
Petroleum wax	Complying with § 172.886.
Petroleum wax synthetic	Complying with § 172.888.
Polyethylene	Molecular weight 2,000–21,000.
Polyisobutylene	Minimum molecular weight 37,000 (Flory).
Polyvinyl acetate	Molecular weight, minimum 2,000.

PLASTICIZING MATERIALS (SOFTENERS)

Glycerol ester of partially dimerized rosin	Having an acid number of 3–8, a minimum drop-softening point of 109 °C, and a color of M or paler.
Glycerol ester of partially hydrogenated gum or wood rosin.	Having an acid number of 3–10, a minimum drop-softening point of 79 °C, and a color of N or paler.
Glycerol ester of polymerized rosin	Having an acid number of 3–12, a minimum melting-point of 80 °C, and a color of M or paler.
Glycerol ester of gum rosin	Having an acid number of 5–9, a minimum drop-softening point of 88 °C, and a color of N or paler. The ester is purified by steam stripping.
Glycerol ester of tall oil rosin	Having an acid number of 2–12, a softening point (ring and ball) of 80°–88 °C, and a color of N or paler. The ester is purified by steam stripping.
Glycerol ester of wood rosin	Having an acid number of 3–9, a drop-softening point of 88 °C–96 °C, and a color of N or paler. The ester is purified by steam stripping.

MASTICATORY SUBSTANCES—Continued

NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	Genus and species
Lanolin	
Methyl ester of rosin, partially hydrogenated	Having an acid number of 4–8, a refractive index of 1.5170–1.5205 at 20 °C, and a viscosity of 23–66 poises at 25 °C. The ester is purified by steam stripping.
Pentaerythritol ester of partially hydrogenated gum or wood rosin.	Having an acid number of 7–18, a minimum drop-softening point of 102 °C, and a color of K or paler.
Pentaerythritol ester of gum or wood rosin	Having an acid number of 6–16, a minimum drop-softening point of 109 °C, and a color of M or paler.
Rice bran wax	Complying with § 172.890.
Stearic acid	Complying with § 172.860.
Sodium and potassium stearates	Complying with § 172.863.
TERPENE RESINS	
Synthetic resin	Consisting of polymers of αpinene, βpinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirit solution.
Natural resin	Consisting of polymers of α-pinene; softening point minimum 155 °C, determined by U.S.P. closed-capillary method, United States Pharmacopeia XX (1980) (page 961).
ANTIOXIDANTS	
Butylated hydroxyanisole	Not to exceed antioxidant content of 0.1% when used alone or in any combination.
Butylated hydroxytoluene	Do.
Propyl gallate	Do.
MISCELLANEOUS	
Sodium sulfate	
Sodium sulfide	Reaction-control agent in synthetic polymer production.

(b) In addition to the substances listed in paragraph (a) of this section, chewing gum base may also include substances generally recognized as safe in food.

(c) To assure safe use of the additive, in addition to the other information required by the act, the label and labeling of the food additive shall bear the name of the additive, ''chewing gum base.'' As used in this paragraph, the term ''chewing gum base'' means the manufactured or partially manufactured nonnutritive masticatory substance comprised of one or more of the ingredients named and so defined in paragraph (a) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 45 FR 56051, Aug. 22, 1980; 49 FR 5747, Feb. 15, 1984; 49 FR 10105, Mar. 19, 1984; 66 FR 38153, July 23, 2001; 66 FR 53711, Oct. 24, 2001]

§ 172.620 Carrageenan.

The food additive carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction from the following members of the families Gigartinaceae and Solieriaceae of the class Rodophyceae (red seaweed):

Chondrus crispus.
Chondrus ocellatus.
Eucheuma cottonii.
Eucheuma spinosum.
Gigartina acicularis.
Gigartina pistillata.
Gigartina radula.
Gigartina stellata.

(b) The food additive conforms to the following conditions:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 20 percent to 40 percent on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, carrageenan.

§ 172.623 Carrageenan with polysorbate 80.

Carrageenan otherwise meeting the definition and specifications of § 172.620 (a) and (b) and salts of carrageenan otherwise meeting the definition of § 172.626(a) may be safely produced with the use of polysorbate 80 meeting the specifications and requirements of § 172.840 (a) and (b) in accordance with the following prescribed conditions:

(a) The polysorbate 80 is used only to facilitate separation of sheeted carrageenan and salts of carrageenan from drying rolls.

(b) The carrageenan and salts of carrageenan contain not more than 5 percent by weight of polysorbate 80, and the final food containing the additives contains polysorbate 80 in an amount not to exceed 500 parts per million.

(c) The carrageenan and salts of carrageenan so produced are used only in producing foods in gel form and only for the purposes defined in §§ 172.620(c) and 172.626(b), respectively.

(d) The carrageenan and salts of carrageenan so produced are not used in foods for which standards of identity exist unless the standards provide for the use of carrageenan, or salts of carrageenan, combined with polysorbate 80.

(e) The carrageenan and salts of carrageenan produced in accordance with this section, and foods containing the same, in addition to the other requirements of the Act, are labeled to show the presence of polysorbate 80, and the label or labeling of the carrageenan and salts of carrageenan so produced bear adequate directions for use.

§ 172.626 Salts of carrageenan.

The food additive salts of carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of carrageenan, meeting the provisions of § 172.620, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of carrageenan to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of carrageenan that dominates the mixture by reason of the modification, e.g., ''sodium carrageenan'', ''potassium carrageenan'', etc.

§ 172.655 Furcelleran.

The food additive furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction of furcellaria fastigiata of the class Rodophyceae (red seaweed).

(b) The food additive conforms to the following:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 8 percent to 19 percent, on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, furcelleran.

§ 172.660 Salts of furcelleran.

The food additive salts of furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of furcelleran, meeting the provisions of § 172.655, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of furcelleran to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary

for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of furcelleran that dominates the mixture by reason of the modification, e.g., ''sodium furcelleran'', ''potassium furcelleran'', etc.

§ 172.665 Gellan gum.

The food additive gellan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a high molecular weight polysaccharide gum produced from *Pseudomonas elodea* by a pure culture fermentation process and purified by recovery with isopropyl alcohol. It is composed of tetrasaccharide repeat units, each containing one molecule of rhamnose and glucuronic acid, and two molecules of glucose. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. The polysaccharide may contain acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters.

(b) The strain of *P. elodea* is nonpathogenic and nontoxic in man and animals.

(c) The additive is produced by a process that renders it free of viable cells of *P. elodea*.

(d) The additive meets the following specifications:

(1) Positive for gellan gum when subjected to the following identification tests:

(i) A 1-percent solution is made by hydrating 1 gram of gellan gum in 99 milliliters of distilled water. The mixture is stirred for about 2 hours, using a motorized stirrer and a propeller-type stirring blade. A small amount of the above solution is drawn into a wide bore pipet and transferred into a solution of 10-percent calcium chloride. A tough worm-like gel will form instantly.

(ii) To the 1-percent distilled water solution prepared for identification test (i), 0.50 gram of sodium chloride is added. The solution is heated to 80 °C with stirring, held at 80 °C for 1 minute, and allowed to cool to room temperature without stirring. A firm gel will form.

(2) Residual isopropyl alcohol (IPA) not to exceed 0.075 percent as determined by the procedure described in the ''Gellan gum'' monograph in the Food Chemicals Codex, 7th ed. (2010), pp. 425–426, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(e) The additive is used or intended for use in accordance with current good manufacturing practice as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter. The additive may be used in foods where standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the name of the additive and the designation ''food grade''.

(2) The label or labeling of the food additive container shall bear adequate directions for use.

[55 FR 39614, Sept. 28, 1990, as amended at 57 FR 55445, Nov. 25, 1992; 64 FR 1758, Jan. 12, 1999; 78 FR 71463, Nov. 29, 2013]

§ 172.695 Xanthan gum.

The food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery

with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.

(b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris*.

(d) The additive meets the following specifications:

(1) Residual isopropyl alcohol not to exceed 750 parts per million.

(2) An aqueous solution containing 1 percent of the additive and 1 percent of potassium chloride stirred for 2 hours has a minimum viscosity of 600 centipoises at 75 °F, as determined by Brookfield Viscometer, Model LVF (or equivalent), using a No. 3 spindle at 60 r.p.m., and the ratio of viscosities at 75 °F and 150 °F is in the range of 1.02 to 1.45.

(3) Positive for xanthan gum when subjected to the following procedure:

LOCUST BEAN GUM GEL TEST

Blend on a weighing paper or in a weighing pan 1.0 gram of powdered locust bean gum with 1.0 gram of the powdered polysaccharide to be tested. Add the blend slowly (approximately ½ minute) at the point of maximum agitation to a stirred solution of 200 milliliters of distilled water previously heated to 80 °C in a 400-milliliter beaker. Continue mechanical stirring until the mixture is in solution, but stir for a minimum time of 30 minutes. Do not allow the water temperature to drop below 60 °C.

Set the beaker and its contents aside to cool in the absence of agitation. Allow a minimum time of 2 hours for cooling. Examine the cooled beaker contents for a firm rubbery gel formation after the temperature drops below 40 °C.

In the event that a gel is obtained, make up a 1 percent solution of the polysaccharide to be tested in 200 milliliters of distilled water previously heated to 80 °C (omit the locust bean gum). Allow the solution to cool without agitation as before. Formation of a gel on cooling indicates that the sample is a gelling polysaccharide and not xanthan gum.

Record the sample as ''positive'' for xanthan gum if a firm, rubbery gel forms in the presence of locust bean gum but not in its absence. Record the sample as ''negative'' for xanthan gum if no gel forms or if a soft or brittle gel forms both with locust bean gum and in a 1 percent solution of the sample (containing no locust bean gum).

(4) Positive for xanthan gum when subjected to the following procedure:

PYRUVIC ACID TEST

Pipet 10 milliliters of an 0.6 percent solution of the polysaccharide in distilled water (60 milligrams of water-soluble gum) into a 50-milliliter flask equipped with a standard taper glass joint. Pipet in 20 milliliters of 1*N* hydrochloric acid. Weigh the flask. Reflux the mixture for 3 hours. Take precautions to avoid loss of vapor during the refluxing. Cool the solution to room temperature. Add distilled water to make up any weight loss from the flask contents.

Pipet 1 milliliter of a 2,4-dinitrophenylhydrazine reagent (0.5 percent in 2*N* hydrochloric acid) into a 30-milliliter separatory funnel followed by a 2-milliliter aliquot (4 milligrams of water-soluble gum) of the polysaccharide hydrolyzate. Mix and allow the reaction mixture to stand at room temperature for 5 minutes. Extract the mixture with 5 milliliters of ethyl acetate. Discard the aqueous layer.

Extract the hydrazone from the ethyl acetate with three 5 milliliter portions of 10 percent sodium carbonate solution. Dilute the combined sodium carbonate extracts to 100 milliliters with additional 10 percent sodium carbonate in a 10-milliliter volumetric flask. Measure the optical density of the sodium carbonate solution at 375 millimicrons.

Compare the results with a curve of the optical density versus concentration of an authentic sample of pyruvic acid that has been run through the procedure starting with the preparation of the hydrazone.

Record the percent by weight of pyruvic acid in the test polysaccharide. Note ''positive'' for xanthan gum if the sample contains more than 1.5 percent of pyruvic acid and ''negative'' for xanthan gum if the sample contains less than 1.5 percent of pyruvic acid by weight.

(e) The additive is used or intended for use in accordance with good manufacturing practice as a stabilizer, emulsifier, thickener, suspending agent, bodying agent, or foam enhancer in foods for which standards of identity established under section 401 of the Act do not preclude such use.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the Act, the name of the additive and the designation ''food grade''.

(2) The label or labeling of the food additive container shall bear adequate directions for use.

Subpart H—Other Specific Usage Additives

§ 172.710 Adjuvants for pesticide use dilutions.

The following surfactants and related adjuvants may be safely added to pesticide use dilutions by a grower or applicant prior to application to the growing crop:

n-Alkyl (C_8-C_{18}) amine acetate, where the alkyl groups (C_8-C_{18}) are derived from coconut oil, as a surfactant in emulsifier blends at levels not in excess of 5 percent by weight of the emulsifier blends that are added to herbicides for application to corn and sorghum.

Di-*n*-alkyl (C_8-C_{18}) dimethyl ammonium chloride, where the alkyl groups (C_8-C_{18}) are derived from coconut oil, as surfactants in emulsifier blends at levels not in excess of 5 percent by weight of emulsifier blends that are added to herbicides for application to corn or sorghum.

Diethanolamide condensate based on a mixture of saturated and unsaturated soybean oil fatty acids (C_{16}-C_{18}) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

Diethanolamide condensate based on stripped coconut fatty acids (C_{10} C_{18}) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

α-(*p*-Dodecylphenyl)-*omega*-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a proplyene tetramer isomer) with an average of 4–14 or 30–70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4–14 or 30–70.

Ethylene dichloride.

Polyglyceryl phthalate ester of coconut oil fatty acids.

α-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with an average of 4–14 or 30–70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4–14 or 30–70.

α-[*p*-(1,1,3,3-Tetramethylbutyl) phenyl]-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl) phenol with 1 mole of ethylene oxide.

Sodium acrylate and acrylamide copolymer with a minimum average molecular weight of 10,000,000 in which 30 percent of the polymer is comprised of acrylate units and 70 percent acrylamide units, for use as a drift control agent in herbicide formulations applied to crops at a level not to exceed 0.5 ounces of the additive per acre.

§ 172.712 1,3-Butylene glycol.

The food additive 1,3-butylene glycol (CAS Reg. No. 107–88–0) may be safely used in food in accordance with the following prescribed conditions:

(a) It is prepared by the aldol condensation of acetaldehyde followed by catalytic hydrogenation.

(b) The food additive shall conform to the identity and specifications of the Food Chemicals Codex, 7th ed. (2010), p. 126, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) It is used in the manufacture of sausage casings as a formulation aid as defined in §170.3(o)(14) of this chapter and as a processing aid as defined in §170.3(o)(24) of this chapter.

[62 FR 26228, May 13, 1997, as amended at 78 FR 14664, Mar. 7, 2013; 78 FR 71463, Nov. 29, 2013]

§ 172.715 Calcium lignosulfonate.

Calcium lignosulfonate may be safely used in or on food, subject to the provisions of this section.

(a) Calcium lignosulfonate consists of sulfonated lignin, primarily as calcium and sodium salts.

(b) It is used in an amount not to exceed that reasonably required to accomplish the intended physical or technical effect when added as a dispersing agent and stabilizer in pesticides for

preharvest or postharvest application to bananas.

§ 172.720 Calcium lactobionate.

The food additive calcium lactobionate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the calcium salt of lactobionic acid (4-(β,D-galactosido)-D-gluconic acid) produced by the oxidation of lactose.

(b) It is used or intended for use as a firming agent in dry pudding mixes at a level not greater than that required to accomplish the intended effect.

§ 172.723 Epoxidized soybean oil.

Epoxidized soybean oil may be safely used in accordance with the following prescribed conditions:

(a) The additive is prepared by reacting soybean oil in toluene with hydrogen peroxide and formic acid.

(b) It meets the following specifications:

(1) Epoxidized soybean oil contains oxirane oxygen, between 7.0 and 8.0 percent, as determined by the American Oil Chemists' Society (A.O.C.S.) method Cd 9–57, ''Oxirane Oxygen,'' reapproved 1989, which is incorporated by reference in accordance with 5 U.S.C 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists' Society, P. O. Box 3489, Champaign, IL 61826–3489, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(2) The maximum iodine value is 3.0, as determined by A.O.C.S. method Cd 1–25, ''Iodine Value of Fats and Oils Wijs Method,'' revised 1993, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(3) The heavy metals (as Pb) content cannot be more than 10 parts per million, as determined by the ''Heavy Metals Test,'' of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, Method II (with a 2-gram sample and 20 microgram of lead ion in the control), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The additive is used as a halogen stabilizer in brominated soybean oil at a level not to exceed 1 percent.

[60 FR 32903, June 26, 1995, as amended at 64 FR 1759, Jan. 12, 1999; 78 FR 14665, Mar. 7, 2013; 81 FR 5591, Feb. 3, 2016]

§ 172.725 Gibberellic acid and its potassium salt.

The food additives gibberellic acid and its potassium salt may be used in the malting of barley in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) The gibberellic acid is produced by deep-culture fermentation of a suitable nutrient medium by a strain of Fusarium moniliforme or a selection of this culture.

(2) The gibberellic acid produced is of 80 percent purity or better.

(3) The empirical formula of gibberellic acid is represented by $C_{19}H_{22}O_6$.

(4) Potassium gibberellate is the potassium salt of the specified gibberellic acid.

(5) The potassium gibberellate is of 80 percent purity or better.

(6) The gibberellic acid or potassium gibberellate may be diluted with substances generally recognized as safe in

foods or with salts of fatty acids conforming to § 172.863.

(b) They are used or intended for use in the malting of barley under conditions whereby the amount of either or both additives present in the malt is not in excess of 2 parts per million expressed as gibberellic acid, and the treated malt is to be used in the production of fermented malt beverages or distilled spirits only, whereby the finished distilled spirits contain none and the finished malt beverage contains not more than 0.5 part per million of gibberellic acid.

(c) To insure the safe use of the food additives the label of the package shall bear, in addition to the other information required by the Act:

(1) The name of the additive, ''gibberellic acid'' or ''potassium gibberellate'', whichever is appropriate.

(2) An accurate statement of the concentration of the additive contained in the package.

(3) Adequate use directions to provide not more than 2 parts per million of gibberellic acid in the finished malt.

(4) Adequate labeling directions to provide that the final malt is properly labeled as described in paragraph (d) of this section.

(d) To insure the safe use of the additive the label of the treated malt shall bear, in addition to the other information required by the Act, the statements:

(1) ''Contains not more than 2 parts per million _____'', the blank being filled in with the words ''gibberellic acid'' or ''potassium gibberellate'', whichever is appropriate; and

(2) ''Brewer's malt—To be used in the production of fermented malt beverages only'' or ''Distiller's malt—To be used in the production of distilled spirits only'', whichever is appropriate.

§ 172.730 Potassium bromate.

The food additive potassium bromate may be safely used in the malting of barley under the following prescribed conditions:

(a)(1) It is used or intended for use in the malting of barley under conditions whereby the amount of the additive present in the malt from the treatment does not exceed 75 parts per million of bromate (calculated as Br), and the treated malt is used only in the production of fermented malt beverages or distilled spirits.

(2) The total residue of inorganic bromides in fermented malt beverages, resulting from the use of the treated malt plus additional residues of inorganic bromides that may be present from uses in accordance with other regulations in this chapter promulgated under sections 408 and/or 409 of the act, does not exceed 25 parts per million of bromide (calculated as Br). No tolerance is established for bromide in distilled spirits because there is evidence that inorganic bromides do not pass over in the distillation process.

(b) To assure safe use of the additive, the label or labeling of the food additive shall bear, in addition to the other information required by the Act, the following:

(1) The name of the additive.

(2) Adequate directions for use.

(c) To assure safe use of the additive, the label or labeling of the treated malt shall bear, in addition to other information required by the Act, the statement, ''Brewer's Malt—To be used in the production of fermented malt beverages only'', or ''Distiller's Malt—To be used in the production of distilled spirits only'', whichever is the case.

§ 172.735 Glycerol ester of rosin.

Glycerol ester of wood rosin, gum rosin, or tall oil rosin may be safely used in food in accordance with the following prescribed conditions:

(a) It has an acid number of 3 to 9, a drop-softening point of 88 to 96 °C; and a color of N or paler as determined in accordance with Official Naval Stores Standards of the United States. It is purified by countercurrent steam distillation or steam stripping.

(b) It is used to adjust the density of citrus oils used in the preparation of beverages whereby the amount of the additive does not exceed 100 parts per million of the finished beverage.

[42 FR 14491, Mar. 15, 1977, as amended at 70 FR 15758, Mar. 29, 2005; 72 FR 46896, Aug. 22, 2007]

§ 172.736 Glycerides and polyglycides of hydrogenated vegetable oils.

The food additive glycerides and polyglycides of hydrogenated vegetable oils may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is manufactured by heating a mixture of hydrogenated oils of vegetable origin and polyethylene glycol in the presence of an alkaline catalyst followed by neutralization with any acid that is approved or is generally recognized as safe for this use to yield the finished product.

(b) The additive consists of a mixture of mono-, di- and tri-glycerides and polyethylene glycol mono- and di-esters of fatty acids (polyglycides) of hydrogenated vegetable oils and meets the following specifications:

(1) Total ester content, greater than 90 percent as determined by a method entitled ''Determination of Esterified Glycerides and Polyoxyethylene Glycols,'' approved November 16, 2001, printed by Gattefosse S.A.S., and incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety, 5001 Campus Dr., College Park, MD 20740 or you may examine a copy at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(2) Acid value, not greater than 2, and hydroxyl value, not greater than 56, as determined by the methods entitled ''Acid Value,'' p. 1220 and ''Hydroxyl Value,'' p. 1223, respectively, in the Food Chemicals Codex, 7th ed. (2010), which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(3) Lead, not greater than 0.1 mg/kg as determined by the American Oil Chemists' Society (A.O.C.S.) method Ca 18c–91, ''Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrophotometry,'' updated 1995, and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from American Oil Chemists' Society, P. O. Box 3489, Champaign, IL 61826–3489, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(4) 1,4-Dioxane, not greater than 10 milligrams per kilogram (mg/kg), and ethylene oxide, not greater than 1 mg/kg, as determined by a gas chromatographic method entitled ''Determination of Ethylene Oxide and 1,4-Dioxane by Headspace Gas Chromatography,'' approved November 5, 1998, printed by Gattefosse S.A.S., and incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51; see paragraph (b)(1) of this section for availability of the incorporation by reference.

(c) The additive is used or intended for use as an excipient in dietary supplement tablets, capsules, and liquid formulations that are intended for ingestion in daily quantities measured in

drops or similar small units of measure.

[71 FR 12620, Mar. 13, 2006, as amended at 78 FR 71463, Nov. 29, 2013; 81 FR 5591, Feb. 3, 2016]

§ 172.755 Stearyl monoglyceridyl citrate.

The food additive stearyl monoglyceridyl citrate may be safely used in food in accordance with the following provisions:

(a) The additive is prepared by controlled chemical reaction of the following:

Reactant	Limitations
Citric acid	
Monoglycerides of fatty acids.	Prepared by the glycerolysis of edible fats and oils or derived from fatty acids conforming with § 172.860.
Stearyl alcohol	Derived from fatty acids conforming with § 172.860, or derived synthetically in conformity with § 172.864.

(b) The additive stearyl monoglyceridyl citrate, produced as described under paragraph (a) of this section, meets the following specifications:

Acid number 40 to 52.
Total citric acid 15 to 18 percent.
Saponification number 215–255.

(c) The additive is used or intended for use as an emulsion stabilizer in or with shortenings containing emulsifiers.

§ 172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).

The food additive succistearin (stearoyl propylene glycol hydrogen succinate) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is the reaction product of succinic anhydride, fully hydrogenated vegetable oil (predominantly C_{16} or C_{18} fatty acid chain length), and propylene glycol.

(b) The additive meets the following specifications:

Acid number 50–150.
Hydroxyl number 15–50.
Succinated ester content 45–75 percent.

(c) The additive is used or intended for use as an emulsifier in or with shortenings and edible oils intended for use in cakes, cake mixes, fillings, icings, pastries, and toppings, in accordance with good manufacturing practice.

§ 172.770 Ethylene oxide polymer.

The polymer of ethylene oxide may be safely used as a foam stabilizer in fermented malt beverages in accordance with the following conditions.

(a) It is the polymer of ethylene oxide having a minimum viscosity of 1,500 centipoises in a 1 percent aqueous solution at 25 °C.

(b) It is used at a level not to exceed 300 parts per million by weight of the fermented malt beverage.

(c) The label of the additive bears directions for use to insure compliance with paragraph (b) of this section.

§ 172.775 Methacrylic acid-divinylbenzene copolymer.

Methacrylic acid-divinylbenzene copolymer may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by the polymerization of methacrylic acid and divinylbenzene. The divinylbenzene functions as a cross-linking agent and constitutes a minimum of 4 percent of the polymer.

(b) Aqueous extractives from the additive do not exceed 2 percent (dry basis) after 24 hours at 25 °C.

(c) The additive is used as a carrier of vitamin B_{12} in foods for special dietary use.

§ 172.780 Acacia (gum arabic).

The food additive may be safely used in food in accordance with the following prescribed conditions:

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family Leguminosae.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 8th ed. (2012), p. 516, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address:

http://www.usp.org). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, 3d Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) The ingredient is used in food in accordance with good manufacturing practices under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Beverages, alcoholic	20.0	Thickener, emulsifier, or stabilizer.
Breakfast cereals, § 170.3(n)(4) of this chapter	6.0	Dietary fiber; emulsifier and emulsifier salt; flavoring agent and adjuvant; formulation aid; processing aid; stabilizer and thickener; surface-finishing agent; texturizer.
Cakes, brownies, pastries, biscuits, muffins, and cookies.	3.0	Do.
Grain-based bars (e.g., breakfast bars, granola bars, rice cereal bars).	35.0	Do.
Soups and soup mixes, § 170.3(n)(40) of this chapter, except for soups and soup mixes containing meat or poultry that are subject to regulation by the U.S. Department of Agriculture under the Federal Meat Inspection Act or the Poultry Products Inspection Act.	2.5	Do.
Food categories listed in § 184.1330 of this chapter, except for meat, poultry, and foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act preclude the use of acacia.	Levels prescribed in § 184.1330 of this chapter.	Dietary fiber.

[70 FR 8034, Feb. 17, 2005, as amended at 78 FR 71464, Nov. 29, 2013; 78 FR 73437, Dec. 6, 2013]

§ 172.785 *Listeria*-specific bacteriophage preparation.

The additive may be safely used as an antimicrobial agent specific for *Listeria monocytogenes* (*L. monocytogenes*) in accordance with the following conditions:

(a) *Identity*. (1) The additive consists of a mixture of equal proportions of six different individually purified lytic-type (lacking lysogenic activity) bacteriophages (phages) specific against *L. monocytogenes*.

(2) Each phage is deposited at, and assigned an identifying code by, a scientifically-recognized culture collection center, and is made available to FDA upon request.

(3) The additive is produced from one or more cell cultures of *L. monocytogenes* in a safe and suitable nutrient medium.

(b) *Specifications*. (1) The additive achieves a positive lytic result (OD_{600} ≤0.06) when tested against any of the following *L. monocytogenes* isolates available from American Type Culture Collection (ATCC): ATCC 35152 (serogroup 1/2a), ATCC 19118 (serogroup 4b), and ATCC 15313 (serogroup 1/2b). The analytical method for determining the potency of the additive entitled ''Determination of Potency of LMP–102™,'' dated October 9, 2003, and printed by Intralytix, Inc., is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety (HFS–200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/*

code_of_federal_regulations/ibr_locations.html.

(2) The mean phage titer of each monophage in the additive is 1×10^9 plaque forming units (PFU)/ml. The analytical method for determining phage titer entitled ''Method to Determine Lytic Activity/Phage Titer,'' dated November 6, 2001, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(3) The phages present in the preparation must not contain a functional portion of any of the toxin-encoding sequences described in 40 CFR 725.421(d). No sequences derived from genes encoding bacterial 16S ribosomal RNA are present in the complete genomic sequence of the phages.

(4) *L. monocytogenes* toxin, listeriolysin O (LLO), is not greater than 5 hemolytic units (HU)/ml. The analytical method for determining LLO entitled ''Quantitation of Listeriolysin O Levels in LMP–102™,'' dated September 27, 2004, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(5) The additive is negative for *L. monocytogenes*. The modified version of the U.S. Department of Agriculture's method for determining *L. monocytogenes* entitled ''LMP–102™ *Listeria monocytogenes* Sterility Testing,'' dated May 24, 2004, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(6) The additive is negative for gram-positive and gram-negative bacteria capable of growing in commonly used microbiological media (e.g., Luria-Bertani (LB) medium), including *Escherichia coli*, *Salmonella* species and coagulase-positive *Staphylococci*, as determined by the ''Method to Determine Microbial Contamination,'' dated July 11, 2003, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(7) Total organic carbon (TOC) is less than or equal to 36 mg/kg. The analytical method for determining TOC entitled ''Determination of Total Organic Carbon by Automated Analyzer,'' dated March 30, 2001, and printed by Intralytix, Inc., is incorporated by reference. Copies are available at locations cited in paragraph (b)(1) of this section.

(c) *Conditions of use*. The additive is used in accordance with current good manufacturing practice to control *L. monocytogenes* by direct application to meat and poultry products that comply with the ready-to-eat definition in 9 CFR 430.1. Current good manufacturing practice is consistent with direct spray application of the additive at a rate of approximately 1 mL of the additive per 500 cm^2 product surface area.

[71 FR 47731, Aug. 18, 2006, as amended at 81 FR v5591, Feb. 3, 2016]

Subpart I—Multipurpose Additives

§ 172.800 Acesulfame potassium.

Acesulfame potassium (CAS Reg. No. 55589–62–3), also known as acesulfame K, may be safely used as a general-purpose sweetener and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended technical effect in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use, under the following conditions:

(a) Acesulfame potassium is the potassium salt of 6-methyl-1,2,3-oxathiazine-4(3*H*)-one-2,2-dioxide.

(b) The additive meets the following specifications:

(1) Purity is not less than 99 percent on a dry basis. The purity shall be determined by a method titled ''Acesulfame Potassium Assay,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/*

code__of__federal__regulations/ibr__locations.html.

(2) Fluoride content is not more than 30 milligrams per kilogram, as determined by method III of the Fluoride Limit Test of the Food Chemicals Codex, 7th ed. (2010), p. 1151, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(c) If the food containing the additive is represented to be for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.

[53 FR 28382, July 28, 1988, as amended at 57 FR 57961, Dec. 8, 1992; 59 FR 61540, 61543, 61545, Dec. 1, 1994; 60 FR 21702, May 3, 1995; 63 FR 36362, July 6, 1998; 68 FR 75413, Dec. 31, 2003; 78 FR 71464, Nov. 29, 2013]

§ 172.802 Acetone peroxides.

The food additive acetone peroxides may be safely used in flour, and in bread and rolls where standards of identity do not preclude its use, in accordance with the following prescribed conditions:

(a) The additive is a mixture of monomeric and linear dimeric acetone peroxide, with minor proportions of higher polymers, manufactured by reaction of hydrogen peroxide and acetone.

(b) The additive may be mixed with an edible carrier to give a concentration of: (1) 3 grams to 10 grams of hydrogen peroxide equivalent per 100 grams of the additive, plus carrier, for use in flour maturing and bleaching; or (2) approximately 0.75 gram of hydrogen peroxide equivalent per 100 grams of the additive, plus carrier, for use in dough conditioning.

(c) It is used or intended for use: (1) In maturing and bleaching of flour in a quantity not more than sufficient for such effect; and (2) as a dough-conditioning agent in bread and roll production at not to exceed the quantity of hydrogen peroxide equivalent necessary for the artificial maturing effect.

(d) To insure safe use of the additive, the label of the food additive container and any intermediate premix thereof shall bear, in addition to the other information required by the act:

(1) The name of the additive, ''acetone peroxides''.

(2) The concentration of the additive expressed in hydrogen peroxide equivalents per 100 grams.

(3) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.803 Advantame.

(a) Advantame is the chemical *N*-[*N*-[3-(3-hydroxy-4-methoxyphenyl)propyl]-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (CAS Reg. No. 714229–20–6).

(b) Advantame meets the following specifications when it is tested according to the methods described or referenced in the document entitled ''Specifications and Analytical Methods for Advantame'' dated April 1, 2009, by the Ajinomoto Co. Inc., Sweetener Department 15–1, Kyobashi 1-chome, Chuo-ku, Tokyo 104–8315, Japan. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://*

www.archives.gov/federal-register/cfr/ibr-locations.html.

(1) Assay for advantame, not less than 97.0 percent and not more than 102.0 percent on a dry basis.

(2) Free *N*-[*N*-[3-(3-hydroxy-4-methoxyphenyl)propyl]-α-aspartyl]-L-phenylalanine, not more than 1.0 percent.

(3) Total other related substances, not more than 1.5 percent.

(4) Lead, not more than 1.0 milligram per kilogram.

(5) Water, not more than 5.0 percent.

(6) Residue on ignition, not more than 0.2 percent.

(7) Specific rotation, determined at20 °C $[\alpha]_D$: −45.0 to −38.0° calculated on a dry basis.

(c) The food additive advantame may be safely used as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice, in an amount not to exceed that reasonably required to achieve the intended technical effect, in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(d) If the food containing the additive purports to be or is represented to be for special dietary use, it must be labeled in compliance with part 105 of this chapter.

[79 FR 29085, May 21, 2014]

§ 172.804 Aspartame.

The food additive aspartame may be safely used in food in accordance with good manufacturing practice as a sweetening agent and a flavor enhancer in foods for which standards of identity established under section 401 of the act do not preclude such use under the following conditions:

(a) Aspartame is the chemical 1-methyl *N*-L-α-aspartyl-L-phenylalanine ($C_{14}H_{18}N_2O_5$).

(b) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 73–74, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c)(1) When aspartame is used as a sugar substitute tablet for sweetening hot beverages, including coffee and tea, L-leucine may be used as a lubricant in the manufacture of such tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(2) When aspartame is used in baked goods and baking mixes, the amount of the additive is not to exceed 0.5 percent by weight of ready-to-bake products or of finished formulations prior to baking. Generally recognized as safe (GRAS) ingredients or food additives approved for use in baked goods shall be used in combination with aspartame to ensure its functionality as a sweetener in the final baked product. The level of aspartame used in these products is determined by an analytical method entitled ''Analytical Method for the Determination of Aspartame and Diketopiperazine in Baked Goods and Baking Mixes,'' October 8, 1992, which was developed by the Nutrasweet Co. Copies are available from the Office of Premarket Approval (HFS–200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or are available for inspection at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The principal display panel of any intermediate mix of the additive for manufacturing purposes shall bear a statement of the concentration of the additive contained therein;

(2) The label of any food containing the additive shall bear, either on the principal display panel or on the information panel, the following statement:

PHENYLKETONURICS: CONTAINS PHENYLALANINE

The statement shall appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) When the additive is used in a sugar substitute for table use, its label shall bear instructions not to use in cooking or baking.

(4) Packages of the dry, free-flowing additive shall prominently display the sweetening equivalence in teaspoons of sugar.

(e) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.

[39 FR 27319, July 26, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 172.804, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 172.806 Azodicarbonamide.

The food additive azodicarbonamide may be safely used in food in accordance with the following prescribed conditions:

(a) It is used or intended for use:

(1) As an aging and bleaching ingredient in cereal flour in an amount not to exceed 2.05 grams per 100 pounds of flour (0.0045 percent; 45 parts per million).

(2) As a dough conditioner in bread baking in a total amount not to exceed 0.0045 percent (45 parts per million) by weight of the flour used, including any quantity of azodicarbonamide added to flour in accordance with paragraph (a)(1) of this section.

(b) To assure safe use of the additive:

(1) The label and labeling of the additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the Act, the following:

(i) The name of the additive.

(ii) A statement of the concentration or the strength of the additive in any intermediate premixes.

(2) The label or labeling of the food additive shall also bear adequate directions for use.

§ 172.808 Copolymer condensates of ethylene oxide and propylene oxide.

Copolymer condensates of ethylene oxide and propylene oxide may be safely used in food under the following prescribed conditions:

(a) The additive consists of one of the following:

(1) α-Hydro-*omega*-hydroxy-poly (oxyethylene) poly(oxypropylene)-(55–61 moles)poly(oxyethylene) block copolymer, having a molecular weight range of 9,760–13,200 and a cloud point above 100 °C in 1 percent aqueous solution.

(2) α-Hydro-*omega*-hydroxy-poly (oxyethylene)poly(oxypropylene)-(53–59 moles)poly(oxyethylene)(14–16 moles) block copolymer, having a molecular weight range of 3,500–4,125 and a cloud point of 9 °C–12 °C in 10 percent aqueous solution.

(3) α-Hydro-*omega*-hydroxy-poly(oxyethylene)/poly(oxypropylene) (minimum 15 moles)/poly(oxyethylene) block copolymer, having a minimum average molecular weight of 1900 and a minimum cloud point of 9 °C–12 °C in 10 percent aqueous solution.

(4) α-Hydro-*omega*-hydroxy-poly(oxyethylene) poly (oxypropylene)-(51–57 moles) poly(oxyethylene) block copolymer, having an average molecular weight of 14,000 and a cloud point above 100 °C in 1 percent aqueous solution.

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used in practice as a solubilizing and stabilizing agent in flavor concentrates (containing authorized flavoring oils) for use in foods for which standards of identity established under section 401

of the Act do not preclude such use, provided that the weight of the additive does not exceed the weight of the flavoring oils in the flavor concentrate.

(2) The additive identified in paragraph (a)(2) of this section is used as a processing aid and wetting agent in combination with dioctyl sodium sulfosuccinate for fumaric acid as prescribed in § 172.810.

(3) The additive identified in paragraph (a)(3) of this section is used:

(i) As a surfactant and defoaming agent, at levels not to exceed 0.05 percent by weight, in scald baths for poultry defeathering, followed by potable water rinse. The temperatures of the scald baths shall be not less than 125 °F.

(ii) As a foam control and rinse adjuvant in hog dehairing machines at a use level of not more than 5 grams per hog.

(4) The additive identified in paragraph (a)(4) of this section is used as a dough conditioner in yeast-leavened bakery products for which standards of identity established under section 401 of the Act do not preclude such use, provided that the amount of the additive dose not exceed 0.5 percent by weight of the flour used.

[42 FR 14491, Mar. 15, 1977, as amended at 46 FR 57476, Nov. 24, 1981]

§ 172.809 Curdlan.

Curdlan may be safely used in accordance with the following conditions:

(a) Curdlan is a high molecular weight polymer of glucose (β-1,3-glucan; CAS Reg. No. 54724–00–4) produced by pure culture fermentation from the nonpathogenic and nontoxicogenic bacterium *Alcaligenes faecalis* var. *myxogenes*.

(b) Curdlan meets the following specifications when it is tested according to the methods described or referenced in the document entitled ''Analytical Methods for Specification Tests for Curdlan,'' by Takeda Chemical Industries, Ltd., 12–10 Nihonbashi, 2–Chome, Chuo-ku, Tokyo, 103, Japan, 1996, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, 240–402–1200, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(1) Positive for curdlan.

(2) Assay for curdlan (calculated as anhydrous glucose), not less than 80 percent.

(3) pH of 1 percent aqueous suspension, 6.0–7.5.

(4) Lead, not more than 0.5 mg/kg.

(5) Heavy metals (as Pb), not more than 0.002 percent.

(6) Total nitrogen, not more than 0.2 percent.

(7) Loss on drying, not more than 10 percent.

(8) Residue on ignition, not more than 6 percent.

(9) Gel strength of 2 percent aqueous suspension, not less than 600×10^3 dyne per square centimeter.

(10) Aerobic plate count, not more than 10^3 per gram.

(11) Coliform bacteria, not more than 3 per gram.

(c) Curdlan is used or intended for use in accordance with good manufacturing practice as a formulation aid, processing aid, stabilizer and thickener, and texturizer in foods for which standards of identity established under section 401 of the act do not preclude such use.

[61 FR 65941, Dec. 16, 1996, as amended at 78 FR 14665, Mar. 7, 2013; 81 FR 5591, Feb. 3, 2016]

§ 172.810 Dioctyl sodium sulfosuccinate.

The food additive, dioctyl sodium sulfosuccinate, meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 313–314, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial

Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*). The food additive, dioctyl sodium sulfosuccinate, may be safely used in food in accordance with the following prescribed conditions:

(a) As a wetting agent in the following fumaric acid-acidulated foods: Dry gelatin dessert, dry beverage base, and fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry gelatin dessert and dry beverage base shall bear adequate directions for use, and the additive shall be used in such an amount that the finished gelatin dessert will contain not in excess of 15 parts per million of the additive and the finished beverage or fruit juice drink will contain not in excess of 10 parts per million of the additive.

(b) As a processing aid in sugar factories in the production of unrefined cane sugar, in an amount not in excess of 0.5 part per million of the additive per percentage point of sucrose in the juice, syrup, or massecuite being processed, and so used that the final molasses will contain no more than 25 parts per million of the additive.

(c) As a solubilizing agent on gums and hydrophilic colloids to be used in food as stabilizing and thickening agents, when standards of identity do not preclude such use. The additive is used in an amount not to exceed 0.5 percent by weight of the gums or hydrophilic colloids.

(d) As an emulsifying agent for cocoa fat in noncarbonated beverages containing cocoa, whereby the amount of the additive does not exceed 25 parts per million of the finished beverage.

(e) As a dispersing agent in ''cocoa with dioctyl sodium sulfosuccinate for manufacturing'' that conforms to the provisions of §163.117 of this chapter and the use limitations prescribed in §172.520, in an amount not to exceed 0.4 percent by weight thereof.

(f) As a processing aid and wetting agent in combination with α-hydro-*omega* -hydroxy - poly(oxyethylene) - poly-(oxypropylene) (53–59 moles) poly(oxyethylene) (14–16 moles) block copolymer, having a molecular weight range of 3,500–4,125 and a cloud point of 9 °C–12 °C in 10 percent aqueous solution, for fumaric acid used in fumaric acid-acidulated dry beverage base and in fumaric acid-acidulated fruit juice drinks, when standards of identity do not preclude such use. The labeling of the dry beverage base shall bear adequate directions for use, and the additives shall be used in such an amount that the finished beverage or fruit juice drink will contain not in excess of a total of 10 parts per million of the dioctyl sodium sulfosuccinate-block copolymer combination.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984; 78 FR 71464, Nov. 29, 2013]

§ 172.811 Glyceryl tristearate.

The food additive glyceryl tristearate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive (CAS Reg. No. 555–43–1) is prepared by reacting stearic acid with glycerol in the presence of a suitable catalyst.

(b) The food additive meets the following specifications:

Acid number: Not to exceed 1.0.
Iodine number: Not to exceed 1.0.
Saponification number: 186–192.
Hydroxyl number: Not to exceed 5.0.
Free glycerol content: Not to exceed 0.5 percent.
Unsaponifiable matter: Not to exceed 0.5 percent.
Melting point (Class II): 69 °C–73 °C.

(c) The additive is used or intended for use as follows when standards of identity established under section 401 of the Act do not preclude such use:

Uses	Limitations
1. As a crystallization accelerator in cocoa products, in imitation chocolate, and in compound coatings.	Not to exceed 1 percent of the combined weight of the formulation.

Uses	Limitations
2. As a formulation aid as defined in § 170.3(o)(14) of this chapter, lubricant and release agent as defined in § 170.3(o)(18) of this chapter, and surface-finishing agent as defined in § 170.3(o)(30) of this chapter in food.	Not to exceed 0.5 percent.
3. As a formulation aid as defined in § 170.3(o)(14) of this chapter in confections.	Not to exceed 3.0 percent of the combined weight of the formulation.
4. As a formulation aid as defined in § 170.3(o)(14) of this chapter in fats and oils as defined in § 170.3 (n)(12) of this chapter.	Not to exceed 1.0 percent of the combined weight of the formulation.
5. As a winterization and fractionation aid in fat and oil processing.	Not to exceed 0.5 percent by weight of the processed fat or oil.

(d) To assure safe use of the additive:

(1) In addition to the other information required by the act, the label or labeling of the additive shall bear the name of the additive.

(2) The label of the additive shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[53 FR 21632, June 9, 1988, as amended at 59 FR 24924, May 13, 1994]

§ 172.812 Glycine.

The food additive glycine may be safely used for technological purposes in food in accordance with the following prescribed conditions:

(a) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 457–458, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(b) The additive is used or intended for use as follows:

Uses	Limitations
As a masking agent for the bitter aftertaste of saccharin used in manufactured beverages and beverage bases.	Not to exceed 0.2 percent in the finished beverage.
As a stabilizer in mono- and diglycerides prepared by the glycerolysis of edible fats or oils.	Not to exceed 0.02 percent of the mono- and diglycerides.

(c) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The labeling of the additive shall bear adequate directions for use of the additive in compliance with the provisions of this section.

(2) The labeling of beverage bases containing the additive shall bear adequate directions for use to provide that beverages prepared therefrom shall contain no more than 0.2 percent glycine.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984; 78 FR 71464, Nov. 29, 2013]

§ 172.814 Hydroxylated lecithin.

The food additive hydroxylated lecithin may be safely used as an emulsifier in foods in accordance with the following conditions:

(a) The additive is obtained by the treatment of lecithin in one of the following ways, under controlled conditions whereby the separated fatty acid fraction of the resultant product has an acetyl value of 30 to 38:

(1) With hydrogen peroxide, benzoyl peroxide, lactic acid, and sodium hydroxide.

(2) With hydrogen peroxide, acetic acid, and sodium hydroxide.

(b) It is used or intended for use, in accordance with good manufacturing practice, as an emulsifier in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive, ''hydroxylated lecithin''.

(2) Adequate directions for its use.

§ 172.816 Methyl glucoside-coconut oil ester.

Methyl glucoside-coconut oil ester may be safely used in food in accordance with the following conditions:

(a) It is the methyl glucoside-coconut oil ester having the following specifications:

Acid number: 10–20
Hydroxyl number: 200–300
pH (5% aqueous): 4.8–5.0
Saponification number: 178–190

(b) It is used or intended for use as follows:

(1) As an aid in crystallization of sucrose and dextrose at a level not to exceed the minimum quantity required to produce its intended effect.

(2) As a surfactant in molasses at a level not to exceed 320 parts per million in the molasses.

§ 172.818 Oxystearin.

The food additive oxystearin may be safely used in foods, when such use is not precluded by standards of identity in accordance with the following conditions:

(a) The additive is a mixture of the glycerides of partially oxidized stearic and other fatty acids obtained by heating hydrogenated cottonseed or soybean oil under controlled conditions, in the presence of air and a suitable catalyst which is not a food additive as so defined. The resultant product meets the following specifications:

Acid number: Maximum 15.
Iodine number: Maximum 15.
Saponification number: 225–240.
Hydroxyl number: 30–45.
Unsaponifiable material: Maximum 0.8 percent.
Refractive index (butyro): 60±1 at 48 °C.

(b) It is used or intended for use as a crystallization inhibitor in vegetable oils and as a release agent in vegetable oils and vegetable shortenings, whereby the additive does not exceed 0.125 percent of the combined weight of the oil or shortening.

(c) To insure safe use of the additive, the label and labeling of the additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive.

(2) Adequate directions to provide an oil or shortening that complies with the limitations prescribed in paragraph (b) of this section.

§ 172.820 Polyethylene glycol (mean molecular weight 200-9,500).

Polyethylene glycol identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a) *Identity.* (1) The additive is an addition polymer of ethylene oxide and water with a mean molecular weight of 200 to 9,500.

(2) It contains no more than 0.2 percent total by weight of ethylene and diethylene glycols when tested by the analytical methods prescribed in paragraph (b) of this section.

(b) *Analytical method.* (1) The analytical method prescribed in the National Formulary XV (1980), page 1244, for polyethylene glycol 400 shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights of 450 or higher.

(2) The following analytical method shall be used to determine the total ethylene and diethylene glycol content of polyethylene glycols having mean molecular weights below 450.

ANALYTICAL METHOD

ETHYLENE GLYCOL AND DIETHYLENE GLYCOL CONTENT OF POLYETHYLENE GLYCOLS

The analytical method for determining ethylene glycol and diethylene glycol is as follows:

APPARATUS

Gas chromatograph with hydrogen flame ionization detector (Varian Aerograph 600 D or equivalent). The following conditions shall be employed with the Varian Aerograph 600 D gas chromatograph:

Column temperature: 165 °C.

Inlet temperature: 260 °C.

Carrier gas (nitrogen) flow rate: 70 milliliters per minute.

Hydrogen and air flow to burner: Optimize to give maximum sensitivity.

Sample size: 2 microliters.

Elution time: Ethylene glycol: 2.0 minutes. Diethylene glycol: 6.5 minutes.

Recorder: −0.5 to + 1.05 millivolt, full span, 1 second full response time.

Syringe: 10-microliter (Hamilton 710 N or equivalent).

Chromatograph column: 5 feet × ⅛ inch. I.D. stainless steel tube packed with sorbitol (Mathieson-Coleman-Bell 2768 Sorbitol

SX850, or equivalent) 12 percent in H_2O by weight on 60–80 mesh nonacid washed diatomaceous earth (Chromosorb W. Johns-Manville, or equivalent).

REAGENTS AND MATERIALS

Carrier gas, nitrogen: Commercial grade in cylinder equipped with reducing regulator to provide 50 p.s.i.g. to the gas chromatograph.

Ethylene glycol: Commercial grade. Purify if necessary, by distillation.

Diethylene glycol: Commercial grade. Purify, if necessary, by distillation.

Glycol standards: Prepare chromatographic standards by dissolving known amounts of ethylene glycol and diethylene glycol in water. Suitable concentrations for standardization range from 1 to 6 milligrams of each component per milliliter (for example 10 milligrams diluted to volume in a 10-milliliter volumetric flask is equivalent to 1 milligram per milliliter).

STANDARDIZATION

Inject a 2-microliter aliquot of the glycol standard into the gas chromatograph employing the conditions described above. Measure the net peak heights for the ethylene glycol and for the diethylene glycol. Record the values as follows:

A = Peak height in millimeters of the ethylene glycol peak.

B = milligrams of ethylene glycol per milliliter of standard solution.

C = Peak height in millimeters of the diethylene glycol peak.

D = Milligrams of diethylene glycol per milliliter of standard solution.

PROCEDURE

Weigh approximately 4 grams of polyethylene glycol sample accurately into a 10-milliliter volumetric flask. Dilute to volume with water. Mix the solution thoroughly and inject a 2-microliter aliquot into the gas chromatograph. Measure the heights, in millimeters, of the ethylene glycol peak and of the diethylene glycol peak and record as E and F, respectively.

Percent ethylene glycol = $(E \times B) / (A \times$ sample weight in grams$)$

Percent diethylene glycol = $(F \times D) / (C \times$ sample weight in grams$)$

(c) *Uses*. It may be used, except in milk or preparations intended for addition to milk, as follows:

(1) As a coating, binder, plasticizing agent, and/or lubricant in tablets used for food.

(2) As an adjuvant to improve flavor and as a bodying agent in nonnutritive sweeteners identified in §180.37 of this chapter.

(3) As an adjuvant in dispersing vitamin and/or mineral preparations.

(4) As a coating on sodium nitrite to inhibit hygroscopic properties.

(d) *Limitations*. (1) It is used in an amount not greater than that required to produce the intended physical or technical effect.

(2) A tolerance of zero is established for residues of polyethylene glycol in milk.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.822 Sodium lauryl sulfate.

The food additive sodium lauryl sulfate may be safely used in food in accordance with the following conditions:

(a) The additive meets the following specifications:

(1) It is a mixture of sodium alkyl sulfates consisting chiefly of sodium lauryl sulfate [$CH_2(CH_2)_{10}CH_2OSO_2Na$].

(2) It has a minimum content of 90 percent sodium alkyl sulfates.

(b) It is used or intended for use:

(1) As an emulsifier in or with egg whites whereby the additive does not exceed the following limits:

Egg white solids, 1,000 parts per million.
Frozen egg whites, 125 parts per million.
Liquid egg whites, 125 parts per million.

(2) As a whipping agent at a level not to exceed 0.5 percent by weight of gelatine used in the preparation of marshmallows.

(3) As a surfactant in:

(i) Fumaric acid-acidulated dry beverage base whereby the additive does not exceed 25 parts per million of the finished beverage and such beverage base is not for use in a food for which a standard of identity established under section 401 of the Act precludes such use.

(ii) Fumaric acid-acidulated fruit juice drinks whereby the additive does not exceed 25 parts per million of the finished fruit juice drink and it is not used in a fruit juice drink for which a standard of identity established under section 401 of the Act precludes such use.

(4) As a wetting agent at a level not to exceed 10 parts per million in the partition of high and low melting fractions of crude vegetable oils and animal fats, provided that the partition

step is followed by a conventional refining process that includes alkali neutralization and deodorization of the fats and oils.

(c) To insure the safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the Act:

(1) The name of the additive, sodium lauryl sulfate.

(2) Adequate use directions to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 18668, May 2, 1978]

§ 172.824 Sodium mono- and dimethyl naphthalene sulfonates.

The food additive sodium mono- and dimethyl naphthalene sulfonates may be safely used in accordance with the following prescribed conditions:

(a) The additive has a molecular weight range of 245–260.

(b) The additive is used or intended for use:

(1) In the crystallization of sodium carbonate in an amount not to exceed 250 parts per million of the sodium carbonate. Such sodium carbonate is used or intended for use in potable water systems to reduce hardness and aid in sedimentation and coagulation by raising the pH for the efficient utilization of other coagulation materials.

(2) As an anticaking agent in sodium nitrite at a level not in excess of 0.1 percent by weight thereof for authorized uses in cured fish and meat.

(c) In addition to the general labeling requirements of the Act:

(1) Sodium carbonate produced in accordance with paragraph (b)(1) of this section shall be labeled to show the presence of the additive and its label or labeling shall bear adequate directions for use.

(2) Sodium nitrite produced in accordance with paragraph (b)(2) of this section shall bear the labeling required by § 172.175 and a statement declaring the presence of sodium mono- and dimethyl naphthalene sulfonates.

[42 FR 14491, Mar. 15, 1977, as amended at 63 FR 7069, Feb. 12, 1998]

§ 172.826 Sodium stearyl fumarate.

Sodium stearyl fumarate may be safely used in food in accordance with the following conditions:

(a) It contains not less than 99 percent sodium stearyl fumarate calculated on the anhydrous basis, and not more than 0.25 percent sodium stearyl maleate.

(b) The additive is used or intended for use:

(1) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(2) As a conditioning agent in dehydrated potatoes in an amount not to exceed 1 percent by weight thereof.

(3) As a stabilizing agent in nonyeast-leavened bakery products in an amount not to exceed 1 percent by weight of the flour used.

(4) As a conditioning agent in processed cereals for cooking in an amount not to exceed 1 percent by weight of the dry cereal, except for foods for which standards of identity preclude such use.

(5) As a conditioning agent in starch-thickened or flour-thickened foods in an amount not to exceed 0.2 percent by weight of the food.

§ 172.828 Acetylated monoglycerides.

The food additive acetylated monoglycerides may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive is manufactured by:

(1) The interesterification of edible fats with triacetin and in the presence of catalytic agents that are not food additives or are authorized by regulation, followed by a molecular distillation or by steam stripping; or

(2) The direct acetylation of edible monoglycerides with acetic anhydride without the use of catalyst or molecular distillation, and with the removal by vacuum distillation, if necessary, of the acetic acid, acetic anhydride, and triacetin.

(b) The food additive has a Reichert-Meissl value of 75–200 and an acid value of less than 6.

(c) The food additive is used at a level not in excess of the amount reasonably required to produce its intended effect in food, or in food-processing, food-packing, or food-storage equipment.

[42 FR 14491, Mar. 15, 1977, as amended at 50 FR 3508, Jan. 25, 1985]

§ 172.829 Neotame.

(a) Neotame is the chemical *N*-[*N*-(3,3-dimethylbutyl)-L-α-asparty1]-L-phenylalanine-1-methyl ester (CAS Reg. No. 165450–17–9).

(b) Neotame meets the following specifications when it is tested according to the methods described or referenced in the document entitled ''Specifications and Analytical Methods for Neotame'' dated April 3, 2001, by the NutraSweet Co., 699 North Wheeling Rd., Mount Prospect, IL 60056. The Director of the Office of the Federal Register has approved the incorporation by reference of this material in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5001 Campus Dr., rm. 1C–100, College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(1) Assay for neotame, not less than 97.0 percent and not more than 102.0 percent on a dry basis.

(2) Free dipeptide acid (*N*-[*N*-(3,3-dimethylbutyl)-L-α-asparty1]-L-phenylalanine), not more than 1.5 percent.

(3) Other related substances, not more than 2.0 percent.

(4) Lead, not more than 2.0 milligrams per kilogram.

(5) Water, not more than 5.0 percent.

(6) Residue on ignition, not more than 0.2 percent

(7) Specific rotation, determined at 20 °C $[\alpha]_D$: −40.0° to 43.4° calculated on a dry basis.

(c) The food additive neotame may be safely used as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice, in an amount not to exceed that reasonably required to accomplish the intended technical effect, in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(d) When neotame is used as a sugar substitute tablet, L-leucine may be used as a lubricant in the manufacture of tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(e) If the food containing the additive purports to be or is represented to be for special dietary use, it shall be labeled in compliance with part 105 of this chapter.

[67 FR 45310, July 9, 2002, as amended at 81 FR 5591, Feb. 3, 2016]

§ 172.830 Succinylated monoglycerides.

The food additive succinylated monoglycerides may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of semi- and neutral succinic acid esters of mono- and diglycerides produced by the succinylation of a product obtained by the glycerolysis of edible fats and oils, or by the direct esterification of glycerol with edible fat-forming fatty acids.

(b) The additive meets the following specifications:

Succinic acid content: 14.8%–25.6%
Melting point: 50 °C–60 °C.
Acid number: 70–120

(c) The additive is used or intended for use in the following foods:

(1) As an emulsifier in liquid and plastic shortenings at a level not to exceed 3 percent by weight of the shortening.

(2) As a dough conditioner in bread baking, when such use is permitted by an appropriate food standard, at a level not to exceed 0.5 percent by weight of the flour used.

§ 172.831 Sucralose.

(a) Sucralose is the chemical 1,6-dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside (CAS Reg. No. 56038–13–2).

(b) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 993–995, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) The additive may be used as a sweetener in foods generally, in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect.

(d) If the food containing the additive purports to be or is represented to be for special dietary use, it shall be labeled in compliance with part 105 of this chapter.

[63 FR 16433, Apr. 3, 1998, as amended at 64 FR 43909, Aug. 12, 1999; 78 FR 14665, Mar. 7, 2013; 78 FR 71464, Nov. 29, 2013]

§ 172.832 Monoglyceride citrate.

A food additive that is a mixture of glyceryl monooleate and its citric acid monoester manufactured by the reaction of glyceryl monooleate with citric acid under controlled conditions may be safely used as a synergist and solubilizer for antioxidants in oils and fats, when used in accordance with the conditions prescribed in this section.

(a) The food additive meets the following specifications:

Acid number, 70–100.
Total citric acid (free and combined), 14 percent–17 percent.

(b) It is used, or intended for use, in antioxidant formulations for addition to oils and fats whereby the additive does not exceed 200 parts per million of the combined weight of the oil or fat and the additive.

(c) To assure safe use of the additive:

(1) The container label shall bear, in addition to the other information required by the Act, the name of the additive.

(2) The label or accompanying labeling shall bear adequate directions for the use of the additive which, if followed, will result in a food that complies with the requirements of this section.

§ 172.833 Sucrose acetate isobutyrate (SAIB).

Sucrose acetate isobutyrate may be safely used in foods in accordance with the following prescribed conditions:

(a) Sucrose acetate isobutyrate (CAS Reg. No. 27216–37–1), or SAIB, is the chemical *alpha*-D-glucopyranoside, O-acetyl-tris-O-(2-methyl-1-oxopropyl)-*beta*-D-fructofuranosyl, acetate tris(2-methyl propanoate).

(b) SAIB, a pale, straw-colored liquid, meets the following specifications: (1) Assay: Not less than 98.8 percent and not more than 101.9 percent, based on the following formula:

$$\text{Assay} = ((\text{SV}\ 0.10586) \div 56.1) \times 100$$

Where SV = Saponification value

(2) Saponification value: 524–540 determined using 1 gram of sample by the ''Guide to Specifications for General Notices, General Analytical Techniques, Identification Tests, Test Solutions, and Other Reference Materials,'' in the ''Compendium of Food Additive Specifications, Addendum 4, Food and Agriculture Organization of the United Nations (FAO), Food and Nutrition Paper 5, Revision 2'' (1991), pp. 203 and 204, which is incorporated by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, 240–402–1200, or may be examined at the Center

for Food Safety and Applied Nutrition's Library, 5001 Campus Dr., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(3) Acid value: Not to exceed 0.20 determined using 50 grams of sample by the ''Guide to Specifications for General Notices, General Analytical Techniques, Identification Tests, Test Solutions, and Other Reference Materials,'' in the ''Compendium of Food Additive Specifications, Addendum 4, FAO Food and Nutrition Paper 5, Revision 2,'' p. 189 (1991), which is incorporated by reference; see paragraph (b)(2) of this section for availability of the incorporation by reference.

(4) Lead: Not to exceed 1.0 milligrams/kilogram determined by the ''Atomic Absorption Spectrophotometric Graphite Furnace Method, Method I,'' in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 763 and 764, with an attached modification to the sample digestion section in Appendix III.B (July 1996), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Box 285, Washington, DC 20055 (Internet *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(5) Triacetin: Not to exceed 0.10 percent determined by gas chromatography as described in the ''Guide to Specifications for General Notices, General Analytical Techniques, Identification Tests, Test Solutions, and Other Reference Materials,'' in the ''Compendium of Food Additive Specifications, Addendum 4, FAO Food and Nutrition Paper 5, Revision 2,'' (1991), pp. 13–26, which is incorporated by reference; see paragraph (b)(2) of this section for availability of the incorporation by reference.

(c) The food additive is used as a stabilizer (as defined in § 170.3(o)(28) of this chapter) of emulsions of flavoring oils in nonalcoholic beverages.

(d) The total SAIB content of a beverage containing the additive does not exceed 300 milligrams/kilogram of the finished beverage.

[64 FR 29958, June 4, 1999; 64 FR 43072, Aug. 9, 1999, as amended at 78 FR 14665, Mar. 7, 2013; 81 FR 5591, Feb. 3, 2016]

§ 172.834 Ethoxylated mono- and diglycerides.

The food additive ethoxylated mono- and diglycerides (polyoxyethylene (20) mono- and diglycerides of fatty acids) (polyglycerate 60) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by:

(1) Glycerolysis of edible fats primarily composed of stearic, palmitic, and myristic acids; or

(2) Direct esterification of glycerol with a mixture of primarily stearic, palmitic, and myristic acids;

to yield a product with less than 0.3 acid number and less than 0.2 percent water, which is then reacted with ethylene oxide.

(b) The additive meets the following specifications:

Saponification number, 65–75.
Acid number, 0–2.
Hydroxyl number, 65–80.
Oxyethylene content, 60.5–65.0 percent.

(c) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

Use	Limitations
1. As an emulsifier in pan-release agents for and as a dough conditioner in yeast-leavened bakery products.	Not to exceed levels required to produce the intended effects, total not to exceed 0.5 percent by weight of the flour used.
2. As an emulsifier in cakes and cake mixes.	Not to exceed 0.5 percent by weight of the dry ingredients.
3. As an emulsifier in whipped vegetable oil toppings and topping mixes.	Not to exceed 0.45 percent by weight of the finished whipped vegetable oil toppings.

Use	Limitations
4. As an emulsifier in icings and icing mixes.	Not to exceed 0.5 percent by weight of the finished icings.
5. As an emulsifier in frozen desserts.	Not to exceed 0.2 percent by weight of the finished frozen desserts.
6. As an emulsifier in edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee.	Not to exceed 0.4 percent by weight of the finished vegetable fat-water emulsions.

(d) When the name ''polyglycerate 60'' is used in labeling it shall be followed by either ''polyoxyethylene (20) mono-and diglycerides of fatty acids'' or ''ethoxylated mono- and diglycerides'' in parentheses.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 37973, July 26, 1977; 50 FR 49536, Dec. 3, 1985]

§ 172.836 Polysorbate 60.

The food additive polysorbate 60 (polyoxyethylene (20) sorbitan monostearate) which is a mixture of polyoxyethylene ethers of mixed partial stearic and palmitic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 10 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45–55.
Acid number 0–2.
Hydroxyl number 81–96.
Oxyethylene content 65 percent–69.5 percent.

(c) It is used or intended for use as follows:

(1) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;

(ii) Polysorbate 65;

(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping; except that a combination of the additive with sorbitan monostearate may be used in excess of 0.4 percent, provided that the amount of the additive does not exceed 0.77 percent and the amount of sorbitan monostearate does not exceed 0.27 percent of the weight of the finished whipped edible oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Sorbitan monostearate.

When used alone, the maximum amount of polysorbate 60 shall not exceed 0.46 percent of the cake or cake mix, on a dry-weight basis. When used with polysorbate 65 and/or sorbitan monostearate, it shall not exceed 0.46 percent, nor shall the polysorbate 65 exceed 0.32 percent or the sorbitan monostearate exceed 0.61 percent, and no combination of these emulsifiers shall exceed 0.66 percent of the cake or cake mix, all calculated on a dry-weight basis.

(3) As an emulsifier, alone or in combination with sorbitan monostearate, in nonstandardized confectionery coatings and standardized cacao products specified in §§163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:

(i) It is used alone in an amount not to exceed 0.5 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(ii) It is used with sorbitan monostearate in any combination of up to 0.5 percent of polysorbate 60 and up to 1 percent of sorbitan monostearate: *Provided,* That the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) [Reserved]

(5) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Sorbitan monostearate.

When used alone, the maximum amount of polysorbate 60 shall not exceed 0.46 percent of the weight of the cake icings and cake fillings. When used with polysorbate 65 and/or sorbitan monostearate, it shall not exceed

0.46 percent, nor shall the polysorbate 65 exceed 0.32 percent or the sorbitan monostearate exceed 0.7 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(6) To impart greater opacity to sugar-type confection coatings whereby the maximum amount of the additive does not exceed 0.2 percent of the weight of the finished sugar coating.

(7) As an emulsifier in nonstandardized dressings whereby the maximum amount of the additive does not exceed 0.3 percent of the weight of the finished dressings.

(8) As an emulsifier, alone or in combination with polysorbate 80, in shortenings and edible oils intended for use in foods as follows, when standards of identity established under section 401 of the act do not preclude such use:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.

(ii) It is used with polysorbate 80 in any combination providing no more than 1 percent of polysorbate 60 and no more than 1 percent of polysorbate 80, provided that the total combination does not exceed 1 percent of the finished shortening or oil.

(iii) The 1–percent limitation specified in paragraph (c)(8)(i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Sorbitan monostearate.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(10) As a foaming agent in nonalcoholic mixes, to be added to alcoholic beverages in the preparation of mixed alcoholic drinks, at a level not to exceed 4.5 percent by weight of the nonalcoholic mix.

(11) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(12) As an emulsifier, alone or in combination with sorbitan monostearate, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with §172.878 and/or petroleum wax conforming with §172.886 for use as protective coatings on raw fruits and vegetables.

(13) As a dispersing agent in artificially sweetened gelatin desserts and in artificially sweetened gelatin dessert mixes, whereby the amount of the additive does not exceed 0.5 percent on a dry-weight basis.

(14) As an emulsifier in chocolate flavored syrups, whereby the maximum amount of the additive does not exceed 0.05 percent in the finished product.

(15) As a surfactant and wetting agent for natural and artificial colors in food as follows:

(i) In powdered soft drink mixes in an amount not to exceed 4.5 percent by weight of the mix.

(ii) In sugar-based gelatin dessert mixes in an amount not to exceed 0.5 percent by weight of the mix.

(iii) In artificially sweetened gelatin dessert mixes in an amount not to exceed 3.6 percent by weight of the mix.

(iv) In sugar-based pudding mixes in an amount not to exceed 0.5 percent by weight of the mix.

(v) In artificially sweetened pudding mixes in an amount not to exceed 0.5 percent by weight of the mix.

(16) As an emulsifier in ice cream, frozen custard, fruit sherbet, and nonstandardized frozen desserts when used alone or in combination with polysorbate 65 and/or polysorbate 80, whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final

product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 25, 1978; 45 FR 58836, Sept. 5, 1980; 46 FR 8466, Jan. 27, 1981; 64 FR 57976, Oct. 28, 1999]

§ 172.838 Polysorbate 65.

The food additive polysorbate 65 (polyoxyethylene (20) sorbitan tristearate), which is a mixture of polyoxyethylene ethers of mixed stearic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield a product with a maximum acid number of 15 and a maximum water content of 0.2 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 88–98.
Acid number 0–2.
Hydroxyl number 44–60.
Oxyethylene content 46 percent–50 percent.

(c) The additive is used, or intended for use, as follows:

(1) As an emulsifier in ice cream, frozen custard, ice milk, fruit sherbet and nonstandardized frozen desserts when used alone or in combination with polysorbate 80, whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Sorbitan monostearate.

(ii) Polysorbate 60.

When used alone, the maximum amount of polysorbate 65 shall not exceed 0.32 percent of the cake or cake mix, on a dry-weight basis. When used with sorbitan monostearate and/or polysorbate 60, it shall not exceed 0.32 percent, nor shall the sorbitan monostearate exceed 0.61 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 0.66 percent of the cake or cake mix, all calculated on a dry-weight basis.

(3) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;

(ii) Polysorbate 60;

(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping.

(4) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Sorbitan monostearate.

(ii) Polysorbate 60.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(5) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Sorbitan monostearate.

(ii) Polysorbate 60.

When used alone, the maximum amount of polysorbate 65 shall not exceed 0.32 percent of the weight of the cake icing or cake filling. When used with sorbitan monostearate and/or polysorbate 60, it shall not exceed 0.32 percent, nor shall the sorbitan monostearate exceed 0.7 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 20, 1978]

§ 172.840 Polysorbate 80.

The food additive polysorbate 80 (polyoxyethylene (20) sorbitan monooleate), which is a mixture of polyoxyethylene ethers of mixed partial oleic acid esters of sorbitol anhydrides and related compounds, may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting oleic acid (usually containing associated fatty acids) with sorbitol to yield a product with a maximum acid number of 7.5 and a maximum water content of 0.5 percent, which is then reacted with ethylene oxide.

(b) The food additive meets the following specifications:

Saponification number 45–55.
Acid number 0–2.
Hydroxyl number 65–80.
Oxyethylene content 65 percent–69.5 percent.

(c) The additive is used or intended for use as follows:

(1) An emulsifier in ice cream, frozen custard, ice milk, fruit sherbet, and nonstandardized frozen desserts, when used alone or in combination with polysorbate 65 whereby the maximum amount of the additives, alone or in combination, does not exceed 0.1 percent of the finished frozen dessert.

(2) In yeast-defoamer formulations whereby the maximum amount of the additive does not exceed 4 percent of the finished yeast defoamer and the maximum amount of the additive in the yeast from such use does not exceed 4 parts per million.

(3) As a solubilizing and dispersing agent in pickles and pickle products, whereby the maximum amount of the additive does not exceed 500 parts per million.

(4) As a solubilizing and dispersing agent in:

(i) Vitamin-mineral preparations containing calcium caseinate in the absence of fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 175 milligrams from the recommended daily dose of the preparations.

(ii) Fat-soluble vitamins in vitamin and vitamin-mineral preparations containing no calcium caseinate, whereby the maximum intake of polysorbate 80 shall not exceed 300 milligrams from the recommended daily dose of the preparations.

(iii) In vitamin-mineral preparations containing both calcium caseinate and fat-soluble vitamins, whereby the maximum intake of polysorbate 80 shall not exceed 475 milligrams from the recommended daily dose of the preparations.

(5) As a surfactant in the production of coarse crystal sodium chloride whereby the maximum amount of the additive in the finished sodium chloride does not exceed 10 parts per million.

(6) In special dietary foods, as an emulsifier for edible fats and oils, with directions for use which provide for the ingestion of not more than 360 milligrams of polysorbate 80 per day.

(7) As a solubilizing and dispersing agent for dill oil in canned spiced green beans, not to exceed 30 parts per million.

(8) As an emulsifier, alone or in combination with polysorbate 60, in shortenings and edible oils intended for use in foods as follows, when standards of identity established under section 401 of the act do not preclude such use:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished shortening or oil.

(ii) It is used with polysorbate 60 in any combination providing no more than 1 percent of polysorbate 80 and no more than 1 percent of polysorbate 60, provided that the total combination does not exceed 1 percent of the finished shortening or oil.

(iii) The 1–percent limitation specified in paragraph (c)(8)(i) and (ii) of this section may be exceeded in premix concentrates of shortening or edible oil if the labeling complies with the requirements of paragraph (d) of this section.

(9) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Sorbitan monostearate;

(ii) Polysorbate 60;

(iii) Polysorbate 65;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping.

(10) It is used as a wetting agent in scald water for poultry defeathering, followed by potable water rinse. The concentration of the additive in the scald water does not exceed 0.0175 percent.

(11) As a dispersing agent in gelatin desserts and in gelatin dessert mixes, whereby the amount of the additive does not exceed 0.082 percent on a dry-weight basis.

(12) As an adjuvant added to herbicide use and plant-growth regulator use dilutions by a grower or applicator prior to application of such dilutions to the growing crop. Residues resulting from such use are exempt from the requirement of a tolerance. When so used or intended for use, the additive shall be exempt from the requirements of paragraph (d)(1) of this section.

(13) As a defoaming agent in the preparation of the creaming mixture for cottage cheese as identified in §133.128 of this chapter, whereby the amount of the additive does not exceed .008 percent by weight of the finished product.

(14) As a surfactant and wetting agent for natural and artificial colors for use in barbecue sauce where the level of the additive does not exceed 0.005 percent by weight of the barbecue sauce.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 20, 1978; 45 FR 58835, Sept. 5, 1980; 46 FR 8466, Jan. 27, 1981; 85 FR 72907, Nov. 16, 2020]

§ 172.841 Polydextrose.

Polydextrose as identified in this section may be safely used in food in accordance with the following prescribed conditions:

(a)(1) Polydextrose (CAS Reg. No. 68424–04–4) is a partially metabolizable water-soluble polymer prepared by the condensation of a melt which consists either of approximately 89 percent D-glucose, 10 percent sorbitol, and 1 percent citric acid or of approximately 90 percent D-glucose, 10 percent sorbitol, and 0.1 percent phosphoric acid, on a weight basis.

(2) Polydextrose may be partially neutralized with potassium hydroxide, or partially reduced by transition metal catalytic hydrogenation in aqueous solution.

(b) The additive meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 811–814, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) When standards of identity established under section 401 of the act do not preclude such use, polydextrose may be used in accordance with current good manufacturing practices as a bulking agent, formulation aid, humectant, and texturizer in all foods, except meat and poultry, baby food, and infant formula.

(d) If the food containing the additive purports to be or is represented for special dietary uses, it shall be labeled in compliance with part 105 of this chapter.

(e) The label and labeling of food a single serving of which would be expected to exceed 15 grams of the additive shall bear the statement: ''Sensitive individuals may experience a

laxative effect from excessive consumption of this product''.

[46 FR 30081, June 5, 1981, as amended at 59 FR 37421, July 22, 1994; 60 FR 54425, Oct. 24, 1995; 61 FR 14480, Apr. 2, 1996; 62 FR 30985, June 6, 1997; 63 FR 57597, Oct. 28, 1998; 65 FR 64605, Oct. 30, 2000; 65 FR 79719, Dec. 20, 2000; 72 FR 46564, Aug. 21, 2007; 78 FR 71464, Nov. 29, 2013]

§ 172.842 Sorbitan monostearate.

The food additive sorbitan monostearate, which is a mixture of partial stearic and palmitic acid esters of sorbitol anhydrides, may be safely used in or on food in accordance with the following prescribed conditions:

(a) The food additive is manufactured by reacting stearic acid (usually containing associated fatty acids, chiefly palmitic) with sorbitol to yield essentially a mixture of esters.

(b) The food additive meets the following specifications:

Saponification number, 147–157
Acid number, 5–10
Hydroxyl number, 235–260

(c) It is used or intended for use, alone or in combination with polysorbate 60 as follows:

(1) As an emulsifier in whipped edible oil topping with or without one or a combination of the following:

(i) Polysorbate 60;

(ii) Polysorbate 65;

(iii) Polysorbate 80;

whereby the maximum amount of the additive or additives used does not exceed 0.4 percent of the weight of the finished whipped edible oil topping; except that a combination of the additive with polysorbate 60 may be used in excess of 0.4 percent: *Provided*, That the amount of the additive does not exceed 0.27 percent and the amount of polysorbate 60 does not exceed 0.77 percent of the weight of the finished whipped edible oil topping.

(2) As an emulsifier in cakes and cake mixes, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Polysorbate 60.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.61 percent of the cake or cake mix, on a dry-weight basis. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.61 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of the emulsifiers shall exceed 0.66 percent of the weight of the cake or cake mix, calculated on a dry-weight basis.

(3) As an emulsifier, alone or in combination with polysorbate 60 in nonstandardized confectionery coatings and standardized cacao products specified in §§ 163.123, 163.130, 163.135, 163.140, 163.145, and 163.150 of this chapter, as follows:

(i) It is used alone in an amount not to exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(ii) It is used with polysorbate 60 in any combination of up to 1 percent sorbitan monostearate and up to 0.5 percent polysorbate 60 provided that the total combination does not exceed 1 percent of the weight of the finished nonstandardized confectionery coating or standardized cacao product.

(4) As an emulsifier in cake icings and cake fillings, with or without one or a combination of the following:

(i) Polysorbate 65.

(ii) Polysorbate 60.

When used alone, the maximum amount of sorbitan monostearate shall not exceed 0.7 percent of the weight of the cake icing or cake filling. When used with polysorbate 65 and/or polysorbate 60, it shall not exceed 0.7 percent, nor shall the polysorbate 65 exceed 0.32 percent or the polysorbate 60 exceed 0.46 percent, and no combination of these emulsifiers shall exceed 1 percent of the weight of the cake icing or cake filling.

(5) As an emulsifier in solid-state, edible vegetable fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, with or without one or a combination of the following:

(i) Polysorbate 60.

(ii) Polysorbate 65.

The maximum amount of the additive or additives shall not exceed 0.4 percent by weight of the finished edible vegetable fat-water emulsion.

(6) It is used alone as a rehydration aid in the production of active dry

yeast in an amount not to exceed 1 percent by weight of the dry yeast.

(7) As an emulsifier, alone or in combination with polysorbate 60, in the minimum quantity required to accomplish the intended effect, in formulations of white mineral oil conforming with §172.878 and/or petroleum wax conforming with §172.886 for use as protective coatings on raw fruits and vegetables.

(d) To assure safe use of the additive, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate premixes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling shall bear adequate directions to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 2871, Jan. 20, 1978]

§ 172.844 Calcium stearoyl-2-lactylate.

The food additive calcium stearoyl-2-lactylate may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of calcium salts of stearoyl lactylic acids and minor proportions of other calcium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the calcium salts.

(b) The additive meets the following specifications:

Acid number, 50–86.
Calcium content, 4.2–5.2 percent.
Lactic acid content, 32–38 percent.
Ester number, 125–164.

(c) It is used or intended for use as follows:

(1) As a dough conditioner in yeast-leavened bakery products and prepared mixes for yeast-leavened bakery products in an amount not to exceed 0.5 part for each 100 parts by weight of flour used.

(2) As a whipping agent in:

(i) Liquid and frozen egg white at a level not to exceed 0.05 percent.

(ii) Dried egg white at a level not to exceed 0.5 percent.

(iii) Whipped vegetable oil topping at a level not to exceed 0.3 percent of the weight of the finished whipped vegetable oil topping.

(3) As a conditioning agent in dehydrated potatoes in an amount not to exceed 0.5 percent by weight thereof.

(d) To assure safe use of the additive:

(1) The label and labeling of the food additive and any intermediate premix prepared therefrom shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive.

(ii) A statement of the concentration or strength of the additive in any intermediate premixes.

(2) The label or labeling of the food additive shall also bear adequate directions of use to provide a finished food that complies with the limitations prescribed in paragraph (c) of this section.

§ 172.846 Sodium stearoyl lactylate.

The food additive sodium stearoyl lactylate (CAS Reg. No. 25–383–997) may be safely used in food in accordance with the following prescribed conditions:

(a) The additive, which is a mixture of sodium salts of stearoyl lactylic acids and minor proportions of sodium salts of related acids, is manufactured by the reaction of stearic acid and lactic acid and conversion to the sodium salts.

(b) The additive meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 300–301, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) It is used or intended for use as follows when standards of identity established under section 401 of the Act do not preclude such use:

(1) As a dough strengthener, emulsifier, or processing aid in baked products, pancakes, and waffles, in an amount not to exceed 0.5 part for each 100 parts by weight of flour used.

(2) As a surface-active agent, emulsifier, or stabilizer in icings, fillings, puddings, and toppings, at a level not to exceed 0.2 percent by weight of the finished food.

(3) As an emulsifier or stabilizer in liquid and solid edible fat-water emulsions intended for use as substitutes for milk or cream in beverage coffee, at a level not to exceed 0.3 percent by weight of the finished edible fat-water emulsion.

(4) As a formulation aid, processing aid, or surface-active agent in dehydrated potatoes, in an amount not to exceed 0.5 percent of the dry weight of the food.

(5) As an emulsifier, stabilizer, or texturizer in snack dips, at a level not to exceed 0.2 percent by weight of the finished product.

(6) As an emulsifier, stabilizer, or texturizer in cheese substitutes and imitations and cheese product substitutes and imitations, at a level not to exceed 0.2 percent by weight of the finished food.

(7) As an emulsifier, stabilizer, or texturizer in sauces or gravies, and the products containing the same, in an amount not to exceed 0.25 percent by weight of the finished food.

(8) In prepared mixes for each of the foods listed in paragraphs (c)(1) through (7) of this section, provided the additive is used only as specified in each of those paragraphs.

(9) As an emulsifier, stabilizer, or texturizer in cream liqueur drinks, at a level not to exceed 0.5 percent by weight of the finished product.

[45 FR 51767, Aug. 5, 1980, as amended at 49 FR 10105, Mar. 19, 1984; 50 FR 49536, Dec. 3, 1985; 51 FR 1495, Jan. 14, 1986; 51 FR 3333, Jan. 27, 1986; 65 FR 60859, Oct. 13, 2000]

§ 172.848 Lactylic esters of fatty acids.

Lactylic esters of fatty acids may be safely used in food in accordance with the following prescribed conditions:

(a) They are prepared from lactic acid and fatty acids meeting the requirements of § 172.860(b) and/or oleic acid derived from tall oil fatty acids meeting the requirements of § 172.862.

(b) They are used as emulsifiers, plasticizers, or surface-active agents in the following foods, when standards of identity do not preclude their use:

Foods	Limitations
Bakery mixes	
Baked products	
Cake icings, fillings, and toppings	
Dehydrated fruits and vegetables	
Dehydrated fruit and vegetable juices.	
Edible vegetable fat-water emulsions.	As substitutes for milk or cream in beverage coffee.
Frozen desserts	
Liquid shortening	For household use.
Pancake mixes	
Precooked instant rice	
Pudding mixes	

(c) They are used in an amount not greater than required to produce the intended physical or technical effect, and they may be used with shortening and edible fats and oils when such are required in the foods identified in paragraph (b) of this section.

§ 172.850 Lactylated fatty acid esters of glycerol and propylene glycol.

The food additive lactylated fatty acid esters of glycerol and propylene glycol may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of esters produced by the lactylation of a product obtained by reacting edible fats or oils with propylene glycol.

(b) The additive meets the following specifications: Water insoluble combined lactic acid, 14–18 percent; and acid number, 12 maximum.

(c) It is used in amounts not in excess of that reasonably required to produce the intended physical effect as an emulsifier, plasticizer, or surface-active agent in food.

§ 172.852 Glyceryl-lacto esters of fatty acids.

Glyceryl-lacto esters of fatty acids (the lactic acid esters of mono- and diglycerides) may be safely used in food in accordance with the following prescribed conditions:

(a) They are manufactured from glycerin, lactic acid, and fatty acids conforming with § 172.860 and/or oleic acid

derived from tall oil fatty acids conforming with §172.862 and/or edible fats and oils.

(b) They are used in amounts not in excess of those reasonably required to accomplish their intended physical or technical effect as emulsifiers and plasticizers in food.

§ 172.854 Polyglycerol esters of fatty acids.

Polyglycerol esters of fatty acids, up to and including the decaglycerol esters, may be safely used in food in accordance with the following prescribed conditions:

(a) They are prepared from corn oil, cottonseed oil, lard, palm oil from fruit, peanut oil, safflower oil, sesame oil, soybean oil, and tallow and the fatty acids derived from these substances (hydrogenated and nonhydrogenated) meeting the requirements of §172.860(b) and/or oleic acid derived from tall oil fatty acids meeting the requirements of §172.862.

(b) They are used as emulsifiers in food, in amounts not greater than that required to produce the intended physical or technical effect.

(c) Polyglycerol esters of a mixture of stearic, oleic, and coconut fatty acids are used as a cloud inhibitor in vegetable and salad oils when use is not precluded by standards of identity. The fatty acids used in the production of the polyglycerol esters meet the requirements of §172.860(b), and the polyglycerol esters are used at a level not in excess of the amount required to perform its cloud-inhibiting effect. Oleic acid derived from tall oil fatty acids conforming with §172.862 may be used as a substitute for or together with the oleic acid permitted by this paragraph.

(d) Polyglycerol esters of butter oil fatty acids are used as emulsifiers in combination with other approved emulsifiers in dry, whipped topping base. The fatty acids used in the production of the polyglycerol esters meet the requirements of §172.860(b), and the polyglycerol esters are used at a level not in excess of the amount required to perform their emulsifying effect.

§ 172.856 Propylene glycol mono- and diesters of fats and fatty acids.

Propylene glycol mono- and diesters of fats and fatty acids may be safely used in food, subject to the following prescribed conditions:

(a) They are produced from edible fats and/or fatty acids in compliance with §172.860 and/or oleic acid derived from tall oil fatty acids in compliance with §172.862.

(b) They are used in food in amounts not in excess of that reasonably required to produce their intended effect.

§ 172.858 Propylene glycol alginate.

The food additive propylene glycol alginate (CAS Reg. No. 9005–37–2) may be used as an emulsifier, flavoring adjuvant, formulation aid, stabilizer, surfactant, or thickener in foods in accordance with the following prescribed conditions:

(a) The additive meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 256, which is incorporated by reference (Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*), and the additional specification that it shall have up to 85 percent of the carboxylic acid groups esterified with the remaining groups either free or neutralized.

(b) The additive is used or intended for use in the following foods as defined in §170.3(n) of this chapter, when standards of identity established under section 401 of the act do not preclude such use:

(1) As a stabilizer in frozen dairy desserts, in fruit and water ices, and in confections and frostings at a level not to exceed 0.5 percent by weight of the finished product.

(2) As an emulsifier, flavoring adjuvant, stabilizer, or thickener in baked goods at a level not to exceed 0.5 percent by weight of the finished product.

(3) As an emulsifier, stabilizer, or thickener in cheeses at a level not to

exceed 0.9 percent by weight of the finished product.

(4) As an emulsifier, stabilizer, or thickener in fats and oils at a level not to exceed 1.1 percent by weight of the finished product.

(5) As an emulsifier, stabilizer, or thickener in gelatins and puddings at a level not to exceed 0.6 percent by weight of the finished product.

(6) As a stabilizer or thickener in gravies and in sweet sauces at a level not to exceed 0.5 percent by weight of the finished product.

(7) As a stabilizer in jams and jellies at a level not to exceed 0.4 percent by weight of the finished product.

(8) As an emulsifier, stabilizer, or thickener in condiments and relishes at a level not to exceed 0.6 percent by weight of the finished product.

(9) As a flavoring adjunct or adjuvant in seasonings and flavors at a level not to exceed 1.7 percent by weight of the finished product.

(10) As an emulsifier, flavoring adjuvant, formulation aid, stabilizer or thickener, or surface active agent in other foods, where applicable, at a level not to exceed 0.3 percent by weight of the finished product.

(c) To ensure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the act:

(1) The name of the additive, ''propylene glycol alginate'' or ''propylene glycol ester of alginic acid''.

(2) Adequate directions for use.

[47 FR 29950, July 9, 1982]

§ 172.859 Sucrose fatty acid esters.

Sucrose fatty acid esters identified in this section may be safely used in accordance with the following prescribed conditions:

(a) Sucrose fatty acid esters are the mono-, di-, and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or hydrogenated edible tallow or edible vegetable oils. The only solvents which may be used in the preparation of sucrose fatty acid esters are those generally recognized as safe in food or regulated for such use by an appropriate section in this part. Ethyl acetate or methyl ethyl ketone or dimethyl sulfoxide and isobutyl alcohol (2-methyl-1-propanol) may be used in the preparation of sucrose fatty acid esters.

(b) Sucrose fatty acid esters meet the following specifications:

(1) The total content of mono-, di-, and tri-esters is not less than 80 percent as determined by a method title ''Sucrose Fatty Acid Esters, Method of Assay,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(2) The free sucrose content is not more than 5 percent as determined by Test S.2 in the method titled ''Sucrose Fatty Acid Esters, Method of Assay,'' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(3) The acid value is not more than 6.

(4) The residue on ignition (sulfated ash) is not more than 2 percent.

(5) The total ethyl acetate content is not more than 350 parts per million as determined by a method titled ''Determination of Ethyl Acetate,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(6) Arsenic is not more than 3 parts per million.

(7) Total heavy metal content (as Pb) is not more than 50 parts per million.

(8) Lead is not more than 10 parts per million.

(9) The total content of methyl ethyl ketone or of methanol shall not be

more than 10 parts per million as determined by a method titled ''Methyl Ethyl Ketone Test; Methyl Alcohol Test,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(10) The total dimethyl sulfoxide content is not more than 2 parts per million as determined by a method entitled ''Determination of Dimethyl Sulfoxide,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(11) The total isobuytl alcohol (2-methyl-1-propanol) content is not more than 10 parts per million as determined by a method entitled ''Determination of Isobutyl Alcohol,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) Sucrose fatty acid esters may be used as follows when standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use:

(1) As emulsifiers as defined in §170.3(o)(8) of this chapter, or as stabilizers as defined in §170.3(o)(28) of this chapter, in baked goods and baking mixes as defined in §170.3(n)(1) of this chapter, in chewing gum as defined in §170.3(n)(6) of this chapter, in coffee and tea beverages with added dairy ingredients and/or dairy product analogues, in confections and frostings as defined in §170.3(n)(9) of this chapter, in dairy product analogues as defined in §170.3(n)(10) of this chapter, in frozen dairy desserts and mixes as defined in §170.3(n)(20) of this chapter, and in whipped milk products.

(2) As texturizers as defined in §170.3(o)(32) of this chapter in biscuit mixes, in chewing gum as defined in §170.3(n)(6) of this chapter, in confections and frostings as defined in §170.3(n)(9) of this chapter, and in surimi-based fabricated seafood products.

(3) As components of protective coatings applied to fresh apples, avocados, bananas, banana plantains, limes, melons (honeydew and cantaloupe), papaya, peaches, pears, pineapples, and plums to retard ripening and spoiling.

(d) Sucrose fatty acid esters are used in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended effect.

[47 FR 55475, Dec. 10, 1982, as amended at 48 FR 38226, Aug. 23, 1983; 52 FR 10883, Apr. 6, 1987; 53 FR 22294, 22297, June 15, 1988; 54 FR 24897, June 12, 1989; 60 FR 44756, Aug. 29, 1995]

§ 172.860 Fatty acids.

The food additive fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The food additive consists of one or any mixture of the following straight-chain monobasic carboxylic acids and their associated fatty acids manufactured from fats and oils derived from edible sources: Capric acid, caprylic acid, lauric acid, myristic acid, oleic acid, palmitic acid, and stearic acid.

(b) The food additive meets the following specifications:

(1) Unsaponifiable matter does not exceed 2 percent.

(2) It is free of chick-edema factor:

(i) As evidenced during the bioassay method for determining the chick-edema factor as prescribed in paragraph (c)(2) of this section; or

(ii) As evidenced by the absence of chromatographic peaks with a retention time relative to aldrin (RA) between 10 and 25, using the gas chromatographic-electron capture method prescribed in paragraph (c)(3) of this section. If chromatographic peaks are found with RA values between 10 and 25, the food additive shall meet the requirements of the bioassay method prescribed in paragraph (c)(2) of this section for determining chick-edema factor.

(c) For the purposes of this section:

(1) Unsaponifiable matter shall be determined by the method described in the 13th Ed. (1980) of the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(2) Chick-edema factor shall be determined by the bioassay method described in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), sections 28.127–28.130, which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(3) The gas chromatographic-electron capture method for testing fatty acids for chick-edema shall be the method described in the ''Journal of the Association of Official Analytical Chemists,'' Volume 50 (No. 1), pages 216–218 (1967), or the modified method using a sulfuric acid clean-up procedure, as described in the ''Journal of the Association of the Offical Analytical Chemists,'' Volume 51 (No. 2), pages 489–490 (1968), which are incorporated by reference. See paragraph (c)(2) of this section for availability of these references.

(d) It is used or intended for use as follows:

(1) In foods as a lubricant, binder, and as a defoaming agent in accordance with good manufacturing practice.

(2) As a component in the manufacture of other food-grade additives.

(e) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the act, the following:

(1) The common or usual name of the acid or acids contained therein.

(2) The words ''food grade,'' in juxtaposition with and equally as prominent as the name of the acid.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 172.861 Cocoa butter substitute from coconut oil, palm kernel oil, or both oils.

The food additive, cocoa butter substitute from coconut oil, palm kernel oil, or both oils, may be safely used in food in accordance with the following conditions:

(a) Cocoa butter substitute from coconut oil, palm kernel oil (CAS Reg. No. 85665–33–4), or both oils is a mixture of triglycerides. It is manufactured by esterification of glycerol with food-grade fatty acids (complying with § 172.860) derived from edible coconut oil, edible palm kernel oil, or both oils.

(b) The ingredient meets the following specifications:

Acid number: Not to exceed 0.5.
Saponification number: 220 to 260.
Iodine number: Not to exceed 3.
Melting range: 30 to 44 °C.

(c) The ingredient is used or intended for use as follows:

(1) As coating material for sugar, table salt, vitamins, citric acid, succinic acid, and spices; and

(2) In compound coatings, cocoa creams, cocoa-based sweets, toffees, caramel masses, and chewing sweets as defined in §170.3 (n)(9) and (n)(38) of this chapter, except that the ingredient may not be used in a standardized food unless permitted by the standard of identity.

(d) The ingredient is used in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended effect.

[56 FR 66970, Dec. 27, 1991; 57 FR 2814, Jan. 23, 1992]

§ 172.862 Oleic acid derived from tall oil fatty acids.

The food additive oleic acid derived from tall oil fatty acids may be safely used in food and as a component in the manufacture of food-grade additives in accordance with the following prescribed conditions:

(a) The additive consists of purified oleic acid separated from refined tall oil fatty acids.

(b) The additive meets the following specifications:

(1) Specifications for oleic acid prescribed in the Food Chemicals Codex, 7th ed. (2010), pp. 743–744, which is incorporated by reference, except that titer (solidification point) shall not exceed 13.5 °C and unsaponifiable matter shall not exceed 0.5 percent. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(2) The resin acid content does not exceed 0.01 as determined by ASTM method D1240–82, ''Standard Test Method for Rosin Acids in Fatty Acids,'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(3) The requirements for absence of chick-edema factor as prescribed in §172.860.

(c) It is used or intended for use as follows:

(1) In foods as a lubricant, binder, and defoaming agent in accordance with good manufacturing practice.

(2) As a component in the manufacture of other food-grade additives.

(d) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in addition to the other information required by the Act, the following:

(1) The common or usual name of the acid.

(2) The words ''food grade'' in juxtaposition with and equally as prominent as the name of the acid.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984; 78 FR 71465, Nov. 29, 2013]

§ 172.863 Salts of fatty acids.

The food additive salts of fatty acids may be safely used in food and in the manufacture of food components in accordance with the following prescribed conditions:

(a) The additive consists of one or any mixture of two or more of the aluminum, calcium, magnesium, potassium, and sodium salts of the fatty acids conforming with §172.860 and/or oleic acid derived from tall oil fatty acids conforming with §172.862.

(b) The food additive is used or intended for use as a binder, emulsifier, and anticaking agent in food in accordance with good manufacturing practice.

(c) To assure safe use of the additive, the label and labeling of the additive and any premix thereof shall bear, in

addition to the other information required by the Act, the following:

(1) The common or usual name of the fatty acid salt or salts contained therein.

(2) The words ''food grade,'' in juxtaposition with and equally as prominent as the name of the salt.

§ 172.864 Synthetic fatty alcohols.

Synthetic fatty alcohols may be safely used in food and in the synthesis of food components in accordance with the following prescribed conditions:

(a) The food additive consists of any one of the following fatty alcohols:

(1) Hexyl, octyl, decyl, lauryl, myristyl, cetyl, and stearyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation and hydrolysis of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C_2H_4), and utilizing the hydrocarbon solvent as defined in paragraph (b) of this section, such that:

(i) Hexyl, octyl, decyl, lauryl, and myristyl alcohols contain not less than 99 percent of total alcohols and not less than 96 percent of straight chain alcohols. Any nonalcoholic impurities are primarily paraffins.

(ii) Cetyl and stearyl alcohols contain not less than 98 percent of total alcohols and not less than 94 percent of straight chain alcohols. Any nonalcoholic impurities are primarily paraffins.

(iii) The synthetic fatty alcohols contain no more than 0.1 weight percent of total diols as determined by a method available upon request from the Commissioner of Food and Drugs.

(2) Hexyl, octyl, and decyl; manufactured by fractional distillation of alcohols obtained by a sequence of oxidation, hydrolysis, and catalytic hydrogenation (catalyst consists of copper, chromium, and nickel) of organo-aluminums generated by the controlled reaction of low molecular weight trialkylaluminum with purified ethylene (minimum 99 percent by volume C_2H_4), and utilizing an external coolant such that these alcohols meet the specifications prescribed in paragraph (a)(1)(i) and (iii) of this section.

(3) n-Octyl; manufactured by the hydrodimerization of 1,3-butadiene, followed by catalytic hydrogenation of the resulting dienol, and distillation to produce *n*-octyl alcohol with a minimum purity of 99 percent. The analytical method for *n*-octyl alcohol entitled ''Test Method [Normal-octanol]'' dated October 2003, and printed by Kuraray Co., Ltd., is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Office of Food Additive Safety, 5001 Campus Dr., College Park, MD 20740, or you may examine a copy at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(b) The hydrocarbon solvent used in the process described in paragraph (a)(1) of this section is a mixture of liquid hydrocarbons essentially paraffinic in nature, derived from petroleum and refined to meet the specifications described in paragraph (b)(1) of this section when subjected to the procedures described in paragraph (b)(2) and (3) of this section.

(1) The hydrocarbon solvent meets the following specifications:

(i) Boiling-point range: 175 °C–275 °C.

(ii) Ultraviolet absorbance limits as follows:

Wavelength (millicrons)	Maximum absorbance per centimeter optical path length
280–289	0.15
290–299	.12
300–359	.05
360–400	.02

(2) Use ASTM method D86–82, ''Standard Method for Distillation of Petroleum Products,'' which is incorporated by reference, to determine boiling point range. Copies of the material incorporated by reference may be obtained from the American Society

for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(3) The analytical method for determining ultraviolet absorbance limits is as follows:

GENERAL INSTRUCTIONS

All glassware should be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure, it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of hydrocarbon solvent samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Chromatographic tube. 450 millimeters in length (packing section), inside diameter 19 millimeters ±1 millimeter, equipped with a wad of clean Pyrex brand filtering wool (Corning Glass Works Catalog No. 3950 or equivalent). The tube shall contain a 250-milliliter reservoir and a 2-millimeter tetrafluoroethylene polymer stopcock at the opposite end. Overall length of the tube is 670 millimeters.

Stainless steel rod. 2 feet in length, 2 to 4 millimeters in diameter.

Vacuum oven. Similar to Labline No. 3610 but modified as follows: A copper tube one-fourth inch in diameter and 13 inches in length is bent to a right angle at the 4-inch point and plugged at the opposite end; eight copper tubes one-eighth inch in diameter and 5 inches in length are silver soldered in drilled holes (one-eighth inch in diameter) to the one-fourth-inch tube, one on each side at the 5-, 7.5-, 10- and 12.5-inch points; the one-eighth-inch copper tubes are bent to conform with the inner periphery of the oven.

Beakers. 250-milliliter and 500-milliliter capacity.

Graduated cylinders. 25-milliliter, 50-milliliter, and 150-milliliter capacity.

Tuberculin syringe. 1-milliliter capacity, with 3-inch, 22-gauge needle.

Volumetric flask. 5-milliliter capacity.

Spectrophotometric cells. Fused quartz ground glass stoppered cells, optical path length in the range of 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance difference.

Spectrophotometer. Spectral range 250 millimicrons—400 millimicrons with spectral slit width of 2 millimicrons or less: under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, hexane, and 1,2-dichloroethane designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250-milliliter beaker, add 1 milliliter of purified *n*-hexadecane and evaporate in the vacuum oven under a stream of nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 5-milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 5 milliliters

[1] As determined by using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

volume. Determine the absorbance in the 1-centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue shall not exceed 0.02 per centimeter path length between 280 and 300 mμ and shall not exceed 0.01 per centimeter path length between 300 and 400 mμ.

Isooctane (*2,2,4-trimethylpentane*). Use 10 milliliters for the test described in the preceding paragraph. If necessary, isooctane may be purified by passage through a column of activated silica gel (Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent).

Benzene, spectro grade (*Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent*). Use 80 milliliters for the test. If necessary, benzene may be purified by distillation or otherwise.

Hexane, spectro grade (*Burdick and Jackson Laboratories, Inc., Muskegon, Mich., or equivalent*). Use 650 milliliters for the test. If necessary, hexane may be purified by distillation or otherwise.

1,2-Dichloroethane, spectro grade (*Matheson, Coleman, and Bell, East Rutherford, N.J., or equivalent*). Use 20 milliliters for test. If necessary, 1,2-dichloroethane may be purified by distillation.

Eluting mixtures:

1. *10 percent 1,2-dichloroethane in hexane.* Pipet 100 milliliters of 1,2-dichloroethane into a 1-liter glass-stoppered volumetric flask and adjust to volume with hexane, with mixing.

2. *40 percent benzene in hexane.* Pipet 400 milliliters of benzene into a 1-liter glass-stoppered volumetric flask and adjust to volume with hexane, with mixing.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 5 milliliters with isooctane and determine the absorbance in a 1-centimeter cell compared to isooctane as reference between 280 mμ-400mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. If necessary, *n*-hexadecane may be purified by percolation through activated silica gel or by distillation.

Silica gel, 28–200 mesh (*Grade 12, Davison Chemical Co., Baltimore, Md., or equivalent*). Activate as follows: Weigh about 900 grams into a 1-gallon bottle, add 100 milliliters of de-ionized water, seal the bottle and shake and roll at intervals for 1 hour. Allow to equilibrate overnight in the sealed bottle. Activate the gel at 150 °C for 16 hours, in a 2-inch × 7-inch × 12-inch porcelain pan loosely covered with aluminum foil, cool in a dessicator, transfer to a bottle and seal.

PROCEDURE

Determination of ultraviolet absorbance. Before proceeding with the analysis of a sample determine the absorbance in a 1-centimeter path cell for the reagent blank by carrying out the procedure without a sample. Record the absorbance in the wavelength range of 280 to 400 millimicrons. Typical reagent blank absorbance in this range should not exceed 0.04 in the 280 to 299 millimicron range, 0.02 in the 300 to 359 millimicron range, and 0.01 in the 360 to 400 millimicron range. If the characteristic benzene peaks in the 250 to 260 millimicron region are present, remove the benzene by the procedure described above under ''Reagents and Materials,'' ''Organic Solvents,'' and record absorbance again.

Transfer 50 grams of silica gel to the chromatographic tube for sample analysis. Raise and drop the column on a semisoft, clean surface for about 1 minute to settle the gel. Pour 100 milliliters of hexane into the column with the stopcock open and allow to drain to about one-half inch above the gel. Turn off the stopcock and allow the column to cool for 30 minutes. After cooling, vibrate the column to eliminate air and stir the top 1 to 2 inches with a small diameter stainless steel rod. Take care not to get the gel above the liquid and onto the sides of the column.

Weigh out 40 grams ±0.1 gram of the hydrocarbon solvent sample into a 250-milliliter beaker, add 50 milliliters of hexane, and pour the solution into the column. Rinse the beaker with 50 milliliters of hexane and add this to the column. Allow the hexane sample solution to elute into a 500-milliliter beaker until the solution is about one-half inch above the gel. Rinse the column three times with 50-milliliter portions of hexane. Allow each hexane rinse to separately elute to about one-half inch above the gel. Replace the eluate beaker (discard the hexane eluate) with a 250-milliliter beaker. Add two separate 25-milliliter portions of 10 percent 1,2-dichloroethane and allow each to separately elute as before. Finally, add 150 milliliters of 10 percent 1,2-dichloroethane for a total of 200 milliliters. When the final 10 percent 1,2-dichloroethane fraction is about one-half inch above the top of the gel bed, replace the receiving beaker (discard the 1,2-dichloroethane eluate) with a 250-milliliter beaker containing 1 milliliter of hexadecane. Adjust the elution rate to 2 to 3 milliliters per minute, add two 25-milliliter portions of 40 percent benzene and allow each to separately elute as before to within about one-half inch of the gel bed. Finally, add 150 milliliters of 40 percent benzene for a total of 200 milliliters. Evaporate the benzene in the oven with vacuum and sufficient nitrogen flow to just ripple the top of the benzene solution. When the benzene is removed (as determined by a constant volume of hexadecane) add 5 milliliters of isooctane and evaporate. Repeat once to insure complete removal of benzene. Remove the beaker and cover with aluminum foil (previously rinsed with hexane) until cool.

Quantitatively transfer the hexadecane residue to a 5-milliliter volumetric flask and dilute to volume with isooctane. Determine the absorbance of the solution in 1-centimeter path length cells between 280 and 400 millimicrons using isooctane as a reference. Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a sample. If the corrected absorbance does not exceed the limits prescribed in paragraph (b)(1)(ii) of this section, the sample meets the ultraviolet absorbance specifications for hydrocarbon solvent.

(c) Synthetic fatty alcohols may be used as follows:

(1) As substitutes for the corresponding naturally derived fatty alcohols permitted in food by existing regulations in this part or part 173 of this chapter provided that the use is in compliance with any prescribed limitations.

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 70 FR 72908, Dec. 8, 2005; 81 FR 5591, Feb. 3, 2016]

§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

§ 172.867 Olestra.

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 744–746, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) Olestra may be used in place of fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks and prepackaged, unpopped popcorn kernels that are ready-to-heat. In such foods, the additive may be used in place of fats and oils for frying or baking, in dough conditioners, in sprays, in filling ingredients, or in flavors.

(d) To compensate for any interference with absorption of fat soluble vitamins, the following vitamins shall be added to foods containing olestra: 1.9 milligrams alpha-tocopherol equivalents per gram olestra; 51 retinol equivalents per gram olestra (as retinyl acetate or retinyl palmitate); 12 IU vitamin D per gram olestra; and 8 μg vitamin K_1 per gram olestra.

(e)(1) Vitamins A, D, E, and K present in foods as a result of the requirement in paragraph (d) of this section shall be declared in the listing of ingredients. Such vitamins shall not be considered in determining nutrient content for the nutritional label or for any nutrient claims, express or implied.

(i) An asterisk shall follow vitamins A, D, E, and K in the listing of ingredients;

(ii) The asterisk shall appear as a superscript following each vitamin;

(iii) Immediately following the ingredient list an asterisk and statement, ''Dietarily insignificant'' shall appear

prominently and conspicuously as specified in § 101.2(c) of this chapter;

(2) Olestra shall not be considered as a source of fat or calories for purposes of §§ 101.9 and 101.13 of this chapter.

[61 FR 3171, Jan. 30, 1996; 61 FR 11546, Mar. 21, 1996, as amended at 68 FR 46402, Aug. 5, 2003; 69 FR 29432, May 24, 2004; 78 FR 71465, Nov. 29, 2013]

§ 172.868 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC_2H_5) groups attached by an ether linkage and containing on an anhydrous basis not more than 2.6 ethoxy groups per anhydroglucose unit.

(b) It is used or intended for use as follows:

(1) As a binder and filler in dry vitamin preparations.

(2) As a component of protective coatings for vitamin and mineral tablets.

(3) As a fixative in flavoring compounds.

§ 172.869 Sucrose oligoesters.

Sucrose oligoesters, as identified in this section, may be safely used in accordance with the following conditions:

(a) Sucrose oligoesters consist of mixtures of sucrose fatty acid esters with an average degree of esterification ranging from four to seven. It is produced by interesterification of sucrose with methyl esters of fatty acids derived from edible fats and oils (including hydrogenated fats and oils). The only solvents which may be used in the preparation of sucrose oligoesters are dimethyl sulfoxide, isobutyl alcohol, and those solvents generally recognized as safe in food.

(b) Sucrose oligoesters meet the specifications in the methods listed in the table in this paragraph. The methods for determining compliance with each specification are incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*. Copies of the methods are available from the sources listed in the table in this paragraph:

Specification	Limit	Method Cited	Source for Obtaining Method
(1) Sucrose esters	Not less than 90%	"Method for Analyzing the Purity of Sucrose Fatty Acid Esters," issued by Mitsubishi Chemical Corp., June 17, 1998.	Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.
(2) Mono-, di-, and tri-esters	Not more than 45%	"Method for Measuring the Ester Distribution of Sucrose Oligoesters," issued by Mitsubishi Chemical Corp., June 17, 1998.	Do.
(3) Tetra-, penta-, hexa-, and hepta-esters.	Not less than 50%	Do.	Do.
(4) Octa-esters	Not more than 40%	Do.	Do.
(5) Free Sucrose	Not more than 0.5%	"Free Sucrose Method," issued by Mitsubishi Chemical Corp., June 17, 1998.	Do.

Specification	Limit	Method Cited	Source for Obtaining Method
(6) Acid Value	Not more than 4.0	"Acid Value," Appendix VII, Method I (Commercial Fatty Acids), in the Food Chemicals Codex, 7th ed. (2010), p. 1220.	United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*)
(7) Residue on Ignition	Not more than 0.7%	"Residue on Ignition," Appendix IIC, Method I, in the Food Chemicals Codex, 7th ed. (2010), pp. 1141–1142 (using a 1-gram sample).	Do.
(8) Residual Methanol	Not more than 10 milligrams/kilogram.	Method listed in the monograph for "Sucrose Fatty Acid Esters" in the Food Chemicals Codex, 7th ed. (2010), pp. 998–1000.	Do
(9) Residual Dimethyl Sulfoxide.	Not more than 2.0 milligrams/kilogram.	.....do	Do.
(10) Residual Isobutyl Alcohol	Not more than 10 milligrams/kilogram.	.....do	Do.
(11) Lead	Not more than 1.0 milligram/kilogram.	"Atomic Absorption Spectrophometric Graphite Furnace Method," Method I in the Food Chemicals Codex, 7th ed. (2010), p. 1154–1155	Do.

(c) The additive is used as an emulsifier (as defined in §170.3(o)(8) of this chapter) or stabilizer (as defined in §170.3(o)(28) of this chapter) in chocolate and in butter-substitute spreads, at a level not to exceed 2.0 percent; except that the additive may not be used in a standardized food unless permitted by the standard of identity.

[68 FR 50072, Aug. 20, 2003, as amended at 78 FR 71465, Nov. 29, 2013]

§ 172.870 Hydroxypropyl cellulose.

The food additive hydroxypropyl cellulose may be safely used in food, except standardized foods that do not provide for such use, in accordance with the following prescribed conditions:

(a) The additive consists of one of the following:

(1) A cellulose ether containing propylene glycol groups attached by an ether linkage that contains, on an anhydrous basis, not more than 4.6 hydroxypropyl groups per anhydroglucose unit. The additive has a minimum viscosity of 10 centipoises for a 10 percent by weight aqueous solution at 25 degrees C.

(2) A cellulose ether containing propylene glycol groups attached by an ether linkage having a hydroxypropoxy (OC_3H_6OH) content of 5 to 16 percent weight in weight (w/w) on an anhydrous basis, i.e., 0.1 to 0.4 hydroxypropyl groups per anhydroglucose unit. The common name for this form of the additive is low substituted hydroxypropyl cellulose.

(b) The additive is used or intended for use as follows:

(1) The additive identified in paragraph (a)(1) of this section is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener in food, in accordance with good manufacturing practice. The additive also may be used as a binder in dietary supplements, in accordance with good manufacturing practice.

(2) The additive identified in paragraph (a)(2) of this section is used or intended for use as a binder and disintegrator in tablets or wafers containing dietary supplements of vitamins and/or minerals. The additive is

used in accordance with good manufacturing practice.

[46 FR 50065, Oct. 9, 1981, as amended at 76 FR 41689, July 15, 2011]

§ 172.872 Methyl ethyl cellulose.

The food additive methyl ethyl cellulose may be safely used in food in accordance with the following prescribed conditions.

(a) The additive is a cellulose ether having the general formula $[C_6H_{(10-x-y)}O_5(CH_3)_x(C_2H_5)_y]_n$, where x is the number of methyl groups and y is the number of ethyl groups. The average value of x is 0.3 and the average value of y is 0.7.

(b) The additive meets the following specifications:

(1) The methoxy content shall be not less than 3.5 percent and not more than 6.5 percent, calculated as OCH_3, and the ethoxy content shall be not less than 14.5 percent and not more than 19 percent, calculated as OC_2H_5, both measured on the dry sample.

(2) The viscosity of an aqueous solution, 2.5 grams of the material in 100 milliliters of water, at 20 °C, is 20 to 60 centipoises.

(3) The ash content on a dry basis has a maximum of 0.6 percent.

(c) The food additive is used as an aerating, emulsifying, and foaming agent, in an amount not in excess of that reasonably required to produce its intended effect.

§ 172.874 Hydroxypropyl methylcellulose.

The food additive hydroxypropyl methylcellulose (CAS Reg. No. 9004–65–3) may be safely used in food, except in standardized foods which do not provide for such use if:

(a) The additive complies with the definition and specifications prescribed in the National Formulary, 12th edition.

(b) It is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener, in accordance with good manufacturing practice.

(c) To insure safe use of the additive, the container of the additive, in addition to being labeled as required by the general provisions of the act, shall be accompanied by labeling which contains adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (b) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 38273, Aug. 31, 1982]

§ 172.876 Castor oil.

The food additive castor oil may be safely used in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia XX (1980).

(b) The additive is used or intended for use as follows:

Use and Limitations
Hard candy production—As a release agent and antisticking agent, not to exceed 500 parts per million in hard candy.
Vitamin and mineral tablets—As a component of protective coatings.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.878 White mineral oil.

White mineral oil may be safely used in food in accordance with the following conditions:

(a) White mineral oil is a mixture of liquid hydrocarbons, essentially paraffinic and naphthenic in nature obtained from petroleum. It is refined to meet the following specifications:

(1) It meets the test requirements of the United States Pharmacopeia XX (1980) for readily carbonizable substances (page 532).

(2) It meets the test requirements of U.S.P. XVII for sulfur compounds (page 400).

(3) It meets the specifications prescribed in the ''Journal of the Association of Official Analytical Chemists,'' Volume 45, page 66 (1962), which is incorporated by reference, after correction of the ultraviolet absorbance for any absorbance due to added antioxidants. Copies of the material incorporated by reference are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or

go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(b) White mineral oil may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

(c) White mineral oil is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
1. As a release agent, binder, and lubricant in or on capsules and tablets containing concentrates of flavoring, spices, condiments, and nutrients intended for addition to food, excluding confectionery.	Not to exceed 0.6% of the capsule or tablet.
2. As a release agent, binder, and lubricant in or on capsules and tablets containing food for special dietary use.	Not to exceed 0.6% of the capsule or tablet.
3. As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.	In an amount not to exceed good manufacturing practice.
4. As a defoamer in food	In accordance with § 173.340 of this chapter.
5. In bakery products, as a release agent and lubricant	Not to exceed 0.15% of bakery products.
6. In dehydrated fruits and vegetables, as a release agent	Not to exceed 0.02% of dehydrated fruits and vegetables.
7. In egg white solids, as a release agent	Not to exceed 0.1% of egg white solids.
8. On raw fruits and vegetables, as a protective coating	In an amount not to exceed good manufacturing practice.
9. In frozen meat, as a component of hot-melt coating	Not to exceed 0.095% of meat.
10. As a protective float on brine used in the curing of pickles	In an amount not to exceed good manufacturing practice.
11. In molding starch used in the manufacture of confectionery	Not to exceed 0.3 percent in the molding starch.
12. As a release agent, binder, and lubricant in the manufacture of yeast	Not to exceed 0.15 percent of yeast.
13. As an antidusting agent in sorbic acid for food use	Not to exceed 0.25 percent in the sorbic acid.
14. As release agent and as sealing and polishing agent in the manufacture of confectionery.	Not to exceed 0.2 percent of confectionery.
15. As a dust control agent for wheat, corn, soybean, barley, rice, rye, oats, and sorghum.	Applied at a level of no more than 0.02 percent by weight of grain.
16. As a dust control agent for rice	ISO 100 oil viscosity (100 centistokes (cSt) at 100 °F) applied at a level of no more than 0.08 percent by weight of the rice grain.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 8764, Mar. 2, 1982; 47 FR 11838, Mar. 19, 1982; 48 FR 55728, Dec. 15, 1983; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989; 63 FR 66014, Dec. 1, 1998]

§ 172.880 Petrolatum.

Petrolatum may be safely used in food, subject to the provisions of this section.

(a) Petrolatum complies with the specifications set forth in the United States Pharmacopeia XX (1980) for white petrolatum or in the National Formulary XV (1980) for petrolatum.

(b) Petrolatum meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in § 172.886(b):

Ultraviolet absorbance per centimeter path length:

Millimicrons	Maximum
280–289	0.25
290–299	.20
300–359	.14
360–400	.04

(c) Petrolatum is used or intended for use as follows:

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with petrolatum)
In bakery products; as release agent and lubricant	With white mineral oil, not to exceed 0.15 percent of bakery product.
In confectionery; as release agent and as sealing and polishing agent	Not to exceed 0.2 percent of confectionery.

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with petrolatum)
In dehydrated fruits and vegetables; as release agent	Not to exceed 0.02 percent of dehydrated fruits and vegetables.
In egg white solids; as release agent	Not to exceed 0.1 percent of egg white solids.
On raw fruits and vegetables; as protective coating	In an amount not to exceed good manufacturing practice.
In beet sugar and yeast; as defoaming agent	As prescribed in § 173.340 of this chapter.

(d) Petrolatum may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the Act, in an amount not greater than that required to produce its intended effect.

[42 FR 14491, Mar. 15, 1977, as amended at 49 FR 10105, Mar. 19, 1984]

§ 172.882 Synthetic isoparaffinic petroleum hydrocarbons.

Synthetic isoparaffinic petroleum hydrocarbons may be safely used in food, in accordance with the following conditions:

(a) They are produced by synthesis from petroleum gases and consist of a mixture of liquid hydrocarbons meeting the following specifications:

Boiling point 93–260 °C as determined by ASTM method D86–82, ''Standard Method for Distillation of Petroleum Products,'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

Ultraviolet absorbance:

260–319 millimicrons—1.5 maximum.

320–329 millimicrons—0.08 maximum.

330–350 millimicrons—0.05 maximum.

Nonvolatile residual: 0.002 gram per 100 milliliters maximum.

Synthetic isoparaffinic petroleum hydrocarbons containing antioxidants shall meet the specified ultraviolet absorbance limits after correction for any absorbance due to the antioxidants. The ultraviolet absorbance shall be determined by the procedure described for application of mineral oil, disregarding the last sentence of the procedure, under ''Specifications'' on page 66 of the ''Journal of the Association of Official Analytical Chemists,'' Volume 45 (February 1962), which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. For hydrocarbons boiling below 250 °F, the nonvolatile residue shall be determined by ASTM method D1353–78, ''Standard Test Method for Nonvolatile Matter in Volatile Solvents for Use in Paint, Varnish, Lacquer, and Related Products;'' for those boiling above 121 °C, ASTM method D381–80, ''Standard Test Method for Existent Gum in Fuels by Jet Evaporation'' shall be used. These methods are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(b) Isoparaffinic petroleum hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect nor to exceed any prescribed limitations.

(c) Synthetic isoparaffinic petroleum hydrocarbons are used or intended for use as follows:

Uses	Limitations
1. In the froth-flotation cleaning of vegetables.	In an amount not to exceed good manufacturing practice.
2. As a component of insecticide formulations for use on processed foods.	Do.
3. As a component of coatings on fruits and vegetables.	Do.
4. As a coating on shell eggs	Do.

Uses	Limitations
5. As a float on fermentation fluids in the manufacture of vinegar and wine and on brine used in curing pickles, to prevent or retard access of air, evaporation, and contamination with wild organisms during fermentation.	Do.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11838, Mar. 19, 1982; 49 FR 10106, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 172.884 Odorless light petroleum hydrocarbons.

Odorless light petroleum hydrocarbons may be safely used in food, in accordance with the following prescribed conditions:

(a) The additive is a mixture of liquid hydrocarbons derived from petroleum or synthesized from petroleum gases. The additive is chiefly paraffinic, isoparaffinic, or naphthenic in nature.

(b) The additive meets the following specifications:

(1) Odor is faint and not kerosenic.

(2) Initial boiling point is 300 °F minimum.

(3) Final boiling point is 650 °F maximum.

(4) Ultraviolet absorbance limits determined by method specified in § 178.3620(b)(1)(ii) of this chapter, as follows:

Wavelength mμ	Maximum absorbance per centimeter optical pathlength
280–289	4.0
290–299	3.3
300–329	2.3
330–360	.8

(c) The additive is used as follows:

Use	Limitations
As a coating on shell eggs	In an amount not to exceed good manufacturing practice.
As a defoamer in processing beet sugar and yeast.	Complying with § 173.340 of this chapter.
As a float on fermentation fluids in the manufacture of vinegar and wine to prevent or retard access of air, evaporation, and wild yeast contamination during fermentation.	In an amount not to exceed good manufacturing practice.
In the froth-flotation cleaning of vegetables.	Do.
As a component of insecticide formulations used in compliance with regulations issued in parts 170 through 189 of this chapter.	Do.

§ 172.886 Petroleum wax.

Petroleum wax may be safely used in or on food, in accordance with the following conditions:

(a) Petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum, and refined to meet the specifications prescribed by this section.

(b) Petroleum wax meets the following ultraviolet absorbance limits when subjected to the analytical procedure described in this paragraph.

	Maximum ultraviolet absorbance per centimeter path length
280–289 millimicrons	0.15
290–299 millimicrons	0.12
300–359 millimicrons	0.08
360–400 millimicrons	0.02

ANALYTICAL SPECIFICATION FOR PETROLEUM WAX

GENERAL INSTRUCTIONS

Because of the sensitivity of the test, the possibility of errors arising from contamination is great. It is of the greatest importance that all glassware be scrupulously cleaned to remove all organic matter such as oil, grease, detergent residues, etc. Examine all glassware, including stoppers and stopcocks, under ultraviolet light to detect any residual fluorescent contamination. As a precautionary measure it is recommended practice to rinse all glassware with purified isooctane immediately before use. No grease is to be used on stopcocks or joints. Great care to avoid contamination of wax samples in handling and to assure absence of any extraneous material arising from inadequate packaging is essential. Because some of the polynuclear hydrocarbons sought in this test are very susceptible to photo-oxidation, the entire procedure is to be carried out under subdued light.

APPARATUS

Separatory funnels. 250–milliliter, 500–milliliter, 1,000–milliliter, and preferably 2,000–milliliter capacity, equipped with tetrafluoroethylene polymer stopcocks.

Reservoir. 500–milliliter capacity, equipped with a 24/40 standard taper male fitting at

the bottom and a suitable ball-joint at the top for connecting to the nitrogen supply. The male fitting should be equipped with glass hooks.

Chromatographic tube. 180 millimeters in length, inside diameter to be 15.7 millimeters ±0.1 millimeter, equipped with a coarse, fritted-glass disc, a tetrafluoroethylene polymer stopcock, and a female 24/40 standard tapered fitting at the opposite end. (Overall length of the column with the female joint is 235 millimeters.) The female fitting should be equipped with glass hooks.

Disc. Tetrafluoroethylene polymer 2–inch diameter disc approximately 3/16–inch thick with a hole bored in the center to closely fit the stem of the chromatographic tube.

Heating jacket. Conical, for 500–milliliter separatory funnel. (Used with variable transformer heat control.)

Suction flask. 250–milliliter or 500–milliliter filter flask.

Condenser. 24/40 joints, fitted with a drying tube, length optional.

Evaporation flask (*optional*). 250–milliliter or 500–milliliter capacity all-glass flask equipped with standard taper stopper having inlet and outlet tubes to permit passage of nitrogen across the surface of contained liquid to be evaporated.

Vacuum distillation assembly. All glass (for purification of dimethyl sulfoxide); 2–liter distillation flask with heating mantle; Vigreaux vacuum-jacketed condenser (or equivalent) about 45 centimeters in length and distilling head with separable cold finger condenser. Use of tetrafluoroethylene polymer sleeves on the glass joints will prevent freezing. Do not use grease on stopcocks or joints.

Spectrophotometric cells. Fused quartz cells, optical path length in the range of 5.000 centimeters ±0.005 centimeter; also for checking spectrophotometer performance only, optical path length in the range 1.000 centimeter ±0.005 centimeter. With distilled water in the cells, determine any absorbance differences.

Spectrophotometer. Spectral range 250 millimicrons–400 millimicrons with spectral slit width of 2 millimicrons or less, under instrument operating conditions for these absorbance measurements, the spectrophotometer shall also meet the following performance requirements:

Absorbance repeatability, ±0.01 at 0.4 absorbance.

Absorbance accuracy,[1] ±0.05 at 0.4 absorbance.

Wavelength repeatability, ±0.2 millimicron.

Wavelength accuracy, ±1.0 millimicron.

Nitrogen cylinder. Water-pumped or equivalent purity nitrogen in cylinder equipped with regulator and valve to control flow at 5 p.s.i.g.

REAGENTS AND MATERIALS

Organic solvents. All solvents used throughout the procedure shall meet the specifications and tests described in this specification. The isooctane, benzene, acetone, and methyl alcohol designated in the list following this paragraph shall pass the following test:

To the specified quantity of solvent in a 250–milliliter Erlenmeyer flask, add 1 milliliter of purified *n*-hexadecane and evaporate on the steam bath under a stream of nitrogen (a) loose aluminum foil jacket around the flask will speed evaporation). Discontinue evaporation when not over 1 milliliter of residue remains. (To the residue from benzene add a 10–milliliter portion of purified isooctane, reevaporate, and repeat once to insure complete removal of benzene.)

Alternatively, the evaporation time can be reduced by using the optional evaporation flask. In this case the solvent and *n*-hexadecane are placed in the flask on the steam bath, the tube assembly is inserted, and a stream of nitrogen is fed through the inlet tube while the outlet tube is connected to a solvent trap and vacuum line in such a way as to prevent any flow-back of condensate into the flask.

Dissolve the 1 milliliter of hexadecane residue in isooctane and make to 25 milliliters volume. Determine the absorbance in the 5–centimeter path length cells compared to isooctane as reference. The absorbance of the solution of the solvent residue (except for methyl alcohol) shall not exceed 0.01 per centimeter path length between 280 and 400 mμ. For methyl alcohol this absorbance value shall be 0.00.

Isooctane (*2,2,4–trimethylpentane*). Use 180 milliliters for the test described in the preceding paragraph. Purify, if necessary, by passage through a column of activated silica gel (Grade 12, Davison Chemical Company, Baltimore, Maryland, or equivalent) about 90

[1] As determined by using potassium chromate for reference standard and described in National Bureau of Standards Circular 484, Spectrophotometry, U.S. Department of Commerce, (1949). The accuracy is to be determined by comparison with the standard values at 290, 345, and 400 millimicrons. Circular 484 is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

centimeters in length and 5 centimeters to 8 centimeters in diameter.

Benzene, A.C.S. reagent grade. Use 150 milliliters for the test. Purify, if necessary, by distillation or otherwise.

Acetone, A.C.S. reagent grade. Use 200 milliliters for the test. Purify, if necessary, by distillation.

Eluting mixtures:

1. *10 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 500–milliliter glass-stoppered volumetric flask and adjust to volume with isooctane, with mixing.

2. *20 percent benzene in isooctane.* Pipet 50 milliliters of benzene into a 250–milliliter glass-stoppered volumetric flask, and adjust to volume with isooctane, with mixing.

3. *Acetone-benzene-water mixture.* Add 20 milliliters of water to 380 milliliters of acetone and 200 milliliters of benzene, and mix.

n-Hexadecane, 99 percent olefin-free. Dilute 1.0 milliliter of *n*-hexadecane to 25 milliliters with isooctane and determine the absorbance in a 5–centimeter cell compared to isooctane as reference point between 280 mμ–400 mμ. The absorbance per centimeter path length shall not exceed 0.00 in this range. Purify, if necessary, by percolation through activated silica gel or by distillation.

Methyl alcohol, A.C.S. reagent grade. Use 10.0 milliliters of methyl alcohol. Purify, if necessary, by distillation.

Dimethyl sulfoxide. Pure grade, clear, water-white, m.p. 18° minimum. Dilute 120 milliliters of dimethyl sulfoxide with 240 milliliters of distilled water in a 500–milliliter separatory funnel, mix and allow to cool for 5–10 minutes. Add 40 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the lower aqueous layer into a second 500–milliliter separatory funnel and repeat the extraction with 40 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 40–milliliter extractives three times with 50–milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium sulfate under* ''Reagents and Materials'' for preparation of filter), into a 250–milliliter Erlenmeyer flask, or optionally into the evaporating flask. Wash the first separatory funnel with the second 40–milliliter isooctane extractive, and pass through the sodium sulfate into the flask. Then wash the second and first separatory funnels successively with a 10–milliliter portion of isooctane, and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10–milliliter portion of isooctane and reevaporate to 1 milliliter of hexadecane. Again, add 10 milliliters of isooctane to the residue and evaporate to 1 milliliter of hexadecane to insure complete removal of all volatile materials. Dissolve the 1 milliliter of hexadecane in isooctane and make to 25–milliliter volume. Determine the reference. The absorbance of the solution should not exceed 0.02 per centimeter path length in the 280 mμ–400 mμ range. (NOTE. Difficulty in meeting this absorbance specification may be due to organic impurities in the distilled water. Repetition of the test omitting the dimethyl sulfoxide will disclose their presence. If necessary to meet the specification, purify the water by redistillation, passage through an ion-exchange resin, or otherwise.)

Purify, if necessary, by the following procedure: To 1,500 milliliters of dimethyl sulfoxide in a 2–liter glass-stoppered flask, add 6.0 milliliters of phosphoric acid and 50 grams of Norit A (decolorizing carbon, alkaline) or equivalent. Stopper the flask, and with the use of a magnetic stirrer (tetrafluoroethylene polymer coated bar) stir the solvent for 15 minutes. Filter the dimethyl sulfoxide through four thicknesses of fluted paper (18.5 centimeters, Schleicher & Schuell, No. 597, or equivalent). If the initial filtrate contains carbon fines, refilter through the same filter until a clear filtrate is obtained. Protect the sulfoxide from air and moisture during this operation by covering the solvent in the funnel and collection flask with a layer of isooctane. Transfer the filtrate to a 2–liter separatory funnel and draw off the dimethyl sulfoxide into the 2–liter distillation flask of the vacuum distillation assembly and distill at approximately 3–millimeter Hg pressure or less. Discard the first 200–milliliter fraction of the distillate and replace the distillate collection flask with a clean one. Continue the distillation until approximately 1 liter of the sulfoxide has been collected.

At completion of the distillation, the reagent should be stored in glass-stoppered bottles since it is very hygroscopic and will react with some metal containers in the presence of air.

Phosphoric acid. 85 percent A.C.S. reagent grade.

Sodium borohydride. 98 percent.

Magnesium oxide (Sea Sorb 43, Food Machinery Company, Westvaco Division, distributed by chemical supply firms, or equivalent). Place 100 grams of the magnesium oxide in a large beaker, add 700 milliliters of distilled water to make a thin slurry, and heat on a steam bath for 30 minutes with intermittent stirring. Stir well initially to insure that all the absorbent is completely wetted. Using a Buchner funnel and a filter paper (Schleicher & Schuell No. 597, or equivalent) of suitable diameter, filter with suction. Continue suction until water no longer drips from the funnel. Transfer the absorbent to a glass

trough lined with aluminum foil (free from rolling oil). Break up the magnesia with a clean spatula and spread out the absorbent on the aluminum foil in a layer about 1 centimeter to 2 centimeters thick. Dry for 24 hours at 160 °C ±1 °C. Pulverize the magnesia with mortar and pestle. Sieve the pulverized absorbent between 60–180 mesh. Use the magnesia retained on the 180–mesh sieve.

Celite 545. Johns-Manville Company, diatomaceous earth, or equivalent.

Magnesium oxide-Celite 545 mixture (2 + 1) by weight. Place the magnesium oxide (60–180 mesh) and the Celite 545 in 2 to 1 proportions, respectively, by weight in a glass-stoppered flask large enough for adequate mixing. Shake vigorously for 10 minutes. Transfer the mixture to a glass trough lined with aluminum foil (free from rolling oil) and spread it out on a layer about 1 centimeter to 2 centimeters thick. Reheat the mixture at 160 °C ±1 °C for 2 hours, and store in a tightly closed flask.

Sodium sulfate, anhydrous, A.C.S. reagent grade, preferably in granular form. For each bottle of sodium sulfate reagent used, establish as follows the necessary sodium sulfate prewash to provide such filters required in the method: Place approximately 35 grams of anhydrous sodium sulfate in a 30–milliliter coarse, fritted-glass funnel or in a 65–millimeter filter funnel with glass wool plug; wash with successive 15–milliliter portions of the indicated solvent until a 15–milliliter portion of the wash shows 0.00 absorbance per centimeter path length between 280 mμ and 400 mμ when tested as prescribed under ''Organic solvents.'' Usually three portions of wash solvent are sufficient.

Before proceeding with analysis of a sample, determine the absorbance in a 5–centimeter path cell between 250 mμ and 400 mμ for the reagent blank by carrying out the procedure, without a wax sample, at room temperature, recording the spectra after the extraction stage and after the complete procedure as prescribed. The absorbance per centimeter path length following the extraction stage should not exceed 0.040 in the wavelength range from 280 mμ to 400 mμ; the absorbance per centimeter path length following the complete procedure should not exceed 0.070 in the wavelength range from 280 mμ to 299 mμ, inclusive, nor 0.045 in the wavelength range from 300 mμ to 400 mμ. If in either spectrum the characteristic benzene peaks in the 250 mμ–260 mμ region are present, remove the benzene by the procedure under ''Organic solvents'' and record absorbance again.

Place 300 milliliters of dimethyl sulfoxide in a 1–liter separatory funnel and add 75 milliliters of phosphoric acid. Mix the contents of the funnel and allow to stand for 10 minutes. (The reaction between the sulfoxide and the acid is exothermic. Release pressure after mixing, then keep funnel stoppered.) Add 150 milliliters of isooctane and shake to preequilibrate the solvents. Draw off the individual layers and store in glass-stoppered flasks.

Place a representative 1–kilogram sample of wax, or if this amount is not available, the entire sample, in a beaker of a capacity about three times the volume of the sample and heat with occasional stirring on a steam bath until the wax is completely melted and homogeneous. Weigh four 25–gram ±0.2 gram portions of the melted wax in separate 100–milliliter beakers. Reserve three of the portions for later replicate analyses as necessary. Pour one weighed portion immediately after remelting (on the steam bath) into a 500–milliliter separatory funnel containing 100 milliliters of the preequilibrated sulfoxide-phosphoric acid mixture that has been heated in the heating jacket at a temperature just high enough to keep the wax melted. (NOTE: In preheating the sulfoxide-acid mixture, remove the stopper of the separatory funnel at intervals to release the pressure.)

Promptly complete the transfer of the sample to the funnel in the jacket with portions of the preequilibrated isooctane, warming the beaker, if necessary, and using a total volume of just 50 milliliters of the solvent. If the wax comes out of solution during these operations, let the stoppered funnel remain in the jacket until the wax redissolves. (Remove stopper from the funnel at intervals to release pressure.) When the wax is in solution, remove the funnel from the jacket and shake it vigorously for 2 minutes. Set up three 250–milliliter separatory funnels with each containing 30 milliliters of preequilibrated isooctane. After separation of the liquid phases, allow to cool until the main portion of the wax-isooctane solution begins to show a precipitate. Gently swirl the funnel when precipitation first occurs on the inside surface of the funnel to accelerate this process. Carefully draw off the lower layer, filter it slowly through a thin layer of glass wool fitted loosely in a filter funnel into the first 250–milliliter separatory funnel, and wash in tandem with the 30–milliliter portions of isooctane contained in the 250–milliliter separatory funnels. Shaking time for each wash is 1 minute. Repeat the extraction operation with two additional portions of the sulfoxide-acid mixture, replacing the funnel in the jacket after each extraction to keep the wax in solution and washing each extractive in tandem through the same three portions of isooctane.

Collect the successive extractives (300 milliliters total) in a separatory funnel (preferably 2–liter), containing 480 milliliters of distilled water, mix, and allow to cool for a few minutes after the last extractive has been added. Add 80 milliliters of isooctane to the solution and extract by shaking the funnel vigorously for 2 minutes. Draw off the

lower aqueous layer into a second separatory funnel (preferably 2–liter) and repeat the extraction with 80 milliliters of isooctane. Draw off and discard the aqueous layer. Wash each of the 80–milliliter extractives three times with 100–milliliter portions of distilled water. Shaking time for each wash is 1 minute. Discard the aqueous layers. Filter the first extractive through anhydrous sodium sulfate prewashed with isooctane (see *Sodium Sulfate* under ''Reagents and Materials'' for preparation of filter) into a 250–milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the first separatory funnel with the second 80–milliliter isooctane extractive and pass through the sodium sulfate. Then wash the second and first separatory funnels successively with a 20–milliliter portion of isooctane and pass the solvent through the sodium sulfate into the flask. Add 1 milliliter of *n*-hexadecane and evaporate the isooctane on the steam bath under nitrogen. Discontinue evaporation when not over 1 milliliter of residue remains. To the residue, add a 10–milliliter portion of isooctane, reevaporate to 1 milliliter of hexadecane, and repeat this operation once.

Quantitatively transfer the residue with isooctane to a 25–milliliter volumetric flask, make to volume, and mix. Determine the absorbance of the solution in the 5–centimeter path length cells compared to isooctane as reference between 280 mμ–400 mμ (take care to lose none of the solution in filling the sample cell). Correct the absorbance values for any absorbance derived from reagents as determined by carrying out the procedure without a wax sample. If the corrected absorbance does not exceed the limits prescribed in this paragraph (b), the wax meets the ultraviolet absorbance specifications. If the corrected absorbance per centimeter path length exceeds the limits prescribed in this paragraph (b), proceed as follows:

Quantitatively transfer the isooctane solution to a 125–milliliter flask equipped with 24/40 joint and evaporate the isooctane on the steam bath under a stream of nitrogen to a volume of 1 milliliter of hexadecane. Add 10 milliliters of methyl alcohol and approximately 0.3 gram of sodium borohydride. (Minimize exposure of the borohydride to the atmosphere. A measuring dipper may be used.) Immediately fit a water-cooled condenser equipped with a 24/40 joint and with a drying tube into the flask, mix until the borohydride is dissolved, and allow to stand for 30 minutes at room temperature, with intermittent swirling. At the end of this period, disconnect the flask and evaporate the methyl alcohol on the steam bath under nitrogen until the sodium borohydride begins to come out of the solution. Then add 10 milliliters of isooctane and evaporate to a volume of about 2–3 milliliters. Again, add 10 milliliters of isooctane and concentrate to a volume of approximately 5 milliliters. Swirl the flask repeatedly to assure adequate washing of the sodium borohydride residues.

Fit the tetrafluoroethylene polymer disc on the upper part of the stem of the chromatographic tube, then place the tube with the disc on the suction flask and apply the vacuum (approximately 135 millimeters Hg pressure). Weight out 14 grams of the 2:1 magnesium oxide-Celite 545 mixture and pour the adsorbent mixture into the chromatographic tube in approximately 3–centimeter layers. After the addition of each layer, level off the top of the adsorbent with a flat glass rod or metal plunger by pressing down firmly until the adsorbent is well packed. Loosen the topmost few millimeters of each adsorbent layer with the end of a metal rod before the addition of the next layer. Continue packing in this manner until all the 14 grams of the adsorbent is added to the tube. Level off the top of the adsorbent by pressing down firmly with a flat glass rod or metal plunger to make the depth of the adsorbent bed approximately 12.5 centimeters in depth. Turn off the vacuum and remove the suction flask. Fit the 500–milliliter reservoir onto the top of the chromatographic column and prewet the column by passing 100 milliliters of isooctane through the column. Adjust the nitrogen pressure so that the rate of descent of the isooctane coming off of the column is between 2–3 milliliters per minute. Discontinue pressure just before the last of the isooctane reaches the level of the adsorbent. (CAUTION: Do not allow the liquid level to recede below the adsorbent level at any time.) Remove the reservoir and decant the 5–milliliter isooctane concentrate solution onto the column and with slight pressure again allow the liquid level to recede to barely above the adsorbent level. Rapidly complete the transfer similarly with two 5–milliliter portions of isooctane, swirling the flask repeatedly each time to assure adequate washing of the residue. Just before the final 5–milliliter wash reaches the top of the adsorbent, add 100 milliliters of isooctane to the reservoir and continue the percolation at the 2–3 milliliter per minute rate. Just before the last of the isooctane reaches the adsorbent level, add 100 milliliters of 10 percent benzene in isooctane to the reservoir and continue the percolation at the aforementioned rate. Just before the solvent mixture reaches adsorbent level, add 25 milliliters of 20 percent benzene in isooctane to the reservoir and continue the percolation at 2–3 milliliters per minute until all this solvent mixture has been removed from the column. Discard all the elution solvents collected up to this point. Add 300 milliliters of the acetone-benzene-water mixture to the reservoir and percolate through the column to elute the polynuclear compounds. Collect the eluate in a clean 1–liter separatory funnel. Allow the column to drain

until most of the solvent mixture is removed. Wash the eluate three times with 300–milliliter portions of distilled water, shaking well for each wash. (The addition of small amounts of sodium chloride facilitates separation.) Discard the aqueous layer after each wash. After the final separation, filter the residual benzene through anhydrous sodium sulfate prewashed with benzene (see *Sodium sulfate* under ''Reagents and Materials'' for preparation of filter) into a 250–milliliter Erlenmeyer flask (or optionally into the evaporation flask). Wash the separatory funnel with two additional 20–milliliter portions of benzene which are also filtered through the sodium sulfate. Add 1 milliliter of *n*-hexadecane and completely remove the benzene by evaporation under nitrogen, using the special procedure to eliminate benzene as previously described under ''Organic Solvents.'' Quantitatively transfer the residue with isooctane to a 25–milliliter volumetric flask and adjust to volume. Determine the absorbance of the solution in the 5–centimeter path length cells compared to isooctane as reference between 250 mμ–400 mμ. Correct for any absorbance derived from the reagents as determined by carrying out the procedure without a wax sample. If either spectrum shows the characteristic benzene peaks in the 250 mμ–260 mμ region, evaporate the solution to remove benzene by the procedure under ''Organic Solvents.'' Dissolve the residue, transfer quantitatively, and adjust to volume in isooctane in a 25–milliliter volumetric flask. Record the absorbance again. If the corrected absorbance does not exceed the limits prescribed in this paragraph (b), the wax meets the ultraviolet absorbance specifications.

(c) Petroleum wax may contain one or more of the following adjuvants in amounts not greater than that required to produce their intended effect:

(1) Antioxidants permitted in food by regulations issued in accordance with section 409 of the act.

(2) Poly(alkylacrylate) (CAS Reg. No. 27029–57–8), made from long chain (C_{16}-C_{22}) alcohols and acrylic acid, or poly(alkylmethacrylate) (CAS Reg. No. 179529–36–3), made from long chain (C_{18}-C_{22}) methacrylate esters, having:

(i) A number average molecular weight between 40,000 and 100,000;

(ii) A weight average molecular weight (MW_w) to number average molecular weight (MW_n) ratio (MW_w/MW_n) of not less than 3; and

(iii) Unreacted alkylacrylate or alkylmethacrylate monomer content not in excess of 14 percent, as determined by a method entitled ''Method for Determining Weight-Average and Number-Average Molecular Weight and for Determining Alkylacrylate Monomer Content of Poly(alkylacrylate) used as Processing Aid in Manufacture of Petroleum Wax,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. Petroleum wax shall contain not more than 1,050 parts per million of poly(alkylacrylate) or poly(alkylmethacrylate) residues as determined by a method entitled ''Method for Determining Residual Level of Poly(alkylacrylate) in Petroleum Wax,'' which is incorporated by reference. Copies are available from the addresses cited in this paragraph.

(d) Petroleum wax is used or intended for use as follows:

Use	Limitations
In chewing gum base, as a masticatory substance.	In an amount not to exceed good manufacturing practice.
On cheese and raw fruits and vegetables as a protective coating.	Do.
As a defoamer in food	In accordance with § 173.340 of this chapter.
As a component of microcapsules for spice-flavoring substances.	In accordance with § 172.230 of this chapter.

[42 FR 14491, Mar. 15, 1977, as amended at 45 FR 48123, July 18, 1980; 47 FR 11838, Mar. 19, 1982; 50 FR 32561, Aug. 13, 1985; 51 FR 19544, May 30, 1986; 54 FR 24897, June 12, 1989; 64 FR 44122, Aug. 13, 1999; 78 FR 14665, Mar. 7, 2013; 81 FR 5592, Feb. 3, 2016]

§ 172.888 Synthetic petroleum wax.

Synthetic petroleum wax may be safely used in or on foods in accordance with the following conditions:

(a) Synthetic petroleum wax is a mixture of solid hydrocarbons, paraffinic in nature, prepared by either catalytic polymerization of ethylene or copolymerization of ethylene with linear (C_3 to C_{12}) alpha-olefins, and refined to meet the specifications prescribed in this section.

(b) Synthetic petroleum wax meets the ultraviolet absorbance limits of § 172.886(b) when subjected to the analytical procedure described therein.

(c) Synthetic petroleum wax has a number average molecular weight of not less than 500 nor greater than 1,200 as determined by vapor pressure osmometry.

(d) Synthetic petroleum wax may contain any antioxidant permitted in food by regulations issued in accordance with section 409 of the act, in an amount not greater than that required to produce its intended effect.

(e) Synthetic petroleum wax is used or intended for use as follows:

Use	Limitations
In chewing gum base, as a masticatory substance.	In accordance with § 172.615 in an amount not to exceed good manufacturing practice.
On cheese and raw fruits and vegetables as a protective coating.	In an amount not to exceed good manufacturing practice.
As a defoamer in food	In accordance with § 173.340 of this chapter.

[42 FR 14491, Mar. 15, 1977, as amended at 59 FR 10986, Mar. 9, 1994]

§ 172.890 Rice bran wax.

Rice bran wax may be safely used in food in accordance with the following conditions:

(a) It is the refined wax obtained from rice bran and meets the following specifications:

Melting point 75 °C to 80 °C.
Free fatty acids, maximum 10 percent.
Iodine number, maximum 20.
Saponification number 75 to 120.

(b) It is used or intended for use as follows:

Food	Limitation in food	Use
Candy	50 p.p.m	Coating.
Fresh fruits and fresh vegetables.	do	Do.
Chewing gum	2½ pct	Plasticizing material.

§ 172.892 Food starch-modified.

Food starch-modified as described in this section may be safely used in food. The quantity of any substance employed to effect such modification shall not exceed the amount reasonably required to accomplish the intended physical or technical effect, nor exceed any limitation prescribed. To insure safe use of the food starch-modified, the label of the food additive container shall bear the name of the additive ''food starch-modified'' in addition to other information required by the Act. Food starch may be modified by treatment prescribed as follows:

(a) Food starch may be acid-modified by treatment with hydrochloric acid or sulfuric acid or both.

(b) Food starch may be bleached by treatment with one or more of the following:

	Limitations
Active oxygen obtained from hydrogen peroxide and/or peracetic acid, not to exceed 0.45 percent of active oxygen.	
Ammonium persulfate, not to exceed 0.075 percent and sulfur dioxide, not to exceed 0.05 percent.	
Chlorine, as calcium hypochlorite, not to exceed 0.036 percent of dry starch.	The finished food starch-modified is limited to use only as a component of batter for commercially processed foods.
Chlorine, as sodium hypochlorite, not to exceed 0.0082 pound of chlorine per pound of dry starch.	
Potassium permanganate, not to exceed 0.2 percent.	Residual manganese (calculated as Mn), not to exceed 50 parts per million in food starch-modified.
Sodium chlorite, not to exceed 0.5 percent.	

(c) Food starch may be oxidized by treatment with chlorine, as sodium hypochlorite, not to exceed 0.055 pound of chlorine per pound of dry starch.

(d) Food starch may be esterified by treatment with one of the following:

	Limitations
Acetic anhydride	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Adipic anhydride, not to exceed 0.12 percent, and acetic anhydride.	Do.

	Limitations
Monosodium orthophosphate	Residual phosphate in food starch-modified not to exceed 0.4 percent calculated as phosphorus.
1–Octenyl succinic anhydride, not to exceed 3 percent.	
1–Octenyl succinic anhydride, not to exceed 2 percent, and aluminum sulfate, not to exceed 2 percent.	
1-Octenyl succinic anhydride, not to exceed 3 percent, followed by treatment with a *beta*-amylase enzyme that is either an approved food additive of is generally recognized as safe.	Limited to use as a stabilizer or emulsifier in beverages and beverage bases as defined in § 170.3(n)(3) of this chapter.
Phosphorus oxychloride, not to exceed 0.1 percent.	
Phosphorus oxychloride, not to exceed 0.1 percent, followed by either acetic anhydride, not to exceed 8 percent, or vinyl acetate, not to exceed 7.5 percent.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Sodium trimetaphosphate	Residual phosphate in food starch-modified not to exceed 0.04 percent, calculated as phosphorus.
Sodium tripolyphosphate and sodium trimetaphosphate.	Residual phosphate in food starch-modified not to exceed 0.4 percent calculated as phosphorus.
Succinic anhydride, not to exceed 4 percent.	
Vinyl acetate	Acetyl groups in food starch-modified not to exceed 2.5 percent.

(e) Food starch may be etherified by treatment with one of the following:

	Limitations
Acrolein, not to exceed 0.6 percent.	
Epichlorohydrin, not to exceed 0.3 percent.	
Epichlorohydrin, not to exceed 0.1 percent, and propylene oxide, not to exceed 10 percent, added in combination or in any sequence.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.
Epichlorohydrin, not to exceed 0.1 percent, followed by propylene oxide, not to exceed 25 percent.	Do.
Propylene oxide, not to exceed 25 percent.	Do.

(f) Food starch may be esterified and etherified by treatment with one of the following:

	Limitations
Acrolein, not to exceed 0.6 percent and vinyl acetate, not to exceed 7.5 percent.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Epichlorohydrin, not to exceed 0.3 percent, and acetic anhydride.	Acetyl groups in food starch-modified not to exceed 2.5 percent.
Epichlorohydrin, not to exceed 0.3 percent, and succinic anhydride, not to exceed 4 percent.	
Phosphorus oxychloride, not to exceed 0.1 percent, and propylene oxide, not to exceed 10 percent.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.

(g) Food starch may be modified by treatment with one of the following:

	Limitations
Chlorine, as sodium hypochlorite, not to exceed 0.055 pound of chlorine per pound of dry starch; 0.45 percent of active oxygen obtained from hydrogen peroxide; and propylene oxide, not to exceed 25 percent.	Residual propylene chlorohydrin not more than 5 parts per million in food starch-modified.
Sodium hydroxide, not to exceed 1 percent.	

(h) Food starch may be modified by a combination of the treatments prescribed by paragraphs (a), (b), and/or (i) of this section and any one of the treatments prescribed by paragraph (c), (d), (e), (f), or (g) of this section, subject to any limitations prescribed by the paragraphs named.

(i) Food starch may be modified by treatment with the following enzymes:

Enzyme	Limitations
Alpha-amylase (E.C. 3.2.1.1)	The enzyme must be generally recognized as safe or approved as a food additive for this purpose. The resulting nonsweet nutritive saccharide polymer has a dextrose equivalent of less than 20.
Beta-amylase (E.C. 3.2.1.2).	
Glucoamylase (E.C. 3.2.1.3).	
Isoamylase (E.C. 3.2.1.68).	
Pullulanase (E.C. 3.2.1.41).	

[42 FR 14491, Mar. 15, 1977, as amended at 43 FR 11697, Mar. 21, 1978; 46 FR 32015, June 19, 1981; 57 FR 54700, Nov. 20, 1992; 58 FR 21100, Apr. 19, 1993; 66 FR 17509, Apr. 2, 2001]

§ 172.894 Modified cottonseed products intended for human consumption.

The food additive modified cottonseed products may be used for human consumption in accordance with the following prescribed conditions:

(a) The additive is derived from:

(1) Decorticated, partially defatted, cooked, ground cottonseed kernels; or

(2) Decorticated, ground cottonseed kernels, in a process that utilizes *n*-hexane as an extracting solvent in such a way that no more than 60 parts per million of *n*-hexane residues and less than 1 percent fat by weight remain in the finished product; or

(3) Glandless cottonseed kernels roasted to attain a temperature of not less than 250 °F in the kernel for not less than 5 minutes for use as a snack food, or in baked goods, or in soft candy; or

(4) Raw glandless cottonseed kernels may be used in hard candy where the kernel temperature during cooking will exceed 250 °F for not less than 5 minutes.

(b) The additive is prepared to meet the following specifications:

(1) Free gossypol content not to exceed 450 parts per million.

(2) It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

(c) To assure safe use of the additive, the label of the food additive container shall bear, in addition to other information required by the act, the name of the additive as follows:

(1) The additive identified in paragraph (a)(1) of this section as ''partially defatted, cooked cottonseed flour''.

(2) The additive identified in paragraph (a)(2) of this section as ''defatted cottonseed flour''.

(3) The additive identified in paragraph (a)(3) of this section as ''roasted glandless cottonseed kernels''.

(4) The additive identified in paragraph (a)(4) of this section as ''raw glandless cottonseed kernels for use in cooked hard candy''.

(d) The Food and Drug Administration and the Environmental Protection Agency have determined that glandless cottonseed kernels permitted for use by this section are a distinct commodity from glanded cottonseed.

§ 172.896 Dried yeasts.

Dried yeast (*Saccharomyces cerevisiae* and *Saccharomyces fragilis*) and dried torula yeast (*Candida utilis*) may be safely used in food provided the total folic acid content of the yeast does not exceed 0.04 milligram per gram of yeast (approximately 0.008 milligram of pteroyglutamic acid per gram of yeast).

§ 172.898 Bakers yeast glycan.

Bakers yeast glycan may be safely used in food in accordance with the following conditions:

(a) Bakers yeast glycan is the comminuted, washed, pasteurized, and dried cell walls of the yeast, *Saccharomyces cerevisiae*. It is composed principally of long chain carbohydrates, not less than 85 percent on a dry solids basis. The carbohydrate is composed of glycan and mannan units in approximately a 2:1 ratio.

(b) The additive meets the following specifications on a dry weight basis: Less than 0.4 part per million (ppm) arsenic, 0.13 ppm cadmium, 0.2 ppm lead, 0.05 ppm mercury, 0.09 ppm selenium, and 10 ppm zinc.

(c) The viable microbial content of the finished ingredient is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The additive is used or intended for use in the following foods when standards of identity established under section 401 of the Act do not preclude such use:

Use	Limitations
(1) In salad dressings as an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter, stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Not to exceed a concentration of 5 percent of the finished salad dressing.
(2) In frozen dessert analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	In an amount not to exceed good manufacturing practice.
(3) In sour cream analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.

Use	Limitations
(4) In cheese spread analogs as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.
(5) In cheese-flavored and sour cream-flavored snack dips as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter, or texturizer as defined in § 170.3(o)(32) of this chapter.	Do.

(e) The label and labeling of the ingredient shall bear adequate directions to assure that use of the ingredient complies with this regulation.

[42 FR 14491, Mar. 15, 1977, as amended at 45 FR 58836, Sept. 5, 1980]

§177.1520(a) of this chapter. The finished film may contain one or more of the following added substances:

Substances	Limitations
Amides of erucic, linoleic, oleic, palmitic, and stearic acid	Not to exceed 1 pct by weight of the polymer.
BHA as described in §172.110 of this chapter	Do.
BHT as described in §172.115 of this chapter	Do.
Calcium and sodium propionates	Do.
Petroleum wax as described in §178.3710 of this chapter	Do.
Polypropylene, noncrystalline, as described in §177.1520(c) of this chapter.	Not to exceed 2 pct by weight of the polymer.
Stearates of aluminum, calcium, magnesium, potassium, and sodium as described in §172.863(a) of this chapter.	Not to exceed 1 pct by weight of the polymer.
Triethylene glycol as described in §178.3740(b) of this chapter	Do.
Mineral oil as described in §178.3620 (a) or (b) of this chapter	Do.

(ii) Polyethylene terephthalate film prepared from the basic polymer as described in §177.1630(e)(4)(ii) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

(iii) Nylon 6 films prepared from the nylon 6 basic polymer as described in §177.1500(a)(6) of this chapter and meeting the specifications of item 6.1 of the table in §177.1500(b) of this chapter. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

(iv) Vinyl chloride-vinyl acetate copolymer film prepared from the basic copolymer containing 88.5 to 90.0 weight percent of vinyl chloride with 10.0 to 11.5 weight percent of vinyl acetate and having a maximum volatility of not over 3.0 percent (1 hour at 105 °C) and viscosity not less than 0.30 determined by ASTM method D1243–79, ''Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers,'' Method A, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(9) of this section. The finished film may contain one or more of the added substances listed in paragraph (d)(2)(i) of this section.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of §180.22 of this chapter.

[42 FR 14635, Mar. 15, 1977, as amended at 49 FR 10113, Mar. 19, 1984; 54 FR 7405, Feb. 21, 1989; 54 FR 24899, June 12, 1989; 59 FR 14551, Mar. 29, 1994; 61 FR 14246, Apr. 1, 1996; 66 FR 10575, Feb. 16, 2001]

PART 180—FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY

Subpart A—General Provisions

Subpart B—Specific Requirements for Certain Food Additives

AUTHORITY: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

EDITORIAL NOTE: Nomenclature changes to part 180 appear at 61 FR 14482, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; and 81 FR 49896, July 29, 2016.

Subpart A—General Provisions

§180.1 General.

(a) Substances having a history of use in food for human consumption or in food contact surfaces may at any time have their safety or functionality brought into question by new information that in itself is not conclusive. An interim food additive regulation for the use of any such substance may be promulgated in this subpart when new information raises a substantial question about the safety or functionality of the substance but there is a reasonable certainty that the substance is not harmful and that no harm to the

public health will result from the continued use of the substance for a limited period of time while the question raised is being resolved by further study.

(b) No interim food additive regulation may be promulgated if the new information is conclusive with respect to the question raised or if there is a reasonable likelihood that the substance is harmful or that continued use of the substance will result in harm to the public health.

(c) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose an interim food additive regulation. A final order promulgating an interim food additive regulation shall provide that continued use of the substance in food is subject to each of the following conditions:

(1) Use of the substance in food or food contact surfaces must comply with whatever limitations the Commissioner deems to be appropriate under the circumstances.

(2) Within 60 days following the effective date of the regulation, an interested person shall satisfy the Commissioner in writing that studies adequate and appropriate to resolve the questions raised about the substance have been undertaken, or the Food and Drug Administration may undertake the studies. The Commissioner may extend this 60-day period if necessary to review and act on proposed protocols. If no such commitment is made, or adequate and appropriate studies are not undertaken, an order shall immediately be published in the FEDERAL REGISTER revoking the interim food additive regulation effective upon publication.

(3) A progress report shall be filed on the studies every January 1 and July 1 until completion. If the progress report is inadequate or if the Commissioner concludes that the studies are not being pursued promptly and diligently or if interim results indicate a reasonable likelihood that a health hazard exists, an order will promptly be published in the FEDERAL REGISTER revoking the interim food additive regulation effective upon publication.

(4) If nonclinical laboratory studies are involved, studies filed with the Commissioner shall include, with respect to each study, either a statement that the study has been or will be conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(5) [Reserved]

(6) If clinical investigations involving human subjects are involved, such investigations filed with the Commissioner shall include, with respect to each investigation, a statement that the investigation either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with §§ 56.104 or 56.105, and that it has been or will be conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(d) Promptly upon completion of the studies undertaken on the substance, the Commissioner will review all available data, will terminate the interim food additive regulation, and will either issue a food additive regulation or will require elimination of the substance from the food supply.

(e) The Commissioner may consult with advisory committees, professional organizations, or other experts in the field, in evaluating:

(1) Whether an interim food additive regulation is justified,

(2) The type of studies necessary and appropriate to resolve questions raised about a substance,

(3) Whether interim results indicate the reasonable likelihood that a health hazard exists, or

(4) Whether the data available at the conclusion of those studies justify a food additive regulation.

(f) Where appropriate, an emergency action level may be issued for a substance subject to paragraph (a) of this section that is not an approved food additive, pending the issuance of a final interim food additive regulation. Such an action level shall be issued pursuant to sections 306 and 402(a) of the act to identify, based upon available data, a safe level of use for the substance.

Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed interim food additive regulation. Where the available data do not permit establishing an action level for the safe use of a substance, use of the substance may be prohibited. The identification of a prohibited substance may be made in part 189 of this chapter when appropriate.

[42 FR 14636, Mar. 15, 1977, as amended at 42 FR 15674, Mar. 22, 1977; 42 FR 52821, Sept. 30, 1977; 46 FR 8952, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 50 FR 7492, Feb. 22, 1985; 54 FR 39634, Sept. 27, 1989]

Subpart B—Specific Requirements for Certain Food Additives

§ 180.22 Acrylonitrile copolymers.

Acrylonitrile copolymers may be safely used on an interim basis as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

(a) Limitations for acrylonitrile monomer extraction for finished food-contact articles, determined by a method of analysis titled ''Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food Simulating Solvents,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) In the case of single-use articles having a volume to surface ratio of 10 milliliters or more per square inch of food contact surface—0.003 milligram/square inch when extracted to equilibrium at 120 °F with food-simulating solvents appropriate to the intended conditions of use.

(2) In the case of single-use articles having a volume to surface ratio of less than 10 milliliters per square inch of food contact surface—0.3 part per million calculated on the basis of the volume of the container when extracted to equilibrium at 120 °F with food-simulating solvents appropriate to the intended conditions of use.

(3) In the case of repeated-use articles—0.003 milligram/square inch when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to the intended conditions of use.

The food-simulating solvents shall include, where applicable, distilled water, 8 percent or 50 percent ethanol, 3 percent acetic acid, and either *n*-heptane or an appropriate oil or fat.

(b) Where necessary, current regulations permitting the use of acrylonitrile copolymers shall be revised to specify limitations on acrylonitrile/mercaptan complexes utilized in the production of acrylonitrile copolymers. Such copolymers, if they contain reversible acrylonitrile/mercaptan complexes and are used in other than repeated-use conditions, shall be tested to determine the identity of the complex and the level of the complex present in the food-contact article. Such testing shall include determination of the rate of decomposition of the complex at temperatures of 100 °F, 160 °F, and 212 °F using 3 percent acetic acid as the hydrolic agent. Acrylonitrile monomer levels, acrylonitrile/mercaptan complex levels, acrylonitrile oligomer levels, descriptions of the analytical methods used to determine the complex and the acrylonitrile migration, and validation studies of these analytical methods shall be submitted by June 9, 1977, to the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, unless an extension is granted by the Food and Drug Administration for good cause shown. Analytical methods for the determination of acrylonitrile complexes with *n*-dodecylmercaptan, n-octyl mercaptan, and 2-mercaptoethanol, titled ''Determination of β-Dodecylmercaptopropionitrile in NR–16R Aqueous Extracts'' and ''Measurement of β-(2-Hdroxyethylmercapto) Propionitrile in Heptane Food-Simulating Solvent,''

are incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) The following data shall be provided for finished food-contact articles intended for repeated use:

(1) Qualitative and quantitative migration values at a time equivalent to initial batch usage, utilizing solvents and temperatures appropriate to the intended conditions of use.

(2) Qualitative and quantitative migration values at the time of equilibrium extractions, utilizing solvents and temperatures appropriate to the intended conditions of use.

(3) Data on the volume and/or weight of food handled during the initial batch time period(s), during the equilibrium test period, and over the estimated life of the food-contact surface.

(d) Where acrylonitrile copolymers represent only a minor component of a polymer system, calculations based on 100 percent migration of the acrylonitrile component may be submitted in lieu of the requirements of paragraphs (a), (b), and (c) of this section in support of the continued safe use of acrylonitrile copolymers.

(e) On or before September 13, 1976, any interested person shall satisfy the Commissioner of Food and Drugs that toxicological feeding studies adequate and appropriate to establish safe conditions for the use of acrylonitrile copolymers have been, or soon will be, undertaken. Toxicity studies of acrylonitrile monomer shall include: (1) Lifetime feeding studies with a mammalian species, preferably with animals exposed in utero to the chemical, (2) studies of multigeneration reproduction with oral administration of the test material, (3) assessment of teratogenic and mutagenic potentials, (4) subchronic oral administration in a nonrodent mammal, (5) tests to determine any synergistic toxic effects between acrylonitrile monomer and cyanide ion, and (6) a literature search on the effects of chronic ingestion of hydrogen cyanide. Data on levels of acrylamide extractable from acrylonitrile copolymers shall also be submitted. Protocols of testing should be submitted for review to the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

(f) Acrylonitrile copolymers may be used in contact with food only if authorized in parts 174 through 179 or §181.32 of this chapter, except that other uses of acrylonitrile copolymers in use prior to June 14, 1976, may continue under the following conditions:

(1) On or before August 13, 1976, each use of acrylonitrile copolymers in a manner not authorized by §181.32 of this chapter or parts 174 through 179 of this chapter shall be the subject of a notice to the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Such notice shall be accompanied by a statement of the basis, including any articles and correspondence, on which the user in good faith believed the use to be prior-sanctioned. The Commissioner of Food and Drugs shall, by notice in the FEDERAL REGISTER, identify any use of acrylonitrile copolymers not in accordance with this paragraph. Those uses are thereafter unapproved food additives and consequently unlawful.

(2) Any use of acrylonitrile copolymers subject to paragraph (f)(1) of this section shall be the subject of a petition submitted on or before December 13, 1976, in accordance with §171.1 of this chapter, unless an extension of time is granted by the Food and Drug Administration for good cause shown. Any application for extension shall be by petition submitted in accordance with the requirements of part 10 of this chapter. If a petition is denied, in whole or in part, those uses subject to the denial are thereafter unapproved food additives and consequently unlawful.

(3) Any use of acrylonitrile copolymers subject to paragraph (f)(1) of this section shall meet the acrylonitrile monomer extraction limitation set

forth in paragraph (a) of this section and shall be subject to the requirements of paragraph (b) of this section.

(g) In addition to the requirements of this section, the use of acrylonitrile copolymers shall comply with all applicable requirements in other regulations in this part.

[42 FR 14636, Mar. 15, 1977, as amended at 47 FR 11850, Mar. 19, 1982; 54 FR 24899, June 12, 1989; 61 FR 14246, Apr. 1, 1996]

§ 180.25 Mannitol.

(a) Mannitol is the chemical 1,2,3,4,5,6,-hexanehexol ($C_6H_{14}O_6$) a hexahydric alcohol, differing from sorbitol principally by having a different optical rotation. Mannitol is produced by one of the following processes:

(1) The electrolytic reduction or transition metal catalytic hydrogenation of sugar solutions containing glucose or fructose.

(2) The fermentation of sugars or sugar alcohols such as glucose, sucrose, fructose, or sorbitol using the yeast *Zygosaccharomyces rouxii*.

(3) A pure culture fermentation of sugars such as fructose, glucose, or maltose using the nonpathogenic, nontoxicogenic bacterium *Lactobacillus intermedius* (*fermentum*).

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 188–190, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as an anticaking agent and free-flow agent as defined in §170.3(o)(1) of this chapter, formulation aid as defined in §170.3(o)(14) of this chapter, firming agent as defined in §170.3(o)(10) of this chapter, flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter, lubricant and release agent as defined in §170.3(o)(18) of this chapter, nutritive sweetener as defined in §170.3(o)(21) of this chapter, processing aid as defined in §170.3(o)(24) of this chapter, stabilizer and thickener as defined in §170.3(o)(28) of this chapter, surface-finishing agent as defined in §170.3(o)(30) of this chapter, and texturizer as defined in §170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed 98 percent in pressed mints and 5 percent in all other hard candy and cough drops as defined in §170.3(n)(25) of this chapter, 31 percent in chewing gum as defined in §170.3(n)(6) of this chapter, 40 percent in soft candy as defined in §170.3(n)(38) of this chapter, 8 percent in confections and frostings as defined in §170.3(n)(9) of this chapter, 15 percent in nonstandardized jams and jellies, commercial, as defined in §170.3(n)(28) of this chapter, and at levels less than 2.5 percent in all other foods.

(e) The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 20 grams of mannitol shall bear the statement ''Excess consumption may have a laxative effect''.

(f) In accordance with §180.1, adequate and appropriate feeding studies have been undertaken for this substance. Continued uses of this ingredient are contingent upon timely and adequate progress reports of such tests, and no indication of increased risk to public health during the test period.

(g) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984; 61 FR 7991, Mar. 1, 1996; 69 FR 65542, Nov. 15, 2004]

§ 180.30 Brominated vegetable oil.

The food additive brominated vegetable oil may be safely used in accordance with the following prescribed conditions:

(a) The additive complies with specifications prescribed in the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 40–41, which is incorporated by reference, except that free fatty acids (as oleic) shall not exceed 2.5 percent and iodine value shall not exceed 16. Copies of the material incorporated by reference may be obtained from the National Academy Press, 2101 Constitution Ave.

NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(b) The additive is used on an interim basis as a stabilizer for flavoring oils used in fruit-flavored beverages, for which any applicable standards of identity do not preclude such use, in an amount not to exceed 15 parts per million in the finished beverage, pending the outcome of additional toxicological studies on which periodic reports at 6-month intervals are to be furnished and final results submitted to the Food and Drug Administration promptly after completion of the studies.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

§ 180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

The food additives saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin may be safely used as sweetening agents in food in accordance with the following conditions, if the substitution for nutritive sweeteners is for a valid special dietary purpose and is in accord with current special dietary food regulations and policies or if the use or intended use is for an authorized technological purpose other than calorie reduction:

(a) Saccharin is the chemical, 1,2-benzisothiazolin-3-one - 1,1 - dioxide ($C_7H_5NO_3S$). The named salts of saccharin are produced by the additional neutralization of saccharin with the proper base to yield the desired salt.

(b) The food additives meet the specifications of the Food Chemicals Codex, 7th ed. (2010), pp. 52–54, 153–154, 898–899, 961–962, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(c) Authority for such use shall expire when the Commissioner receives the final reports on the ongoing studies in Canada and publishes an order on the safety of saccharin and its salts based on those reports and other available data.

(d) The additives are used or intended for use as a sweetening agent only in special dietary foods, as follows:

(1) In beverages, fruit juice drinks, and bases or mixes when prepared for consumption in accordance with directions, in amounts not to exceed 12 milligrams of the additive, calculated as saccharin, per fluid ounce.

(2) As a sugar substitute for cooking or table use, in amounts not to exceed 20 milligrams of the additive, calculated as saccharin, for each expressed teaspoonful of sugar sweetening equivalency.

(3) In processed foods, in amounts not to exceed 30 milligrams of the additive, calculated as saccharin, per serving of designated size.

(e) The additives are used or intended for use only for the following technological purposes:

(1) To reduce bulk and enhance flavors in chewable vitamin tablets, chewable mineral tablets, or combinations thereof.

(2) To retain flavor and physical properties of chewing gum.

(3) To enhance flavor of flavor chips used in nonstandardized bakery products.

(f) To assure safe use of the additives, in addition to the other information required by the Act:

(1) The label of the additive and any intermediate mixes of the additive for manufacturing purposes shall bear:

(i) The name of the additive.

(ii) A statement of the concentration of the additive, expressed as saccharin, in any intermediate mix.

(iii) Adequate directions for use to provide a final food product that complies with the limitations prescribed in paragraphs (d) and (e) of this section.

(2) The label of any finished food product containing the additive shall bear:

(i) The name of the additive.

(ii) The amount of the additive, calculated as saccharin, as follows:

(*a*) For beverages, in milligrams per fluid ounce;

(*b*) For cooking or table use products, in milligrams per dispensing unit;

(*c*) For processed foods, in terms of the weight or size of a serving which shall be that quantity of the food containing 30 milligrams or less of the additive.

(iii) When the additive is used for calorie reduction, such other labeling as is required by part 105 of this chapter.

[42 FR 14636, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984; 72 FR 10357, Mar. 8, 2007; 78 FR 71467, Nov. 29, 2013]

PART 181—PRIOR-SANCTIONED FOOD INGREDIENTS

Subpart A—General Provisions

Subpart B—Specific Prior-Sanctioned Food Ingredients

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14638, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 181 appear at 61 FR 14482, Apr. 2, 1996, and 66 FR 56035, Nov. 6, 2001.

Subpart A—General Provisions

§ 181.1 General.

(a) An ingredient whose use in food or food packaging is subject to a prior sanction or approval within the meaning of section 201(s)(4) of the Act is exempt from classification as a food additive. The Commissioner will publish in this part all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by evidence to show that it falls within section 201(s)(4) of the Act.

(b) Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the Act, the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient.

(c) Where appropriate, an emergency action level may be issued for a prior-sanctioned substance, pending the issuance of a final regulation in accordance with paragraph (b) of this section. Such an action level shall be issued pursuant to section 402(a) of the Act to identify, based upon available data, conditions of use of the substance that may be injurious to health. Such an action level shall be issued in a notice published in the FEDERAL REGISTER and shall be followed as soon as practicable by a proposed regulation in accordance with paragraph (b) of this section. Where the available data demonstrate that the substance may be injurious at any level, use of the substance may be prohibited. The identification of a prohibited substance may be made in part 189 of this chapter when appropriate.

[42 FR 14638, Mar. 15, 1977, as amended at 42 FR 52821, Sept. 30, 1977; 54 FR 39635, Sept. 27, 1989]

§ 181.5 Prior sanctions.

(a) A prior sanction shall exist only for a specific use(s) of a substance in

food, i.e., the level(s), condition(s), product(s), etc., for which there was explicit approval by the Food and Drug Administration or the United States Department of Agriculture prior to September 6, 1958.

(b) The existence of a prior sanction exempts the sanctioned use(s) from the food additive provisions of the Act but not from the other adulteration or the misbranding provisions of the Act.

(c) All known prior sanctions shall be the subject of a regulation published in this part. Any such regulation is subject to amendment to impose whatever limitation(s) or condition(s) may be necessary for the safe use of the ingredient, or revocation to prohibit use of the ingredient, in order to prevent the adulteration of food in violation of section 402 of the Act.

(d) In proposing, after a general evaluation of use of an ingredient, regulations affirming the GRAS status of substances added directly to human food in part 184 of this chapter or substances in food-contact surfaces in part 186 of this chapter, or establishing a food additive regulation for substances added directly to human food in parts 172 and 173 of this chapter or food additives in food-contact surfaces in parts 174, 175, 176, 177, 178 and §179.45 of this chapter, the Commissioner shall, if he is aware of any prior sanction for use of the ingredient under conditions different from those proposed in the regulation, concurrently propose a separate regulation covering such use of the ingredient under this part. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any food additive or GRAS regulation promulgated after a general evaluation of use of an ingredient constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to a proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under this part, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

Subpart B—Specific Prior-Sanctioned Food Ingredients

§ 181.22 Certain substances employed in the manufacture of food-packaging materials.

Prior to the enactment of the food additives amendment to the Federal Food, Drug, and Cosmetic Act, sanctions were granted for the usage of the substances listed in §§181.23, 181.24, 181.25, 181.26, 181.27, 181.28, 181.29, and 181.30 in the manufacture of packaging materials. So used, these substances are not considered ''food additives'' within the meaning of section 201(s) of the Act, provided that they are of good commercial grade, are suitable for association with food, and are used in accordance with good manufacturing practice. For the purpose of this subpart, good manufacturing practice for food-packaging materials includes the restriction that the quantity of any of these substances which becomes a component of food as a result of use in food-packaging materials shall not be intended to accomplish any physical or technical effect in the food itself, shall be reduced to the least amount reasonably possible, and shall not exceed any limit specified in this subpart.

[42 FR 56728, Oct. 28, 1977]

§ 181.23 Antimycotics.

Substances classified as antimycotics, when migrating from food-packaging material shall include:

Calcium propionate.
Methylparaben (methyl *p*-hydroxybenzoate).
Propylparaben (propyl *p*-hydroxybenzoate).
Sodium benzoate.
Sodium propionate.
Sorbic acid.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.24 Antioxidants.

Substances classified as antioxidants, when migrating from food-packaging

material (limit of addition to food, 0.005 percent) shall include:

Butylated hydroxyanisole.
Butylated hydroxytoluene.
Dilauryl thiodipropionate.
Distearyl thiodipropionate.
Gum guaiac.
Nordihydroguairetic acid.
Propyl gallate.
Thiodipropionic acid.
2,4,5-Trihydroxy butyrophenone.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.25 Driers.

Substances classified as driers, when migrating from food-packaging material shall include:

Cobalt caprylate.
Cobalt linoleate.
Cobalt naphthenate.
Cobalt tallate.
Iron caprylate.
Iron linoleate.
Iron naphthenate.
Iron tallate.
Manganese caprylate.
Manganese linoleate.
Manganese naphthenate.
Manganese tallate.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.26 Drying oils as components of finished resins.

Substances classified as drying oils, when migrating from food-packaging material (as components of finished resins) shall include:

Chinawood oil (tung oil).
Dehydrated castor oil.
Linseed oil.
Tall oil.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.27 Plasticizers.

Substances classified as plasticizers, when migrating from food-packaging material shall include:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
p-tert-Butylphenyl salicylate.
Butyl stearate.
Butylphthalyl butyl glycolate.
Dibutyl sebacate.
Di-(2-ethylhexyl) phthalate (for foods of high water content only).
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate (for foods of high water content only).
Diphenyl-2-ethylhexyl phosphate.
Epoxidized soybean oil (iodine number maximum 6; and oxirane oxygen, minimum, 6.0 percent).
Ethylphthalyl ethyl glycolate.
Glycerol monooleate.
Monoisopropyl citrate.
Mono, di-, and tristearyl citrate.
Triacetin (glycerol triacetate).
Triethyl citrate.
3-(2-Xenolyl)-1,2-epoxypropane.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977, as amended at 50 FR 49536, Dec. 3, 1985]

§ 181.28 Release agents.

Substances classified as release agents, when migrating from food-packaging material shall include:

Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups, no more than 18 percent loss in weight after heating 4 hours at 200 °C.; viscosity 300 centisokes, 600 centisokes at 25 °C, specific gravity 0.96 to 0.97 at 25 °C, refractive index 1.400 to 1.404 at 25 °C).
Linoleamide (linoleic acid amide).
Oleamide (oleic acid amide).
Palmitamide (palmitic acid amide).
Stearamide (stearic acid amide).

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.29 Stabilizers.

Substances classified as stabilizers, when migrating from food-packaging material shall include:

Aluminum mono-, di-, and tristearate.
Ammonium citrate.
Ammonium potassium hydrogen phosphate.
Calcium glycerophosphate.
Calcium phosphate.
Calcium hydrogen phosphate.
Calcium oleate.
Calcium acetate.
Calcium carbonate.
Calcium ricinoleate.
Calcium stearate.
Disodium hydrogen phosphate.
Magnesium glycerophosphate.
Magnesium stearate.
Magnesium phosphate.
Magnesium hydrogen phosphate.
Mono-, di-, and trisodium citrate.
Mono-, di-, and tripotassium citrate.
Potassium oleate.
Potassium stearate.
Sodium pyrophosphate.
Sodium stearate.
Sodium tetrapyrophosphate.

Stannous stearate (not to exceed 50 parts per million tin as a migrant in finished food).
Zinc orthophosphate (not to exceed 50 parts per million zinc as a migrant in finished food).
Zinc resinate (not to exceed 50 parts per million zinc as a migrant in finished food).

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.30 Substances used in the manufacture of paper and paperboard products used in food packaging.

Substances used in the manufacture of paper and paperboard products used in food packaging shall include:

Aliphatic polyoxyethylene ethers.*
1-Alkyl (C_6-C_{18})3-amino-3-aminopropane monoacetate.*
Borax or boric acid for use in adhesives, sizes, and coatings.*
Butadiene-styrene copolymer.
Chromium complex of perfluoro-octane sulfonyl glycine for use on paper and paperboard which is waxed.*
Disodium cyanodithioimidocarbamate with ethylene diamine and potassium *N*-methyl dithiocarbamate and/or sodium 2-mercaptobenzothiazole (slimicides).*
Ethyl acrylate and methyl methacrylate copolymers of itaconic acid or methacrylic acid for use only on paper and paperboard which is waxed.*
Hexamethylene tetramine as a setting agent for protein, including casein.*
1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2-alkyl (C_6-C_{17}) imidazolinium chloride.*
Itaconic acid (polymerized).
Melamine formaldehyde polymer.
Methyl acrylate (polymerized).
Methyl ethers of mono-, di-, and tripropylene glycol.*
Myristo chromic chloride complex.
Nitrocellulose.
Polyethylene glycol 400.
Polyvinyl acetate.
Potassium pentachlorophenate as a slime control agent.*
Potassium trichlorophenate as a slime control agent.*
Resins from high and low viscosity polyvinyl alcohol for fatty foods only.
Rubber hydrochloride.
Sodium pentachlorophenate as a slime control agent.*
Sodium-trichlorophenate as a slime control agent.*
Stearato-chromic chloride complex.
Titanium dioxide.*
Urea formaldehyde polymer.
Vinylidine chlorides (polymerized).

*Under the conditions of normal use, these substances would not reasonably be expected to migrate to food, based on available scientific information and data.

§ 181.32 Acrylonitrile copolymers and resins.

(a) Acrylonitrile copolymers and resins listed in this section, containing less than 30 percent acrylonitrile and complying with the requirements of paragraph (b) of this section, may be safely used as follows:

(1) *Films.* (i) Acrylonitrile/butadiene/styrene copolymers—no restrictions.

(ii) Acrylonitrile/butadiene copolymers—no restrictions.

(iii) Acrylonitrile/butadiene copolymer blended with vinyl chloride-vinyl acetate (optional at level up to 5 percent by weight of the vinyl chloride resin) resin—for use only in contact with oleomargarine.

(iv) Acrylonitrile/styrene copolymer—no restrictions.

(2) *Coatings.* (i) Acrylonitrile/butadiene copolymer blended with polyvinyl chloride resins—for use only on paper and paperboard in contact with meats and lard.

(ii) Polyvinyl chloride resin blended with either acrylonitrile/butadiene copolymer or acrylonitrile/butadiene styrene copolymer mixed with neoprene, for use as components of conveyor belts to be used with fresh fruits, vegetables, and fish.

(iii) Acrylonitrile/butadiene/styrene copolymer—no restrictions.

(iv) Acrylonitrile/styrene copolymer—no restrictions.

(3) *Rigid and semirigid containers.* (i) Acrylonitrile/butadiene/styrene copolymer—for use only as piping for handling food products and for repeated-use articles intended to contact food.

(ii) Acrylonitrile/styrene resin—no restrictions.

(iii) Acrylonitrile/butadiene copolymer blended with polyvinyl chloride resin—for use only as extruded pipe.

(b) Limitations for acrylonitrile monomer extraction for finished food-contact articles, determined by using the method of analysis titled ''Gas-Solid Chromatographic Procedure for Determining Acrylonitrile Monomer in Acrylonitrile-Containing Polymers and Food-Simulating Solvents,'' which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–

200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(1) In the case of single-use articles having a volume to surface ratio of 10 milliliters or more per square inch of food-contact surface—0.003 milligram/square inch when extracted to equilibrium at 120 °F with food-simulating solvents appropriate to the intended conditions of use.

(2) In the case of single-use articles having a volume to surface ratio of less than 10 milliliters per square inch of food-contact surface—0.3 part per million calculated on the basis of the volume of the container when extracted to equilibrium at 120 °F with food-simulating solvents appropriate to the intended conditions of use.

(3) In the case of repeated-use articles—0.003 milligram/square inch when extracted at a time equivalent to initial batch usage utilizing food-simulating solvents and temperatures appropriate to the intended conditions of use.

The food-simulating solvents shall include, where applicable, distilled water, 8 percent or 50 percent ethanol, 3 percent acetic acid, and either *n*-heptane or an appropriate oil or fat.

(c) Acrylonitrile monomer may present a hazard to health when ingested. Accordingly, any food-contact article containing acrylonitrile copolymers or resins that yield acrylonitrile monomer in excess of that amount provided for in paragraph (b) of this section shall be deemed to be adulterated in violation of section 402 of the Act.

[42 FR 14638, Mar. 15, 1977, as amended at 47 FR 11850, Mar. 19, 1982; 54 FR 24899, June 12, 1989]

§ 181.33 Sodium nitrate and potassium nitrate.

Sodium nitrate and potassium nitrate are subject to prior sanctions issued by the U.S. Department of Agriculture for use as sources of nitrite, with or without sodium or potassium nitrite, in the production of cured red meat products and cured poultry products.

[48 FR 1705, Jan. 14, 1983]

§ 181.34 Sodium nitrite and potassium nitrite.

Sodium nitrite and potassium nitrite are subject to prior sanctions issued by the U.S. Department of Agriculture for use as color fixatives and preservative agents, with or without sodium or potassium nitrate, in the curing of red meat and poultry products.

[48 FR 1705, Jan. 14, 1983]

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.

Subpart B—Multiple Purpose GRAS Food Substances

AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14640, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 182.1 Substances that are generally recognized as safe.

(a) It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use. This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generaly recognized as safe for such uses.

(b) For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and

(2) The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.

(3) The substance is of appropriate food grade and is prepared and handled as a food ingredient. Upon request the Commissioner will offer an opinion, based on specifications and intended use, as to whether or not a particular

grade or lot of the substance is of suitable purity for use in food and would generally be regarded as safe for the purpose intended, by experts qualified to evaluate its safety.

(c) The inclusion of substances in the list of nutrients does not constitute a finding on the part of the Department that the substance is useful as a supplement to the diet for humans.

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are listed in this part. When the status of a substance has been reevaluated, it will be deleted from this part, and will be issued as a new regulation under the appropriate part, e.g., ''affirmed as GRAS'' under part 184 or 186 of this chapter; ''food additive regulation'' under parts 170 through 180 of this chapter; ''interim food additive regulation'' under part 180 of this chapter; or ''prohibited from use in food'' under part 189 of this chapter.

[42 FR 14640, Mar. 15, 1977, as amended at 53 FR 44875, Nov. 7, 1988]

§ 182.10 Spices and other natural seasonings and flavorings.

Spices and other natural seasonings and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Alfalfa herb and seed	Medicago sativa L.
Allspice	Pimenta officinalis Lindl.
Ambrette seed	Hibiscus abelmoschus L.
Angelica	Angelica archangelica L. or other spp. of Angelica.
Angelica root	Do.
Angelica seed	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Anise, star	Illicium verum Hook. f.
Balm (lemon balm)	Melissa officinalis L.
Basil, bush	Ocimum minimum L.
Basil, sweet	Ocimum basilicum L.
Bay	Laurus nobilis L.
Calendula	Calendula officinalis L.
Camomile (chamomile), English or Roman	Anthemis nobilis L.
Camomile (chamomile), German or Hungarian	Matricaria chamomilla L.
Capers	Capparis spinosa L.
Capsicum	Capsicum frutescens L. or Capsicum annuum L.
Caraway	Carum carvi L.
Caraway, black (black cumin)	Nigella sativa L.
Cardamom (cardamon)	Elettaria cardamomum Maton.
Cassia, Chinese	Cinnamomum cassia Blume.
Cassia, Padang or Batavia	Cinnamomum burmanni Blume.
Cassia, Saigon	Cinnamomum loureirii Nees.
Cayenne pepper	Capsicum frutescens L. or Capsicum annuum L.
Celery seed	Apium graveolens L.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chives	Allium schoenoprasum L.
Cinnamon, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon, Chinese	Cinnamomum cassia Blume.
Cinnamon, Saigon	Cinnamomum loureirii Nees.
Clary (clary sage)	Salvia sclarea L.
Clover	Trifolium spp.
Coriander	Coriandrum sativum L.
Cumin (cummin)	Cuminum cyminum L.
Cumin, black (black caraway)	Nigella sativa L.
Elder flowers	Sambucus canadensis L.
Fennel, common	Foeniculum vulgare Mill.
Fennel, sweet (finocchio, Florence fennel)	Foeniculum vulgare Mill. var. duice (DC.) Alex.
Fenugreek	Trigonella foenum-graecum L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Ginger	Zingiber officinale Rosc.
Grains of paradise	Amomum melegueta Rosc.
Horehound (hoarhound)	Marrubium vulgare L.
Horseradish	Armoracia lapathifolia Gilib.
Hyssop	Hyssopus officinalis L.
Lavender	Lavandula officinalis Chaix.
Linden flowers	Tilia spp.
Mace	Myristica fragrans Houtt.

Common name	Botanical name of plant source
Marigold, pot	Calendula officinalis L.
Marjoram, pot	Majorana onites (L.) Benth.
Marjoram, sweet	Majorana hortensis Moench.
Mustard, black or brown	Brassica nigra (L.) Koch.
Mustard, brown	Brassica juncea (L.) Coss.
Mustard, white or yellow	Brassica hirta Moench.
Nutmeg	Myristica fragrans Houtt.
Oregano (oreganum, Mexican oregano, Mexican sage, origan).	Lippia spp.
Paprika	Capsicum annuum L.
Parsley	Petroselinum crispum (Mill.) Mansf.
Pepper, black	Piper nigrum L.
Pepper, cayenne	Capsicum frutescens L. or Capsicum annuum L.
Pepper, red	Do.
Pepper, white	Piper nigrum L.
Peppermint	Mentha piperita L.
Poppy seed	Papayer somniferum L.
Pot marigold	Calendula officinalis L.
Pot marjoram	Majorana onites (L.) Benth.
Rosemary	Rosmarinus officinalis L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Savory, summer	Satureia hortensis L. (Satureja).
Savory, winter	Satureia montana L. (Satureja).
Sesame	Sesamum indicum L.
Spearmint	Mentha spicata L.
Star anise	Illicium verum Hook. f.
Tarragon	Artemisia dracunculus L.
Thyme	Thymus vulgaris L.
Thyme, wild or creeping	Thymus serpyllum L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.
Zedoary	Curcuma zedoaria Rosc.

[42 FR 14640, Mar. 15, 1977, as amended at 43 FR 3705, Jan. 27, 1978; 44 FR 3963, Jan. 19, 1979; 50 FR 21044, May 22, 1985; 61 FR 14246, Apr. 1, 1996]

§ 182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates).

Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Alfalfa	Medicago sativa L.
Allspice	Pimenta officinalis Lindl.
Almond, bitter (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Ambrette (seed)	Hibiscus moschatus Moench.
Angelica root	Angelica archangelica L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cusparia bark)	Galipea officinalis Hancock.
Anise	Pimpinella anisum L.
Asafetida	Ferula assa-foetida L. and related spp. of Ferula.
Balm (lemon balm)	Melissa officinalis L.
Balsam of Peru	Myroxylon pereirae Klotzsch.
Basil	Ocimum basilicum L.
Bay leaves	Laurus nobilis L.
Bay (myrcia oil)	Pimenta racemosa (Mill.) J. W. Moore.
Bergamot (bergamot orange)	Citrus aurantium L. subsp. bergamia Wright et Arn.
Bitter almond (free from prussic acid)	Prunus amygdalus Batsch, Prunus armeniaca L., or Prunus persica (L.) Batsch.
Bois de rose	Aniba rosaeodora Ducke.
Cacao	Theobroma cacao L.
Camomile (chamomile) flowers, Hungarian	Matricaria chamomilla L.
Camomile (chamomile) flowers, Roman or English	Anthemis nobilis L.
Cananga	Cananga odorata Hook. f. and Thoms.

Common name	Botanical name of plant source
Capsicum	Capsicum frutescens L. and Capsicum annuum L.
Caraway	Carum carvi L.
Cardamom seed (cardamon)	Elettaria cardamomum Maton.
Carob bean	Ceratonia siliqua L.
Carrot	Daucus carota L.
Cascarilla bark	Croton eluteria Benn.
Cassia bark, Chinese	Cinnamomum cassia Blume.
Cassia bark, Padang or Batavia	Cinnamomum burmanni Blume.
Cassia bark, Saigon	Cinnamomum loureirii Nees.
Celery seed	Apium graveolens L.
Cherry, wild, bark	Prunus serotina Ehrh.
Chervil	Anthriscus cerefolium (L.) Hoffm.
Chicory	Cichorium intybus L.
Cinnamon bark, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon bark, Chinese	Cinnamomum cassia Blume.
Cinnamon bark, Saigon	Cinnamomum loureirii Nees.
Cinnamon leaf, Ceylon	Cinnamomum zeylanicum Nees.
Cinnamon leaf, Chinese	Cinnamomum cassia Blume.
Cinnamon leaf, Saigon	Cinnamomum loureirii Nees.
Citronella	Cymbopogon nardus Rendle.
Citrus peels	Citrus spp.
Clary (clary sage)	Salvia sclarea L.
Clover	Trifolium spp.
Coca (decocainized)	Erythroxylum coca Lam. and other spp. of Erythroxylum.
Coffee	Coffea spp.
Cola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Coriander	Coriandrum sativum L.
Cumin (cummin)	Cuminum cyminum L.
Curacao orange peel (orange, bitter peel)	Citrus aurantium L.
Cusparia bark	Galipea officinalis Hancock.
Dandelion	Taraxacum officinale Weber and T. laevigatum DC.
Dandelion root	Do.
Dog grass (quackgrass, triticum)	Agropyron repens (L.) Beauv.
Elder flowers	Sambucus canadensis L. and S. nigra l.
Estragole (esdragol, esdragon, tarragon)	Artemisia dracunculus L.
Estragon (tarragon)	Do.
Fennel, sweet	Foeniculum vulgare Mill.
Fenugreek	Trigonella foenum-graecum L.
Galanga (galangal)	Alpinia officinarum Hance.
Geranium	Pelargonium spp.
Geranium, East Indian	Cymbopogon martini Stapf.
Geranium, rose	Pelargonium graveolens L'Her.
Ginger	Zingiber officinale Rosc.
Grapefruit	Citrus paradisi Macf.
Guava	Psidium spp.
Hickory bark	Carya spp.
Horehound (hoarhound)	Marrubium vulgare L.
Hops	Humulus lupulus L.
Horsemint	Monarda punctata L.
Hyssop	Hyssopus officinalis L.
Immortelle	Helichrysum augustifolium DC.
Jasmine	Jasminum officinale L. and other spp. of Jasminum.
Juniper (berries)	Juniperus communis L.
Kola nut	Cola acuminata Schott and Endl., and other spp. of Cola.
Laurel berries	Laurus nobilis L.
Laurel leaves	Laurus spp.
Lavender	Lavandula officinalis Chaix.
Lavender, spike	Lavandula latifolia Vill.
Lavandin	Hybrids between Lavandula officinalis Chaix and Lavandula latifolin Vill.
Lemon	Citrus limon (L.) Burm. f.
Lemon balm (see balm).	
Lemon grass	Cymbopogon citratus DC. and Cymbopogon lexuosus Stapf.
Lemon peel	Citrus limon (L.) Burm. f.
Lime	Citrus aurantifolia Swingle.
Linden flowers	Tilia spp.
Locust bean	Ceratonia siliqua L,
Lupulin	Humulus lupulus L.
Mace	Myristica fragrans Houtt.
Mandarin	Citrus reticulata Blanco.
Marjoram, sweet	Majorana hortensis Moench.
Maté	Ilex paraguariensis St. Hil.
Melissa (see balm).	
Menthol	Mentha spp.
Menthyl acetate	Do.

Common name	Botanical name of plant source
Molasses (extract)	Saccarum officinarum L.
Mustard	Brassica spp.
Naringin	Citrus paradisi Macf.
Neroli, bigarade	Citrus aurantium L.
Nutmeg	Myristica fragrans Houtt.
Onion	Allium cepa L.
Orange, bitter, flowers	Citrus aurantium L.
Orange, bitter, peel	Do.
Orange leaf	Citrus sinensis (L.) Osbeck.
Orange, sweet	Do.
Orange, sweet, flowers	Do.
Orange, sweet, peel	Do.
Origanum	Origanum spp.
Palmarosa	Cymbopogon martini Stapf.
Paprika	Capsicum annuum L.
Parsley	Petroselinum crispum (Mill.) Mansf.
Pepper, black	Piper nigrum L.
Pepper, white	Do.
Peppermint	Mentha piperita L.
Peruvian balsam	Myroxylon pereirae Klotzsch.
Petitgrain	Citrus aurantium L.
Petitgrain lemon	Citrus limon (L.) Burm. f.
Petitgrain mandarin or tangerine	Citrus reticulata Blanco.
Pimenta	Pimenta officinalis Lindl.
Pimenta leaf	Pimenta officinalis Lindl.
Pipsissewa leaves	Chimaphila umbellata Nutt.
Pomegranate	Punica granatum L.
Prickly ash bark	Xanthoxylum (or Zanthoxylum) Americanum Mill. or Xanthoxylum clava-herculis L.
Rose absolute	Rosa alba L., Rosa centifolia L., Rosa damascena Mill., Rosa gallica L., and vars. of these spp.
Rose (otto of roses, attar of roses)	Do.
Rose buds	Do.
Rose flowers	Do.
Rose fruit (hips)	Do.
Rose geranium	Pelargonium graveolens L'Her.
Rose leaves	Rosa spp.
Rosemary	Rosmarinus officinalis L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Sage, Spanish	Salvia lavandulaefolia Vahl.
St. John's bread	Ceratonia siliqua L.
Savory, summer	Satureia hortensis L.
Savory, winter	Satureia montana L.
Schinus molle	Schinus molle L.
Sloe berries (blackthorn berries)	Prunus spinosa L.
Spearmint	Mentha spicata L.
Spike lavender	Lavandula latifolia Vill.
Tamarind	Tamarindus indica L.
Tangerine	Citrus reticulata Blanco.
Tarragon	Artemisia dracunculus L.
Tea	Thea sinensis L.
Thyme	Thymus vulgaris L. and Thymus zygis var. gracilis Boiss.
Thyme, white	Do.
Thyme, wild or creeping	Thymus serpyllum L.
Triticum (see dog grass).	
Tuberose	Polianthes tuberosa L.
Turmeric	Curcuma longa L.
Vanilla	Vanilla planifolia Andr. or Vanilla tahitensis J. W. Moore.
Violet flowers	Viola odorata L.
Violet leaves	Do.
Violet leaves absolute	Do.
Wild cherry bark	Prunus serotina Ehrh.
Ylang-ylang	Cananga odorata Hook. f. and Thoms.
Zedoary bark	Curcuma zedoaria Rosc.

[42 FR 14640, Mar. 15, 1977, as amended at 44 FR 3963, Jan. 19, 1979; 47 FR 29953, July 9, 1982; 48 FR 51613, Nov. 10, 1983; 50 FR 21043, 21044, May 22, 1985]

§ 182.40 Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings.

Natural extractives (solvent-free) used in conjunction with spices, seasonings, and flavorings that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Botanical name of plant source
Apricot kernel (persic oil)	Prunus armeniaca L.
Peach kernel (persic oil)	Prunus persica Sieb. et Zucc.
Peanut stearine	Arachis hypogaea L.
Persic oil (see apricot kernel and peach kernel).	
Quince seed	Cydonia oblonga Miller.

[42 FR 14640, Mar. 15, 1977, as amended at 47 FR 47375, Oct. 26, 1982]

§ 182.50 Certain other spices, seasonings, essential oils, oleoresins, and natural extracts.

Certain other spices, seasonings, essential oils, oleoresins, and natural extracts that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Common name	Derivation
Ambergris	Physeter macrocephalus L.
Castoreum	Castor fiber L. and C. canadensis Kuhl.
Civet (zibeth, zibet, zibetum)	Civet cats, Viverra civetta Schreber and Viverra zibetha Schreber.
Cognac oil, white and green	Ethyl oenanthate, so-called.
Musk (Tonquin musk)	Musk deer, Moschus moschiferus L.

§ 182.60 Synthetic flavoring substances and adjuvants.

Synthetic flavoring substances and adjuvants that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Acetaldehyde (ethanal).
Acetoin (acetyl methylcarbinol).
Anethole (parapropenyl anisole).
Benzaldehyde (benzoic aldehyde).
N-Butyric acid (butanoic acid).
d- or *l*-Carvone (carvol).
Cinnamaldehyde (cinnamic aldehyde).
Citral (2,6-dimethyloctadien-2,6-*al*-8, geranial, neral).
Decanal (*N*-decylaldehyde, capraldehyde, capric aldehyde, caprinaldehyde, aldehyde C-10).
Ethyl acetate.
Ethyl butyrate.
3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-methyl-phenyl-glycidate, so-called strawberry aldehyde, C-16 aldehyde).
Ethyl vanillin.
Geraniol (3,7-dimethyl-2,6 and 3,6-octadien-1-*ol*).
Geranyl acetate (geraniol acetate).
Limonene (*d*-, *l*-, and *dl*-).
Linalool (linalol, 3,7-dimethyl-1,6-octadien-3-*ol*).
Linalyl acetate (bergamol).
Methyl anthranilate (methyl-2-aminobenzoate).
Piperonal (3,4-methylenedioxy-benzaldehyde, heliotropin).
Vanillin.

[42 FR 14640, Mar. 15, 1977, as amended at 43 FR 47724, Oct. 17, 1978; 44 FR 3963, Jan. 19, 1979; 44 FR 20656, Apr. 6, 1979; 48 FR 51907, Nov. 15, 1983; 54 FR 7402, Feb. 21, 1989]

§ 182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging.

Substances migrating to food from cotton and cotton fabrics used in dry food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Beef tallow.
Carboxymethylcellulose.
Coconut oil, refined.
Cornstarch.
Gelatin.
Lard.
Lard oil.
Oleic acid.
Peanut oil.
Potato starch.
Sodium acetate.
Sodium chloride.

Sodium silicate.
Sodium tripolyphosphate.
Soybean oil (hydrogenated).
Talc.
Tallow (hydrogenated).
Tallow flakes.
Tapioca starch.
Tetrasodium pyrophosphate.
Wheat starch.
Zinc chloride.

[42 FR 14640, Mar. 15, 1977, as amended at 43 FR 11698, Mar. 21, 1978; 44 FR 28323, May 15, 1979; 45 FR 6085, Jan. 25, 1980; 47 FR 27807, 27814, June 25, 1982; 48 FR 51150, Nov. 7, 1983; 48 FR 51616, Nov. 10, 1983; 48 FR 51909, Nov. 15, 1983; 48 FR 52441, 52443, 52445, 52446, Nov. 18, 1983; 51 FR 16830, May 7, 1986; 51 FR 27171, July 30, 1986; 60 FR 62208, Dec. 5, 1995]

§ 182.90 Substances migrating to food from paper and paperboard products.

Substances migrating to food from paper and paperboard products used in food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

Alum (double sulfate of aluminum and ammonium potassium, or sodium).
Aluminum hydroxide.
Aluminum oleate.
Aluminum palmitate.
Casein.
Cellulose acetate.
Cornstarch.
Diatomaceous earth filler.
Ethyl cellulose.
Ethyl vanillin.
Glycerin.
Oleic acid.
Potassium sorbate.
Silicon dioxides.
Sodium aluminate.
Sodium chloride.
Sodium hexametaphosphate.
Sodium hydrosulfite.
Sodium phosphoaluminate.
Sodium silicate.
Sodium sorbate.
Sodium tripolyphosphate.
Sorbitol.
Soy protein, isolated.
Starch, acid modified.
Starch, pregelatinized.
Starch, unmodified.
Talc.
Vanillin.
Zinc hydrosulfite.
Zinc sulfate.

[42 FR 14640, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 182.90, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 182.99 Adjuvants for pesticide chemicals.

Adjuvants, identified and used in accordance with 40 CFR 180.910 and 40 CFR 180.920, which are added to pesticide use dilutions by a grower or applicator prior to application to the raw agricultural commodity, are exempt from the requirement of tolerances under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).

[76 FR 59249, Sept. 26, 2011]

Subpart B—Multiple Purpose GRAS Food Substances

§ 182.1045 Glutamic acid.

(a) *Product.* Glutamic acid.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.

§ 182.1047 Glutamic acid hydrochloride.

(a) *Product.* Glutamic acid hydrochloride.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a salt substitute in accordance with good manufacturing practice.

§ 182.1057 Hydrochloric acid.

(a) *Product.* Hydrochloric acid.
(b) [Reserved]
(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a buffer and neutralizing agent in accordance with good manufacturing practice.

§ 182.1073 Phosphoric acid.

(a) *Product.* Phosphoric acid.
(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1087 Sodium acid pyrophosphate.

(a) *Product.* Sodium acid pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1125 Aluminum sulfate.

(a) *Product.* Aluminum sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1127 Aluminum ammonium sulfate.

(a) *Product.* Aluminum ammonium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1129 Aluminum potassium sulfate.

(a) *Product.* Aluminum potassium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1131 Aluminum sodium sulfate.

(a) *Product.* Aluminum sodium sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1180 Caffeine.

(a) *Product.* Caffeine.

(b) *Tolerance.* 0.02 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in cola-type beverages in accordance with good manufacturing practice.

§ 182.1217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1235 Caramel.

(a) *Product.* Caramel.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1320 Glycerin.

(a) *Product.* Glycerin.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1480 Methylcellulose.

(a) *Product.* U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight basis.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1500 Monoammonium glutamate.

(a) *Product.* Monoammonium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1516 Monopotassium glutamate.

(a) *Product.* Monopotassium glutamate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1711 Silica aerogel.

(a) *Product.* Silica aerogel as a finely powdered microcellular silica foam having a minimum silica content of 89.5 percent.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used as a component of an anti-foaming agent in accordance with good manufacturing practice.

§ 182.1745 Sodium carboxymethylcellulose.

(a) *Product.* Sodium carboxymethylcellulose is the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per

anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25 °C.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1748 Sodium caseinate.

(a) *Product.* Sodium caseinate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1781 Sodium aluminum phosphate.

(a) *Product.* Sodium aluminum phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.1810 Sodium tripolyphosphate.

(a) *Product.* Sodium tripolyphosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart C—Anticaking Agents

§ 182.2122 Aluminum calcium silicate.

(a) *Product.* Aluminum calcium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

§ 182.2227 Calcium silicate.

(a) *Product.* Calcium silicate.

(b) *Tolerance.* 2 percent and 5 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used at levels not exceeding 2 percent in table salt and 5 percent in baking powder in accordance with good manufacturing practice.

§ 182.2437 Magnesium silicate.

(a) *Product.* Magnesium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

§ 182.2727 Sodium aluminosilicate.

(a) *Product.* Sodium aluminosilicate (sodium silicoaluminate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing practice.

§ 182.2729 Sodium calcium aluminosilicate, hydrated.

(a) *Product.* Hydrated sodium calcium aluminosilicate (sodium calcium silicoaluminate).

(b) *Tolerance.* This substance is generally recognized as safe for use at a level not exceeding 2 percent in accordance with good manufacturing practice.

§ 182.2906 Tricalcium silicate.

(a) *Product.* Tricalcium silicate.

(b) *Tolerance.* 2 percent.

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

Subpart D—Chemical Preservatives

§ 182.3013 Ascorbic acid.

(a) *Product.* Ascorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3041 Erythorbic acid.

(a) *Product.* Erythorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3089 Sorbic acid.

(a) *Product.* Sorbic acid.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3109 Thiodipropionic acid.

(a) *Product.* Thiodipropionic acid.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3149 Ascorbyl palmitate.

(a) *Product.* Ascorbyl palmitate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3169 Butylated hydroxyanisole.

(a) *Product.* Butylated hydroxyanisole.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3173 Butylated hydroxytoluene.

(a) *Product.* Butylated hydroxytoluene.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3189 Calcium ascorbate.

(a) *Product.* Calcium ascorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3225 Calcium sorbate.

(a) *Product.* Calcium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3280 Dilauryl thiodipropionate.

(a) *Product.* Dilauryl thiodipropionate.

(b) *Tolerance.* This substance is generally recognized as safe for use in food when the total content of antioxidants is not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food, provided the substance is used in accordance with good manufacturing practice.

§ 182.3616 Potassium bisulfite.

(a) *Product.* Potassium bisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits and vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986; 55 FR 9832, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3637 Potassium metabisulfite.

(a) *Product.* Potassium metabisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits and vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986; 55 FR 9832, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3640 Potassium sorbate.

(a) *Product.* Potassium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3731 Sodium ascorbate.

(a) *Product.* Sodium ascorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3739 Sodium bisulfite.

(a) *Product.* Sodium bisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to the consumer as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986; 55 FR 9832, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3766 Sodium metabisulfite.

(a) *Product.* Sodium metabisulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25025, July 9, 1986; 55 FR 9833, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3795 Sodium sorbate.

(a) *Product.* Sodium sorbate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.3798 Sodium sulfite.

(a) *Product.* Sodium sulfite.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25026, July 9, 1986; 55 FR 9833, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3862 Sulfur dioxide.

(a) *Product.* Sulfur dioxide.

(b) [Reserved]

(c) *Limitations, restrictions, or explanation.* This substance is generally recognized as safe when used in accordance with good manufacturing practice, except that it is not used in meats; in food recognized as a source of vitamin B_1; on fruits or vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh.

[42 FR 14640, Mar. 15, 1977, as amended at 51 FR 25026, July 9, 1986; 55 FR 9833, Mar. 15, 1990; 59 FR 65939, Dec. 22, 1994]

§ 182.3890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

Subpart E—Emulsifying Agents [Reserved]

Subpart F—Dietary Supplements [Reserved]

Subpart G—Sequestrants [1]

§ 182.6085 Sodium acid phosphate.

(a) *Product.* Sodium acid phosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.6197 Calcium diacetate.

(a) *Product.* Calcium diacetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

[1] For the purpose of this subpart, no attempt has been made to designate those sequestrants that may also function as chemical preservatives.

§ 182.8217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8223 Calcium pyrophosphate.

(a) *Product.* Calcium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8250 Choline bitartrate.

(a) *Product.* Choline bitartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8252 Choline chloride.

(a) *Product.* Choline chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8892 α-Tocopherol acetate.

(a) *Product.* α-Tocopherol acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8985 Zinc chloride.

(a) *Product.* Zinc chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8988 Zinc gluconate.

(a) *Product.* Zinc gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8991 Zinc oxide.

(a) *Product.* Zinc oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8994 Zinc stearate.

(a) *Product.* Zinc stearate prepared from stearic acid free from chickedema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8997 Zinc sulfate.

(a) *Product.* Zinc sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Sec.

Subpart B—Listing of Specific Substances Affirmed as GRAS

in accordance with any limitations and good manufacturing practice gudelines prescribed.

(3) Adequate directions for use to provide a final food product that complies with any limitations prescribed for the ingredient(s).

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 48 FR 48457, 48459, Oct. 19, 1983; 62 FR 15110, Mar. 31, 1997; 81 FR 55051, Aug. 17, 2016]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 184.1005 Acetic acid.

(a) Acetic acid ($C_2H_4O_2$, CAS Reg. No. 64–19–7) is known as ethanoic acid. It occurs naturally in plant and animal tissues. It is produced by fermentation of carbohydrates or by organic synthesis. The principal synthetic methods currently employed are oxidation of acetaldehyde derived from ethylene, liquid phase oxidation of butane, and reaction of carbon monoxide with methanol derived from natural gas.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 8, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) The ingredient is used as a curing and pickling agent as defined in §170.3(o)(5) of this chapter; flavor enhancer as defined in §170.3(o)(11) of this chapter; flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; as a solvent and vehicle as defined in §170.3(o)(27) of this chapter; and as a boiler water additive complying with §173.310 of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level as served, of 0.25 percent for baked goods as defined in §170.3(n)(1) of this chapter; 0.8 percent for cheeses as defined in §170.3(n)(5) of this chapter and dairy product analogs as defined in §170.3(n)(10) of this chapter; 0.5 percent for chewing gum as defined in §170.3(n)(6) of this chapter; 9.0 percent for condiments and relishes as defined in §170.3(n)(8) of this chapter; 0.5 percent for fats and oils as defined in §170.3(n)(12) of this chapter; 3.0 percent for gravies and sauces as defined in §170.3(n)(24) of this chapter; 0.6 percent for meat products as defined in §170.3(n)(29) of this chapter; and 0.15 percent or less for all other food categories. The ingredient may also be used in boiler water additives at levels not to exceed current good manufacturing practice.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27814, June 25, 1982]

§ 184.1007 Aconitic acid.

(a) Aconitic acid (1,2,3-propenetricarboxylic acid ($C_6H_6O_6$), CAS Reg. No. 000499–12–7) occurs in the leaves and tubers of *Aconitum napellus* L. and other *Ranunculaceae*. Transaconitic acid can be isolated during sugarcane processing, by precipitation as the calcium salt from cane sugar or molasses. It may be synthesized by sulfuric acid dehydration of citric acid, but not by the methanesulfonic acid method.

(b) The ingredient meets the following specifications:

(1) *Assay*. Not less than 98.0 percent of $C_3H_3(COOH)_3$, using the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 102–103, test for citric acid, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and a molecular weight of 174.11. Copies of the material incorporated by reference are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For

information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(2) *Melting point.* Not less than 195 °C and the determination results in decomposition of aconitic acid.

(3) *Heavy metals* (*as Pb*). Not more than 10 parts per million.

(4) *Arsenic* (*as As*). Not more than 3 parts per million.

(5) *Oxalate.* Passes test.

(6) *Readily carbonizable substances.* Passes the test for citric acid of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 102–103, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(7) *Residue on ignition.* Not more than 0.1 percent as determined by the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 102–103, test for citric acid, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(c) The ingredient is used as a flavoring substance and adjuvant as defined in §170.3(o)(12) of this chapter.

(d) The ingredient is used in food, in accordance with §184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.003 percent for baked goods as defined in §170.3(n)(1) of this chapter, 0.002 percent for alcoholic beverages as defined in §170.3(n)(2) of this chapter, 0.0015 percent for frozen dairy products as defined in §170.3(n)(20) of this chapter, 0.0035 percent for soft candy as defined in §170.3(n)(38) of this chapter, and 0.0005 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 47724, Oct. 17, 1978, as amended at 49 FR 5610, Feb. 14, 1984; 64 FR 1759, Jan. 12, 1999; 81 FR 5595, Feb. 3, 2016]

§184.1009 Adipic acid.

(a) Adipic acid ($C_6H_{10}O_4$, CAS Reg. No. 00124–04–9) is also known as 1,4-butanedicarboxylic acid or hexanedioic acid. It is prepared by nitric acid oxidation of cyclohexanol or cyclohexanone or a mixture of the two.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 11, which is incorporated by reference (Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*), and the following additional specifications:

(1) The adipic acid is converted to its corresponding amide. The amide is purified by recrystallization from water or aqueous ethanol. The melting range of the amide is 219° to 220 °C.

(2) The adipic acid is converted to its corresponding *bis-p-p*-bromophenacyl ester. The ester is purified by recrystallization from ethanol. The melting range of the ester is 153° to 154 °C.

(c) The ingredient is used as a flavoring agent as defined in §170.3(o)(12) of this chapter; leavening agent as defined in §170.3(o)(17) of this chapter; and pH control agent as defined in §170.3(o)(23) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in maximum levels, as served, of 0.05 percent for baked goods as defined in §170.3(n)(1) of this chapter; 0.005 percent for nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; 5.0 percent for condiments and relishes as defined in §170.3(n)(8) of this chapter; 0.45 percent for dairy product analogs as defined in §170.3(n)(10) of this chapter; 0.3 percent for fats and oil as defined in §170.3(n)(12) of this chapter; 0.0004 percent for frozen dairy desserts as defined in §170.3(n)(20) of this chapter; 0.55 percent for gelatin and puddings as defined in §170.3(n)(22) of this chapter; 0.1

percent for gravies as defined in §170.3(n)(24) of this chapter; 0.3 percent for meat products as defined in §170.3(n)(29) of this chapter; 1.3 percent for snack foods as defined in §170.3(n)(37) of this chapter; and 0.02 percent or less for all other food categories.

(e) Prior sanctions for adipic acid different from the uses established in this section do not exist or have been waived.

[47 FR 27810, June 25, 1982]

§ 184.1011 Alginic acid.

(a) Alginic acid is a colloidal, hydrophilic polysaccharide obtained from certain brown algae by alkaline extraction.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 13, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Soup and soup mixes, §170.3(n)(40) of this chapter.	Not to exceed current good manufacturing practice.	Emulsifier, emulsifier salt, §170.3(o)(8) of this chapter; formulation aid, §170.3(o)(14) of this chapter; stabilizer, thickener, §170.3(o)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[47 FR 47375, Oct. 26, 1982]

§ 184.1012 α-Amylase enzyme preparation from Bacillus stearothermophilus.

(a) α-Amylase enzyme preparation is obtained from the culture filtrate that results from a pure culture fermentation of a nonpathogenic and nontoxicogenic strain of *Bacillus stearothermophilus*. Its characterizing enzyme activity is α-amylase (1,4 α-D glucan glucanohydrolase (E.C. 3.2.1.1)).

(b) The ingredient meets the general and additional requirements for enzyme preparations in the ''Food Chemicals Codex,'' 3d ed. (1981), pp. 107–110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practices. The affirmation of this ingredient as GRAS as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in §170.3(o)(9) of this chapter, in the hydrolysis of edible starch to produce maltodextrins and nutritive carbohydrate sweeteners.

(2) The ingredient is used at levels not to exceed current good manufacturing practices.

[60 FR 55789, Nov. 3, 1995, as amended at 78 FR 14666, Mar. 7, 2013]

§ 184.1021 Benzoic acid.

(a) Benzoic acid is the chemical benzenecarboxylic acid ($C_7H_6O_2$), occurring in nature in free and combined forms. Among the foods in which benzoic acid occurs naturally are cranberries, prunes, plums, cinnamon, ripe

cloves, and most berries. Benzoic acid is manufactured by treating molten phthalic anhydride with steam in the presence of a zinc oxide catalyst, by the hydrolysis of benzotrichloride, or by the oxidation of toluene with nitric acid or sodium bichromate or with air in the presence of a transition metal salt catalyst.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 35, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter, and as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.1 percent in food. (The Food and Drug Administration has not determined whether significantly different conditions of use would be GRAS).

(e) Prior sanctions for this ingredient different from those uses established in this section, or different from that set forth in part 181 of this chapter, do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5610, Feb. 14, 1984]

§ 184.1024 Bromelain.

(a) Bromelain (CAS Reg. No. 9001–00–7) is an enzyme preparation derived from the pineapples *Ananas comosus* and *A. bracteatus* L. It is a white to light tan amorphous powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.22.32).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC, or may be examined at Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32910, June 26, 1995, as amended at 78 FR 14666, Mar. 7, 2013]

§ 184.1025 Caprylic acid.

(a) Caprylic acid [$CH_3(CH_2)_6COOH$, CAS Reg. No. 124–07–2] is the chemical name for octanoic acid. It is considered to be a short or medium chain fatty acid. It occurs normally in various foods and is commercially prepared by oxidation of *n*-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 207, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/*

code__of__federal__regulations/ibr__locations.html.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(d) The ingredient is used in foods in accordance with §184.1(b)(1), at levels not to exceed good manufacturing practice. Current good manufacturing practices result in maximum levels, as served, of: 0.013 percent for baked goods as defined in §170.3(n)(1) of this chapter; 0.04 percent for cheeses as defined in §170.3(n)(5) of this chapter; 0.005 percent for fats and oils as defined in §170.3(n)(12) of this chapter, for frozen dairy desserts as defined in §170.3(n)(20) of this chapter, for gelatins and puddings as defined in §170.3(n)(22) of this chapter, for meat products as defined in §170.3(n)(29) of this chapter, and for soft candy as defined in §170.3(n)(38) of this chapter; 0.016 percent for snack foods as defined in §170.3(n)(37) of this chapter; and 0.001 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 19843, May 9, 1978, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1027 Mixed carbohydrase and protease enzyme product.

(a) Mixed carbohydrase and protease enzyme product is an enzyme preparation that includes carbohydrase and protease activity. It is obtained from the culture filtrate resulting from a pure culture fermentation of a nonpathogenic strain of *B. licheniformis.*

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 107, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in §170.3(o)(9) of this chapter, to hydrolyze proteins or carbohydrates.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: alcoholic beverages, as defined in §170.3(n)(2) of this chapter, candy, nutritive sweeteners, and protein hydrolyzates.

[48 FR 240, Jan. 4, 1983]

§ 184.1033 Citric acid.

(a) Citric acid ($C_6H_8O_7$, CAS Reg. No. 77–92–9) is the compound 2-hydroxy-1,2,3-propanetricarboxylic acid. It is a naturally occurring constituent of plant and animal tissues. It occurs as colorless crystals or a white powder and may be anhydrous or contain one mole of water per mole of citric acid. Citric acid may be produced by recovery from sources such as lemon or pineapple juice; by mycological fermentation using *Candida spp.*, described in §§173.160 and 173.165 of this chapter; and by the solvent extraction process described in §173.280 of this chapter for the recovery of citric acid from *Aspergillus niger* fermentation liquor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 86–87, and its third supplement (March 1992), pp. 107–108, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, and the Center for Food Safety and Applied Nutrition (HFS–200), 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[59 FR 63895, Dec. 12, 1994]

§ 184.1034 Catalase (bovine liver).

(a) Catalase (bovine liver) (CAS Reg. No. 81457–95–6) is an enzyme preparation obtained from extracts of bovine liver. It is a partially purified liquid or powder. Its characterizing enzyme activity is catalase (EC 1.11.1.6).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to decompose hydrogen peroxide.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32910, June 26, 1995, as amended at 69 FR 24512, May 4, 2004; 78 FR 14666, Mar. 7, 2013]

§ 184.1061 Lactic acid.

(a) Lactic acid ($C_3H_6O_3$, CAS Reg. Nos.: DL mixture, 598–82–3; L-isomer, 79–33–4; D-isomer, 10326–41–7), the chemical 2-hydroxypropanoic acid, occurs naturally in several foods. It is produced commercially either by fermentation of carbohydrates such as glucose, sucrose, or lactose, or by a procedure involving formation of lactonitrile from acetaldehyde and hydrogen cyanide and subsequent hydrolysis to lactic acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 159, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter; a curing and pickling agent as defined in §170.3(o)(5) of this chapter; a flavor enhancer as defined in §170.3(o)(11) of this chapter; a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; and a solvent and vehicle as defined in §170.3(o)(27) of this chapter.

(2) The ingredient is used in food, except in infant foods and infant formulas, at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 35367, Sept. 7, 1984]

§ 184.1063 Enzyme-modified lecithin.

(a) Enzyme-modified lecithin is prepared by treating lecithin with either phospholipase A_2 (EC 3.1.1.4) or pancreatin.

(b) The ingredient meets the specifications in paragraphs (b)(1) through (b)(8) of this section. Unless otherwise noted, compliance with the specifications listed below is determined according to the methods set forth for lecithin in the Food Chemicals Codex, 4th ed. (1996), pp. 220–221, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(1) Acetone-insoluble matter (phosphatides), not less than 50.0 percent.

(2) Acid value, not more than 40.

(3) Lead, not more than 1.0 part per million, as determined by atomic absorption spectroscopy.

(4) Heavy metals (as Pb), not more than 20 parts per million.

(5) Hexane-insoluble matter, not more than 0.3 percent.

(6) Peroxide value, not more than 20.

(7) Water, not more than 4.0 percent.

(8) Lysolecithin, 50 to 80 mole percent of total phosphatides as determined by ''Determination of Lysolecithin Content of Enzyme-Modified Lecithin: Method I,'' dated 1985, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier as defined in §170.3(o)(8) of this chapter.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

[61 FR 45889, Aug. 30, 1996, as amended at 78 FR 14666, Mar. 7, 2013; 81 FR 5595, Feb. 3, 2016]

§ 184.1065 Linoleic acid.

(a) Linoleic acid ((Z, Z)–9, 12-octadecadienoic acid ($C_{17}H_{31}COOH$) (CAS Reg. No. 60–33–3)), a straight chain unsaturated fatty acid with a molecular weight of 280.5, is a colorless oil at room temperature. Linoleic acid may be prepared from edible fats and oils by various methods including hydrolysis and saponification, the Twitchell method, low pressure splitting with catalyst, continuous high pressure counter current splitting, and medium pressure autoclave splitting with catalyst.

(b) The ingredient must be of a purity suitable for its intended use. The ingredient must also meet the specifications in §172.860(b) of this chapter.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter and as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 48534, Dec. 13, 1984, as amended at 73 FR 8606, Feb. 14, 2008]

§ 184.1069 Malic acid.

(a) Malic acid ($C_4H_6O_5$, CAS Reg. No. of L-form 97–67–6, CAS Reg. No. of DL-form 617–48–1) is the common name for 1-hydroxy-1, 2-ethanedicarboxylic acid. L (+) malic acid, referred to as L-malic acid, occurs naturally in various foods. Racemic DL-malic acid does not occur naturally. It is made commercially by hydration of fumaric acid or maleic acid.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 183–184, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredients are used as a flavor enhancer as defined in §170.3(o)(11) of this chapter, flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter, and pH control agent as defined in §170.3(o)(23) of this chapter.

(d) The ingredients are used in food, except baby food, at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 3.4 percent for nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; 3.0 percent for chewing gum as defined in §170.3(n)(6) of this chapter; 0.8 percent for gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter; 6.9 percent for hard candy as defined in §170.3(n)(25) of this chapter; 2.6 percent for jams and jellies as defined in §170.3(n)(28) of this chapter; 3.5 percent for processed fruits and fruit juices as defined in §170.3(n)(35) of this chapter; 3.0 percent for soft candy as defined in §170.3(n)(38) of this chapter; and 0.7 percent for all other food categories.

(e) Prior sanctions for malic acid different from the uses established in this section do not exist or have been waived.

[44 FR 20656, Apr. 6, 1979, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1077 Potassium acid tartrate.

(a) Potassium acid tartrate ($C_4H_5KO_6$, CAS Reg. No. 868–14–4) is the potassium acid salt of l−(+)−tartaric acid and is also called potassium bitartrate or cream of tartar. It occurs as colorless or slightly opaque crystals or as a white, crystalline powder. It has a pleasant, acid taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), P. 238, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking agent as defined in §170.3(o)(1) of this chapter; an antimicrobial agent as defined in §170.3(o)(2) of this chapter; a formulation aid as defined in §170.3(o)(14) of this chapter; a humectant as defined in §170.3(o)(16) of this chapter; a leavening agent as defined in §170.3(o)(17) of this

chapter; A pH control agent as defined in §170.3(o)(23) of this chapter; a processing aid as defined in §170.3(o)(24) of this chapter; a stabilizer and thickener as defined in §170.3(o)(28) of this chapter; and a surface-active agent as defined in §170.3(o)(29) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; confections and frostings as defined in §170.3(n)(9) of this chapter; gelatins and puddings as defined in §170.3(n)(22) of this chapter; hard candy as defined in §170.3(n)(25) of this chapter; jams and jellies as defined in §170.3(n)(28) of this chapter; and soft candy as defined in §170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52446, Nov. 18, 1983]

§ 184.1081 Propionic acid.

(a) Propionic acid ($C_3H_6O_2$, CAS Reg. No. 79–09–4) is an oily liquid having a slightly pungent, rancid odor. It is manufactured by chemical synthesis or by bacterial fermentation.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 254, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter and a flavoring agent as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 13141, Apr. 3, 1984]

§ 184.1090 Stearic acid.

(a) Stearic acid ($C_{18}H_{36}O_2$, CAS Reg. No. 57–11–4) is a white to yellowish white solid. It occurs naturally as a glyceride in tallow and other animal or vegetable fats and oils and is a principal constituent of most commercially hydrogenated fats. It is produced commercially from hydrolyzed tallow derived from edible sources or from hydrolyzed, completely hydrogenated vegetable oil derived from edible sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 313, which is incorporated by reference, and the requirements of §172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[48 FR 52445, Nov. 18, 1983, as amended at 50 FR 49536, Dec. 3, 1985; 69 FR 24512, May 4, 2004]

§ 184.1091 Succinic acid.

(a) Succinic acid ($C_4H_6O_4$, CAS Reg. No. 110–15–6), also referred to as amber acid and ethylenesuccinic acid, is the chemical 1,4-butanedioic acid. It is commercially prepared by hydrogenation of maleic or fumaric acid. It can also be produced by aqueous alkali or acid hydrolysis of succinonitrile.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 314–315, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as a flavor enhancer as defined in §170.3(o)(11) of this chapter and pH control agent as defined in §170.3(o)(23) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.084 percent in condiments and relishes as defined in §170.3(n)(8) of this chapter and 0.0061 percent in meat products as defined in §170.3(n)(29) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[44 FR 20657, Apr. 6, 1979, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1095 Sulfuric acid.

(a) Sulfuric acid (H_2SO_4, CAS Reg. No. 7664–93–9), also known as oil of vitriol, is a clear, colorless, oily liquid. It is prepared by reacting sulfur dioxide (SO_2) with oxygen and mixing the resultant sulfur trioxide (SO_3) with water, or by reacting nitric oxide (NO) with sulfur dioxide and water.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 317–318, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as a pH control agent as defined in §170.3(o)(23) of this chapter and processing aid as defined in §170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.014 percent for alcoholic beverages as defined in §170.3(n)(2) of this chapter and 0.0003 percent for cheeses as defined in §170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6085, Jan. 25, 1980, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1097 Tannic acid.

(a) Tannic acid (CAS Reg. No. 1401–55–4), or hydrolyzable gallotannin, is a complex polyphenolic organic structure that yields gallic acid and either glucose or quinic acid as hydrolysis products. It is a yellowish-white to light brown substance in the form of an amorphous, bulky powder, glistening scales, or spongy masses. It is also ordorless, or has a faint characteristic odor, and has an astringent taste. Tannic acid is obtained by solvent extraction of nutgalls or excrescences that form on the young twigs of *Quercus infectoria Oliver* and related species of *Quercus*. Tannic acid is also obtained by solvent extraction of the seed pods of Tara (*Caesalpinia spinosa*) or the

nutgalls of various sumac species, including *Rhus semialata*, *R. coriaria*, *R. galabra*, and *R. typhia*.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 319, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c)(1) In accordance with §184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Baked goods and baking mixes, §170.3(n)(1) of this chapter.	0.01	Flavoring agent and adjuvant, §170.3(o)(12) of this chapter.
Alcoholic beverages, §170.3(n)(2) of this chapter	0.015	Flavor enhancer, §170.3(o)(11) of this chapter; flavoring agent and adjuvant, §170.3(o)(12) of this chapter; processing aid, §170.3(o)(24) of this chapter.
Nonalcoholic beverages and beverage bases, §170.3(n)(3) of this chapter and for gelatins, puddings, and fillings, §170.3(n)(22) of this chapter.	0.005	Flavoring agent and adjuvant, §170.3(o)(12) of this chapter; pH control agent, §170.3(o)(23) of this chapter.
Frozen dairy desserts and mixes, §170.3(n)(20) of this chapter and for soft candy, §170.3(n)(38) of this chapter.	0.04	Flavoring agent and adjuvant, §170.3(o)(12) of this chapter.
Hard candy and cough drops, §170.3(n)(25) of this chapter.	0.013	Do.
Meat products, §170.3(n)(29) of this chapter	0.001	Do.

(2) Tannic acid may be used in rendered animal fat in accordance with 9 CFR 424.21.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 21043, May 22, 1985, as amended at 85 FR 72907, Nov. 16, 2020

§ 184.1099 Tartaric acid.

(a) Food grade tartaric acid ($C_4H_6O_6$, CAS Reg. No. 87–69–4) has the l configuration. The l form of tartaric acid is dextrorotatory in solution and is also known as l−(+)−tartaric acid. Tartaric acid occurs as colorless or translucent crystals or as a white, crystalline powder. It is odorless and has an acid taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), P. 320, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a firming agent as defined in §170.3(o)(10) of this chapter; a flavor enhancer as defined in §170.3(o)(11) of this chapter; a flavoring agent as defined in §170.3(o)(12) of this chapter; a humectant as defined in §170.3(o)(16) of this chapter; and a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52447, Nov. 18, 1983, as amended at 50 FR 49536, Dec. 3, 1985]

§ 184.1101 Diacetyl tartaric acid esters of mono- and diglycerides.

(a) Diacetyl tartaric acid esters of mono- and diglycerides, also know as DATEM, are composed of mixed esters of glycerin in which one or more of the hydroxyl groups of glycerin has been esterified by diacetyl tartaric acid and by fatty acids. The ingredient is prepared by the reaction of diacetyl tartaric anhydride with mono- and diglycerides that are derived from edible sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d. Ed. (1981), pp. 98–99, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an emulsifier and emulsifier salt as defined in §170.3(o)(8) of this chapter and a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in §170.3(n)(l) of this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; confections and frostings as defined in §170.3(n)(9) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; and fats and oils as defined in §170.3(n)(12) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

(e) *Labeling:* The acronym ''DATEM'' may be used on food labeling as the alternate common or usual name for the ingredient diacetyl tartaric acid esters of mono- and diglycerides.

[54 FR 7403, Feb. 21, 1989, as amended at 54 FR 13168, Mar. 31, 1989; 54 FR 18382, Apr. 28, 1989; 60 FR 15872, Mar. 28, 1995]

§ 184.1115 Agar-agar.

(a) Agar-agar (CAS Reg. No. PM 9002–18–0) is a dried, hydrophyllic, colloidal polysaccharide extracted from one of a number of related species of red algae (class *Rhodophyceae*).

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 11, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used in food in accordance with §184.1(b)(2) under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Foods (as served)	Percent	Functions
Baked goods and baking mixes, §170.3(n)(1) of this chapter	0.8	Drying agent, §170.3(o)(7) of this chapter; flavoring agent, §170.3(o)(12) of this chapter; stabilizer, thickener, §170.3(o)(28) of this chapter.
Confections and frostings, §170.3(n)(9) of this chapter	2.0	Flavoring agent, §170.3(o)(12) of this chapter; stabilizer, thickener, §170.3(o)(28) of this chapter; surface finisher, §170.3(o)(30) of this chapter.

MAXIMUM USAGE LEVELS PERMITTED—Continued

Foods (as served)	Percent	Functions
Soft candy, § 170.3(n)(38) of this chapter	1.2	Stabilizer and thickener, § 170.3(o)(28) of this chapter.
All other food categories	.25	Flavoring agent, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; humectant, § 170.3(o)(16) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[44 FR 19391, Apr. 3, 1979, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1120 Brown algae.

(a) Brown algae are seaweeds of the species *Analipus japonicus*, *Eisenia bicyclis*, *Hizikia fusiforme*, *Kjellmaniella gyrata*, *Laminaria angustata*, *Laminaria claustonia*, *Laminaria digitata*, *Laminaria japonica*, *Laminaria longicruris*, *Laminaria longissima*, *Laminaria ochotensis*, *Laminaria saccharina*, *Macrocystis pyrifera*, *Petalonia fascia*, *Scytosiphon lomentaria* and *Undaria pinnatifida*. They are harvested principally in coastal waters of the northern Atlantic and Pacific oceans. The material is dried and ground or chopped for use in food.

(b) The ingredient meets the specifications for kelp in the Food Chemicals Codex, 3d Ed. (1981), p. 157, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Spices, seasonings, and flavorings, § 170.3(n)(26) of this chapter.	Not to exceed current good manufacturing practice.	Flavor enhancer, § 170.3(o)(11) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter.

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[47 FR 47376, Oct. 26, 1982]

§ 184.1121 Red algae.

(a) Red algae are seaweeds of the species *Gloiopeltis furcata*, *Porphyra crispata*, *Porphyra deutata*, *Porphyra perforata*, *Porphyra suborbiculata*, *Porphyra tenera* and *Rhodymenia palmata*. *Porphyra* and *Rhodymenia* are harvested principally along the coasts of Japan, Korea, China, Taiwan, and the East and West coasts of the United States. *Gloiopeltis* is harvested principally in southern Pacific coastal waters. The material is dried and ground or chopped for use in food.

(b) The ingredient meets the specifications for kelp in the Food Chemicals Codex, 3d Ed. (1981), p. 157, which is incorporated by reference, except that the loss on drying is not more than 20 percent and the maximum allowable level for iodine is 0.05 percent. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only

within the following specific limitations:

Category of food	Maximum level of use in food (as served)	Functional use
Spices, seasonings, and flavorings, § 170.3(n)(26) of this chapter.	Not to exceed current good manufacturing practice.	Flavor enhancer, § 170.3(o)(11) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter.

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[47 FR 47376, Oct. 26, 1982]

§ 184.1133 Ammonium alginate.

(a) Ammonium alginate (CAS Reg. No. 9005–34–9) is the ammonium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Ammonium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 18, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Confections, frostings, § 170.3(n)(9) of this chapter.	0.4	Stabilizer, thickener, § 170.3(o)(28) of this chapter.
Fats and oils, § 170.3(n)(12) of this chapter.	0.5	Do.
Gelatins, puddings, § 170.3(n)(22) of this chapter.	0.5	Do.
Gravies and sauces, § 170.3(n)(24) of this chapter.	0.4	Do.
Jams and jellies, § 170.3(n)(28) of this chapter.	0.4	Do.
Sweet sauces, § 170.3(n)(43) of this chapter.	0.5	Do.
All other food categories.	0.1	Humectant, § 170.3(o)(16) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter.

(d) Prior sanctions for ammonium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29950, July 9, 1982]

§ 184.1135 Ammonium bicarbonate.

(a) Ammonium bicarbonate (NH_4HCO_3, CAS Reg. No. 1066–33–7) is prepared by reacting gaseous carbon dioxide with aqueous ammonia. Crystals of ammonium bicarbonate are precipitated from solution and subsequently washed and dried.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 19, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter; a leavening agent as

defined in §170.3(o)(17) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; and a texturizer as defined in §170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52439, Nov. 18, 1983]

§ 184.1137 Ammonium carbonate.

(a) Ammonium carbonate ($(NH_4)_2CO_3$, CAS Reg. No. 8000–73–5) is a mixture of ammonium bicarbonate (NH_4HCO_3) and ammonium carbamate (NH_2COONH_4). It is prepared by the sublimation of a mixture of ammonium sulfate and calcium carbonate and occurs as a white powder or a hard, white or translucent mass.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 19, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a leavening agent as defined in §170.3(o)(17) of this chapter and a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52439, Nov. 18, 1983]

§ 184.1138 Ammonium chloride.

(a) Ammonium chloride (NH_4Cl, CAS Reg. No. 12125–02–9) is produced by the reaction of sodium chloride and an ammonium salt in solution. The less soluble sodium salt separates out at elevated temperatures, and ammonium chloride is recovered from the filtrate on cooling. Alternatively, hydrogen chloride formed by the burning of hydrogen in chlorine is dissolved in water and then reacted with gaseous ammonia. Ammonium chloride is crystallized from the solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 20, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave, NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter; a flavor enhancer as defined in §170.3(o)(11) of this chapter; a leavening agent as defined in §170.3(o)(17) of this chapter; and a processing aid as defined in §107.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52439, Nov. 18, 1983]

§ 184.1139 Ammonium hydroxide.

(a) Ammonium hydroxide (NH_4OH, CAS Reg. No. 1336–21–6) is produced by passing ammonia gas into water.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 20, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a leavening agent as defined in §170.3(o)(17) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; a surface-finishing agent as defined in §170.3(o)(30) of this chapter; and as a boiler water additive complying with §173.310 of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. The ingredient may also be used as a boiler water additive at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52440, Nov. 18, 1983, as amended at 59 FR 14551, Mar. 29, 1994]

§ 184.1140 Ammonium citrate, dibasic.

(a) Ammonium citrate, dibasic ($(NH_4)_2HC_6H_5O_7$, CAS Reg. No. 3012–65–5) is the diammonium salt of citric acid. It is prepared by partially neutralizing citric acid with ammonia.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in §170.3(o)(11) of this chapter and as a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in nonalcoholic beverages as defined in §170.3(n)(3) of this chapter and in cheeses as defined in §170.3(n)(5) of this chapter at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63896, Dec. 12, 1994, as amended at 73 FR 8606, Feb. 14, 2008]

§ 184.1141a Ammonium phosphate, monobasic.

(a) Ammonium phosphate, monobasic ($NH_4H_2PO_4$, CAS Reg. No. 7722–76–1) is manufactured by reacting ammonia with phosphoric acid at a pH below 5.8.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 21, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter and a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52440, Nov. 18, 1983]

§ 184.1141b Ammonium phosphate, dibasic.

(a) Ammonium phosphate, dibasic ($(NH_4)_2HPO_4$, CAS Reg. No. 7783–28–0) is manufactured by reacting ammonia with phosphoric acid at a pH above 5.8.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 21, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter; a firming agent as defined in §170.3(o)(10) of this chapter; a leavening agent as defined in §170.3(o)(17) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; and a processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52440, Nov. 18, 1983]

§ 184.1143 Ammonium sulfate.

(a) Ammonium sulfate ($(NH_4)_2SO_4$, CAS Reg. No. 7783–20–2) occurs naturally and consists of colorless or white, odorless crystals or granules. It is prepared by the neutralization of sulfuric acid with ammonium hydroxide.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 22–23, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter, firming agent as defined in §170.3(o)(10) of this chapter, and processing aid as defined in §170.3(o)(24) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.15 percent for baked goods as defined in §170.3(n)(1) of this chapter and 0.1 percent for gelatins and puddings as defined in §170.3(n)(22) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980; 45 FR 16469, Mar. 14, 1980, as amended at 49 FR 5611, Feb. 14, 1984; 85 FR 72907, Nov. 16, 2020]

§ 184.1148 Bacterially-derived carbohydrase enzyme preparation.

(a) Bacterially-derived carbohydrase enzyme preparation is obtained from the culture filtrate resulting from a pure culture fermentation of a nonpathogenic and nontoxigenic strain of *Bacillus subtilis* or *B. amyloliquefaciens*.

The preparation is characterized by the presence of the enzymes α-amylase (EC 3.2.1.1) and β-glucanase (EC 3.2.1.6), which catalyze the hydrolysis of *O*-glycosyl bonds in carbohydrates.

(b) The ingredient meets the general requirements and additional requirements in the monograph on enzyme preparations in the Food Chemicals Codex, 4th ed. (1996), pp. 128–135, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. In addition, antibiotic activity is absent in the enzyme preparation when determined by an appropriate validated method such as the method ''Determination of antibiotic activity'' in the Compendium of Food Additive Specifications, vol. 2, Joint FAO/WHO Expert Committee on Food Additives (JECFA), Food and Agriculture Organization of the United Nations, Rome, 1992. Copies are available from Bernan Associates, 4611–F Assembly Dr., Lanham, MD 20706, or from The United Nations Bookshop, General Assembly Bldg., rm. 32, New York, NY 10017, or by inquiries sent to *http://www.fao.org*. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5001 Campus Dr., College Park, MD 20740.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze polysaccharides (e.g., starch).

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[64 FR 19894, Apr. 23, 1999, as amended at 81 FR 5595, Feb. 3, 2016]

§ 184.1150 Bacterially-derived protease enzyme preparation.

(a) Bacterially-derived protease enzyme preparation is obtained from the culture filtrate resulting from a pure culture fermentation of a nonpathogenic and nontoxigenic strain of *Bacillus subtilis* or *B. amyloliquefaciens*. The preparation is characterized by the presence of the enzymes subtilisin (EC 3.4.21.62) and neutral proteinase (EC 3.4.24.28), which catalyze the hydrolysis of peptide bonds in proteins.

(b) The ingredient meets the general requirements and additional requirements in the monograph on enzyme preparations in the Food Chemicals Codex, 4th ed. (1996), pp. 128–135, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. In addition, antibiotic activity is absent in the enzyme preparation when determined by an appropriate validated method such as the method ''Determination of antibiotic activity'' in the Compendium of Food Additive Specifications, vol. 2, Joint FAO/WHO Expert Committee on Food Additives (JECFA), Food and Agriculture Organization of the United Nations, Rome, 1992. Copies are available from Bernan Associates, 4611–F Assembly Dr., Lanham, MD 20706, or from The United Nations Bookshop, General Assembly Bldg., rm. 32, New York, NY 10017, or by inquiries sent to *http://www.fao.org*. Copies may be examined

at the Center for Food Safety and Applied Nutrition's Library, 5001 Campus Dr., College Park, MD 20740.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[64 FR 19895, Apr. 23, 1999, as amended at 81 FR 5593, Feb. 3, 2016]

§ 184.1155 Bentonite.

(a) Bentonite ($Al_2O_34SiO_2nH_2O$, CAS Reg. No. 1302–78–9) is principally a colloidal hydrated aluminum silicate. Bentonite contains varying quantities of iron, alkalies, and alkaline earths in the commercial products. Depending on the cations present, natural deposits of bentonite range in color from white to gray, yellow, green, or blue. Bentonite's fine particles provide large total surface area and, hence, pronounced adsorptive capability.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice results in no significant residue in foods.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 43367, Oct. 1, 1982, as amended at 73 FR 8606, Feb. 14, 2008; 76 FR 59249, Sept. 26, 2011]

§ 184.1157 Benzoyl peroxide.

(a) Benzoyl peroxide ($(C_6H_5CO)_2O_2$, CAS Reg. No. 94–36–0) is a colorless, rhombic crystalline solid. It is prepared by reaction of benzoyl chloride, sodium hydroxide, and hydrogen peroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 35, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a bleaching agent in food.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: flour; milk used for production of Asiago fresh and Asiago soft cheese (§133.102), Asiago medium cheese (§133.103), Asiago old cheese (§133.104), Blue cheese (§133.106), Caciocavallo siciliano chesse (§133.111), Gorgonzola cheese (§133.141), Parmesan and reggiano cheese (§133.165), Provolone cheese (§133.181), Romano cheese (§133.183), and Swiss and emmentaler cheese (§133.195) in part 133 of this chapter; and annatto-colored whey, such that the final bleached product conforms to the descriptions and specifications for whey, concentrated whey, or dried whey in §184.1979(a)(1), (2), or (3), respectively.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 27173, July 30, 1986]

§ 184.1165 n-Butane and iso-butane.

(a) n-Butane and iso-butane (empirical formula C_4H_{10}, CAS Reg. Nos. 106–97–8 and 75–28–5, respectively) are colorless, flammable gases at normal temperatures and pressures. They are easily liquefied under pressure at room temperature and are stored and shipped in the liquid state. The butanes are obtained from natural gas by fractionation following absorption in oil, adsorption to surface-active agents, or refrigeration.

(b) The ingredients must be of a purity suitable for their intended use.

(c) In accordance with §184.1(b)(1), these ingredients are used in food with no limitations other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as propellants, aerating agents, and gases as defined in §170.3(o)(25) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983, as amended at 73 FR 8607, Feb. 14, 2008; 76 FR 59249, Sept. 26, 2011]

§ 184.1185 Calcium acetate.

(a) Calcium acetate ($Ca(C_2H_3O_2)_2$, CAS Reg. No. 62–54–4), also known as acetate of lime or vinegar salts, is the calcium salt of acetic acid. It may be produced by the calcium hydroxide neutralization of acetic acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 44, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as a firming agent as defined in §170.3(o)(10) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; processing aid as defined in §170.3(o)(24) of this chapter; sequestrant as defined in §170.3(o)(26) of this chapter; stabilizer and thickener as defined in §170.3(o)(28) of this chapter; and texturizer as defined in §170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practices in accordance with §184.1(b)(1). Current good manufacturing practices result in a maximum level, as served, of 0.2 percent for baked goods as defined in §170.3(n)(1) of this chapter; 0.02 percent for cheese as defined in §170.3(n)(5) of this chapter; 0.2 percent for gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter; 0.15 percent for sweet sauces, toppings, and syrups as defined in §170.3(n)(43) of this chapter; and 0.0001 percent for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section or in part 181 of this chapter do not exist or have been waived.

[47 FR 27807, June 25, 1982]

§ 184.1187 Calcium alginate.

(a) Calcium alginate (CAS Reg. No. 9005–35–0) is the calcium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Calcium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents, or from sodium alginate by metathesis with appropriate calcium salts.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 45, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and

Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Baked goods, §170.3(n)(1) of this chapter.	0.002	Stabilizer, thickener, §170.3(o)(28) of this chapter.
Alcoholic beverages, §170.3(n)(2) of this chapter.	0.4	Do.
Confections and frostings, §170.3(n)(9) of this chapter.	0.4	Do.
Egg products, §170.3(n)(11) of this chapter.	0.6	Do.
Fats and oils, §170.3(n)(12) of this chapter.	0.5	Do.
Gelatins, puddings, §170.3(n)(22) of this chapter.	0.25	Do.
Gravies and sauces, §170.3(n)(24) of this chapter.	0.4	Do.
Jams and jellies, §170.3(n)(28) of this chapter.	0.5	Do.
Sweet sauces, §170.3(n)(43) of this chapter.	0.5	Do.
All other food categories.	0.3	Do.

(d) Prior sanctions for calcium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29951, July 9, 1982]

§184.1191 Calcium carbonate.

(a) Calcium carbonate ($CaCO_3$, CAS Reg. No. 471–34–1) is prepared by three common methods of manufacture:

(1) As a byproduct in the ''Lime soda process'';

(2) By precipitation of calcium carbonate from calcium hydroxide in the ''Carbonation process''; or

(3) By precipitation of calcium carbonate from calcium chloride in the ''Calcium chloride process''.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 46, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from that set forth in part 181 of this chapter, do not exist or have been waived.

[48 FR 52441, Nov. 18, 1983]

§184.1193 Calcium chloride.

(a) Calcium chloride ($CaCl_2 \cdot 2H_2O$, CAS Reg. No. 10035–04–8) or anhydrous calcium chloride ($CaCl_2$, CAS Reg. No. 10043–52–4) may be commercially obtained as a byproduct in the ammonia-soda (Solvay) process and as a joint product from natural salt brines, or it may be prepared by substitution reactions with other calcium and chloride salts.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 47, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as an anticaking agent as defined in §170.3(o)(1) of this chapter; antimicrobial agent as defined in §170.3(o)(2) of this chapter; curing or pickling agent as defined in §170.3(o)(5)

of this chapter; firming agent as defined in §170.3(o)(10) of this chapter; flavor enhancer as defined in §170.3(o)(11) of this chapter; humectant as defined in §170.3(o)(16) of this chapter; nutrient supplement as defined in §170.3(o)(20) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; processing aid as defined in §170.3(o)(24) of this chapter; stabilizer and thickener as defined in §170.3(o)(28) of this chapter; surface-active agent as defined in §170.3(o)(29) of this chapter; synergist as defined in §170.3(o)(31) of this chapter; and texturizer as defined in §170.3(o)(32) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practices in accordance with §184.1(b)(1). Current good manufacturing practices result in a maximum level, as served, of 0.3 percent for baked goods as defined in §170.3(n)(1) of this chapter and for dairy product analogs as defined in §170.3(n)(10) of this chapter; 0.22 percent for nonalcoholic beverages and beverage bases as defined in §170.3(n)(3) of this chapter; 0.2 percent for cheese as defined in §170.3(n)(5) of this chapter and for processed fruit and fruit juices as defined in §170.3(n)(35) of this chapter; 0.32 percent for coffee and tea as defined in §170.3(n)(7) of this chapter; 0.4 percent for condiments and relishes as defined in §170.3(n)(8) of this chapter; 0.2 percent for gravies and sauces as defined in §170.3(n)(24) of this chapter; 0.1 percent for commercial jams and jellies as defined in §170.3(n)(28) of this chapter; 0.25 percent for meat products as defined in §170.3(n)(29) of this chapter; 2.0 percent for plant protein products as defined in §170.3(n)(33) of this chapter; 0.4 percent for processed vegetables and vegetable juices as defined in §170.3(n)(36) of this chapter; and 0.05 percent for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27808, June 25, 1982, as amended at 61 FR 14247, Apr. 1, 1996]

§ 184.1195 Calcium citrate.

(a) Calcium citrate ($Ca_3(C_6H_5O_7)_2 \cdot 4H_2O$, CAS Reg. No. 813–0994–095) is the calcium salt of citric acid. It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate. It occurs as a fine white, odorless powder and usually contains four moles of water per mole of calcium citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 49 and 50, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, and the Center for Food Safety and Applied Nutrition (HFS–200), 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. Calcium citrate may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[59 FR 63896, Dec. 12, 1994]

§ 184.1199 Calcium gluconate.

(a) Calcium gluconate ($[CH_2OH(CHOH)_4COO]_2Ca$, CAS Reg. No. 299–28–5) is the calcium salt of gluconic acid which may be produced by neutralization of gluconic acid with lime or calcium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 51, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or

go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as a firming agent as defined in §170.3(o)(10) of this chapter; formulation aid as defined in §170.3(o)(14) of this chapter; sequestrant as defined in §170.3(o)(26) of this chapter; stabilizer or thickener as defined in §170.3(o)(28) of this chapter; and texturizer as defined in §170.3(o)(32) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practices in accordance with §184.1(b)(1). Current good manufacturing practices result in a maximum level, as served, of 1.75 percent for baked goods as defined in §170.3(n)(1) of this chapter; 0.4 percent for dairy product analogs as defined in §170.3(n)(10) of this chapter; 4.5 percent for gelatins and puddings as defined in §170.3(n)(22) of this chapter; and 0.01 percent for sugar substitutes as defined in §170.3(n)(42) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27808, June 25, 1982]

§ 184.1201 Calcium glycerophosphate.

(a) Calcium glycerophosphate ($C_3H_7CaO_6P$, CAS Reg. No. 27214–00–2) is a fine, white, odorless, almost tasteless, slightly hygroscopic powder. It is prepared by neutralizing glycerophosphoric acid with calcium hydroxide or calcium carbonate. The commercial product is a mixture of calcium β-, and *D*-, and *L*-α-glycerophosphate.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 51–52, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section or different from that as set forth in part 181 of this chapter, do not exist or have been waived.

[57 FR 10813, Mar. 31, 1992]

§ 184.1205 Calcium hydroxide.

(a) Calcium hydroxide ($Ca(OH)_2$, CAS Reg. No. 1305–62–0) is also known as slaked lime or calcium hydrate. It is produced by the hydration of lime.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 52, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 26714, June 29, 1984]

§ 184.1206 Calcium iodate.

(a) Calcium iodate [$Ca(IO_3)_2 \cdot H_2O$, CAS Reg. No. 7789–80–2], also referred to as lautarite, does not occur naturally but can be prepared by passing chlorine

into a hot solution of lime ($CaCO_3$) in which iodine has been dissolved.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 53, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter.

(d) The ingredient is used in the manufacture of bread in accordance with §184.1(b)(2) of this chapter in an amount not to exceed 0.0075 percent based on the weight of the flour.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11699, Mar. 21, 1978, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1207 Calcium lactate.

(a) Calcium lactate ($C_6H_{10}CaO_6 . xH_2O$, where x is any integer up to 5, CAS Reg. No. 814–80–2) is prepared commercially by the neutralization of lactic acid with calcium carbonate or calcium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 53, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a firming agent as defined in §170.3(o)(10) of this chapter; a flavor enhancer as defined in §170.3(o)(11) of this chapter; a flavoring agent or adjuvant as defined in §170.3(o)(12) of this chapter; a leavening agent as defined in §170.3(o)(17) of this chapter; a nutrient supplement as defined in §170.3(o)(20) of this chapter; and a stabilizer and thickener as defined in §170.3(o)(28) of this chapter.

(2) The ingredient is used in food, except in infant foods and infant formulas, at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 35367, Sept. 7, 1984]

§ 184.1210 Calcium oxide.

(a) Calcium oxide (CaO, CAS Reg. No. 1305–78–8) is also known as lime, quick lime, burnt lime, or calx. It is produced from calcium carbonate, limestone, or oyster shells by calcination at temperatures of 1,700–2,450 °F.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 55, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 26714, June 29, 1984]

§ 184.1212 Calcium pantothenate.

(a) Calcium pantothenate ($((C_9H_{16}NO_5)_2Ca$, CAS Reg. No. of the *D*-isomer, 137–08–6) is a salt of pantothenic acid, one of the vitamins of the B complex. Only the *D*-isomer of pantothenic acid has vitamin activity, although both the *D*-isomer and the *DL*-racemic mixture of calcium pantothenate are used in food. Commercial calcium pantothenate is prepared synthetically from isobutyraldehyde and formaldehyde via 1,1-dimethyl-2-hydroxy-propionaldehyde and pantolactone.

(b) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 56, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. Calcium pantothenate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51908, Nov. 15, 1983]

§ 184.1221 Calcium propionate.

(a) Calcium propionate ($C_6H_{10}CaO_4$, CAS Reg. No. 4075–81–4) is the calcium salt of propionic acid. It occurs as white crystals or a crystalline solid, possessing not more than a faint odor of propionic acid. It is prepared by neutralizing propionic acid with calcium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 60, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; cheeses as defined in §170.3(n)(5) of this chapter; confections and frostings as defined in §170.3(n)(9) of this chapter; gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter; and jams and jellies as defined in §170.3(n)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 13141, Apr. 3, 1984]

§ 184.1229 Calcium stearate.

(a) Calcium stearate ($Ca(C_{17}H_{35}COO)_2$, CAS Reg. No. 1529–23–0) is the calcium salt of stearic acid derived from edible

sources. It is prepared as a white precipitate by mixing calcium chloride and sodium stearate in aqueous solution.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 64, which is incorporated by reference, and the requirements of §172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; a lubricant and release agent as defined in §170.3(o)(18) of this chapter; and a stabilizer and thickener as defined in §170.3(o)(28) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52445, Nov. 18, 1983]

§184.1230 Calcium sulfate.

(a) Calcium sulfate ($CaSO_4$, CAS Reg. No. 7778–18–9 or $CaSO_4 \cdot 2H_2O$, CAS Reg. No. 10101–41–4), also known as plaster of Paris, anhydrite, and gypsum, occurs naturally and exists as a fine, white to slightly yellow-white odorless powder. The anhydrous form is prepared by complete dehydration of gypsum, below 300 °C, in an electric oven.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 66, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as an anticaking agent as defined in §170.3(o)(1) of this chapter, color and coloring adjunct as defined in §170.3(o)(4) of this chapter, dough strengthener as defined in §170.3(o)(6) of this chapter, drying agent as defined in §170.3(o)(7) of this chapter, firming agent as defined in §170.3(o)(10) of this chapter, flour treating agent as defined in §170.3(o)(13) of this chapter, formulation aid as defined in §170.3(o)(14) of this chapter, leavening agent as defined in §170.3(o)(17) of this chapter, nutrient supplement as defined in §170.3(o)(20) of this chapter, pH control agent as defined in §170.3(o)(23) of this chapter, processing aid as defined in §170.3(o)(24) of this chapter, stabilizer and thickener as defined in §170.3(o)(28) of this chapter, synergist as defined in §170.3(o)(31) of this chapter, and texturizer as defined in §170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 1.3 percent for baked goods as defined in §170.3(n)(1) of this chapter, 3.0 percent for confections and frostings as defined in §170.3(n)(9) of this chapter, 0.5 percent for frozen dairy desserts and mixes as defined in §170.3(n)(20) of this chapter, 0.4 percent for gelatins and puddings as defined in §170.3(n)(22) of this chapter, 0.5 percent for grain products and pastas as defined in §170.3(n)(23) of this chapter, 0.35 percent for processed vegetables as defined in §170.3(n)(36) of this chapter, and 0.07 percent or less for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980; 45 FR 26319, Apr. 18, 1980, as amended at 49 FR 5611, Feb. 14, 1984]

§ 184.1240 Carbon dioxide.

(a) Carbon dioxide (empirical formula CO_2, CAS Reg. No. 124–38–9) occurs as a colorless, odorless, noncombustible gas at normal temperatures and pressures. The solid form, dry ice, sublimes under atmospheric pressure at a temperature of −78.5 °C. Carbon dioxide is prepared as a byproduct of the manufacture of lime during the ''burning'' of limestone, from the combustion of carbonaceous material, from fermentation processes, and from gases found in certain natural springs and wells.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a leavening agent as defined in §170.3(o)(17) of this chapter; a processing aid as defined in §170.3(o)(24) of this chapter; and a propellant, aerating agent, and gas as defined in §170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1245 *Beta*-carotene.

(a) *Beta*-carotene (CAS Reg. No. 7235–40–7) has the molecular formula $C_{40}H_{56}$. It is synthesized by saponification of vitamin A acetate. The resulting alcohol is either reacted to form vitamin A Wittig reagent or oxidized to vitamin A aldehyde. Vitamin A Wittig reagent and vitamin A aldehyde are reacted together to form *beta*-carotene.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 73, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: dairy product analogs as defined in §170.3(n)(10) of this chapter; fats and oils as defined in §170.3(n)(12) of this chapter; and processed fruits and fruit juices as defined in §170.3(n)(35) of this chapter. *Beta*-carotene may be used in infant formula as a source of vitamin A in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act or with regulations promulgated under section 412(g) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[52 FR 25211, July 6, 1987]

§ 184.1250 Cellulase enzyme preparation derived from Trichoderma longibrachiatum.

(a) Cellulase enzyme preparation is derived from a nonpathogenic, nontoxicogenic strain of *Trichoderma longibrachiatum* (formerly *T. reesei*). The enzyme, cellulase, catalyzes the endohydrolysis of 1,4-beta-glycosidic linkages in cellulose. It is obtained from the culture filtrate resulting from a pure culture fermentation process.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the monograph specifications on enzyme preparations in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 129 to 134, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Box 285, Washington, DC 20055 (Internet *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an enzyme as defined in §170.3(o)(9) of this chapter for the breakdown of cellulose.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[64 FR 28361, May 26, 1999, as amended at 81 FR 5595, Feb. 3, 2016]

§184.1257 Clove and its derivatives.

(a) Cloves are the dried unopened flower buds and calyx tubes, harvested before the flowers have opened, of the clove tree *Eugenia caryophyllata* Thunberg, native to tropical Asia. Their derivatives include essential oils (cloves, CAS Reg. No. 8000–34–8; buds; leaves, CAS Reg. No. 8015–97–2; stems, CAS Reg. No. 8015–98–3; and eugenol, CAS Reg. No. 97–53–0), oleoresins, and natural extractives obtained from clove buds, leaves, and stems.

(b) Clove bud oil, clove leaf oil, clove stem oil, and eugenol meet the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 104–105, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. As determined by analytical methods in the ''Food Chemicals Codex,'' clove oleoresin or other natural extractives (other than clove oils) meet the ''Food Chemicals Codex'' specifications for clove (clove bud) oil and the following modifications:

(1) The assay for phenols, as eugenol, by the ''Food Chemicals Codex'' test, 4th ed. (pp. 104–105), or the volatile oils content by the ''Food Chemicals Codex'' test, 4th ed. (pp. 104–105) should conform to the representation of the vendor;

(2) Optical rotation of the volatile oil between −2° and 0°;

(3) Refractive index of the volatile oil between 1.527 and 1.538 at 20 °C;

(4) Specific gravity of the volatile oil between 1.036 and 1.060; and

(5) Residual solvent free, except those solvents that are GRAS or within tolerance levels as specified in part 173, subpart C, of this chapter.

(c) Clove and its derivatives are used as flavoring agents and adjuvants as defined in §170.3(0)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1).

(e) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[44 FR 3964, Jan. 19, 1979, as amended at 47 FR 11852, Mar. 19, 1982; 49 FR 5611, Feb. 14, 1984; 64 FR 1759, Jan. 12, 1999; 81 FR 5595, Feb. 3, 2016]

§ 184.1259 Cocoa butter substitute.

(a) The common or usual name for the triglyceride 1-palmitoyl-2-oleoyl-3-stearin is ''cocoa butter substitute primarily from palm oil.'' The common or usual name for the triglyceride 1-3-distearoyl-2-olein is ''cocoa butter substitute primarily from high-oleic safflower or sunflower oil.''

(1) The ingredient 1-palmitoyl-2-oleoyl-3-stearin is manufactured by:

(i) Directed esterification of fully saturated 1,3-diglycerides (derived from palm oil) with the anhydride of food-grade oleic acid in the presence of the catalyst trifluoromethane sulfonic acid (§ 173.395 of this chapter), or

(ii) By interesterification of partially saturated 1,2,3-triglycerides (derived from palm oil) with ethyl stearate in the presence of a suitable lipase enzyme preparation that is either generally recognized as safe (GRAS) or has food additive approval for such use.

(2) The ingredient 1-3-distearoyl-2-olein is manufactured by interesterification of partially unsaturated 1,2,3-triglycerides (derived from high-oleic safflower or sunflower oil) with ethyl stearate or stearic acid in the presence of a suitable lipase enzyme preparation that is either GRAS or has food additive approval for such use.

(b) The ingredient meets the following specifications:

(1) Over 90 percent triglycerides, not more than 7 percent diglycerides, not more than 1 percent monoglycerides, and not more than 1 percent free fatty acids.

(2) Total glycerides—98 percent minimum.

(3) Heavy metals (as lead), not more than 10 milligrams per kilogram, as determined by the Heavy Metals Test of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(4) Color—clear, bright, and free from suspended matter.

(5) Odor and taste—free from foreign and rancid odor and taste.

(6) Residual catalyst (''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), sections 25.049–25.055, which is incorporated by reference), residual fluorine; limit of detection 0.2 part per million F; multiply fluoride result by 2.63 to convert to residual catalyst. Copies of the material incorporated by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. The ingredient shall be washed three times in batches with 0.5 percent sodium bicarbonate to remove catalyst residuals in accordance with good manufacturing practice.

(7) Residual methanol—5 parts per million maximum.

(8) Residual fatty acid ethyl esters—not more than 20 parts per million as determined by a ''Modification of Japan Institute of Oils and Fats: Analysis Method of Residual Ethyl Esters of Fatty Acids'' issued by the Fuji Oil Co., which is incorporated by reference. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(9) Hexane—not more than 5 parts per million as determined by the method of Dupuy et al., ''Rapid Quantitative Determination of Residual Hexane in Oils by Direct Gas Chromatography,'' published in the ''Journal of the American Oil Chemists' Society,'' Vol. 52, p. 118–120, 1975, which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in the following food categories at levels not to exceed current good manufacturing practice: Confections and frostings as defined in §170.3(n)(9) of this chapter; coatings of soft candy as defined in §170.3(n)(38) of this chapter; and sweet sauces and toppings as defined in §170.3(n)(43) of this chapter; except that the ingredient may not be used in a standardized food unless permitted by the standard of identity.

(d) The ingredient is used in food in accordance with §184.1(b)(1) at levels not to exceed good manufacturing practice.

[43 FR 54239, Nov. 11, 1978, as amended at 47 FR 11852, Mar. 19, 1982; 49 FR 5611, Feb. 14, 1984; 49 FR 22799, June 1, 1984; 52 FR 47920, Dec. 17, 1987; 52 FR 48905, Dec. 28, 1987; 61 FR 36290, July 10, 1996; 64 FR 1760, Jan. 12, 1999; 78 FR 14666, Mar. 7, 2013; 81 FR 5595, Feb. 3, 2016]

§ 184.1260 Copper gluconate.

(a) Copper gluconate (cupric gluconate $(CH_2OH(CHOH)_4COO)_2Cu$, CAS Reg. No. 527–09–3) is a substance that occurs as light blue to bluish-green, odorless crystals, or as a fine, light blue powder. It is prepared by the reaction of gluconic acid solutions with cupric oxide or basic cupric carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 90, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC. 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter and as a synergist as defined in §170.3(o)(31) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Copper gluconate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 24119, June 12, 1984]

§ 184.1261 Copper sulfate.

(a) Copper sulfate (cupric sulfate, $CuSO_4 \cdot 5\ H_2O$, CAS Reg. No. 7758–99–8) usually is used in the pentahydrate form. This form occurs as large, deep blue or ultramarine, triclinic crystals; as blue granules, or as a light blue powder. The ingredient is prepared by the reaction of sulfuric acid with cupric oxide or with copper metal.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon

the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter and as a processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Copper sulfate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 24119, June 12, 1984, as amended at 73 FR 8607, Feb. 14, 2008; 76 FR 59249, Sept. 26, 2011]

§ 184.1262 Corn silk and corn silk extract.

(a) Corn silk is the fresh styles and stigmas of *Zea mays* L. collected when the corn is in milk. The filaments are extracted with dilute ethanol to produce corn silk extract. The extract may be concentrated at a temperature not exceeding 60 °C.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(2), the ingredients are used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) [1]	Functional use
Baked goods and baking mixes, §170.3(n)(1) of this chapter.	30	Flavoring agent, §170.3(o)(12) of this chapter.
Nonalcoholic beverages, §170.3(n)(3) of this chapter.	20	Do.
Frozen dairy desserts, §170.3(n)(20) of this chapter.	10	Do.
Soft candy, §170.3(n)(38) of this chapter.	20	Do.
All other food categories.	4	Do.

[1] Parts per million.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 29953, July 9, 1982, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1265 Cuprous iodide.

(a) Cuprous iodide (copper (I) iodide, CuI, CAS Reg. No. 7681–65–4) is a pure white crystalline powder. It is prepared by the reaction of copper sulfate with potassium iodide under slightly acidic conditions.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum treatment level in food	Functional use
Table salt.	0.01 percent	Source of dietary iodine.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 24119, June 12, 1984, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1271 L-Cysteine.

(a) L-Cysteine is the chemical L-2-amino-3-mercaptopropanoic acid ($C_3H_7O_2NS$).

(b) The ingredient meets the appropriate part of the specification set forth in the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 92–93, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener as defined in §170.3(o)(6) of this chapter in yeast-leavened baked goods and baking mixes as defined in §170.3(n)(1) of this chapter.

(d) This regulation is issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1272 L-Cysteine monohydrochloride.

(a) L-Cysteine monohydrochloride is the chemical L-2-amino-3-mercaptopropanoic acid monohydrochloride monohydrate ($C_3H_7O_2NS$ HCl H_2O).

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 92–93, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used to supply up to 0.009 part of total L-cysteine per 100 parts of flour in dough as a dough strengthener as defined in §170.3(o)(6) of this chapter in yeast-leavened baked goods and baking mixes as defined in §170.3(n)(1) of this chapter.

(d) This regulation is issued prior to a general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1277 Dextrin.

(a) Dextrin ($(C_6H_{10}O_5)_n \cdot H_2O$, CAS Reg. No. 9004–53–9) is an incompletely hydrolyzed starch. It is prepared by dry heating corn, waxy maize, waxy milo, potato, arrowroot, wheat, rice, tapioca, or sago starches, or by dry heating the starches after: (1) Treatment with safe and suitable alkalis, acids, or pH control agents and (2) drying the acid or alkali treated starch.

(b) The ingredient meets the specification of the Food Chemicals Codex, 3d Ed. (1981), p. 96, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in §170.3(o)(14) of this chapter; as a processing aid as defined in §170.3(o)(24) of this chapter; as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter; and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51909, Nov. 15, 1983]

§ 184.1278 Diacetyl.

(a) Diacetyl ($C_4H_6O_2$, CAS Reg. No. 431–03–8) is a clear yellow to yellowish green liquid with a strong pungent odor. It is also known as 2,3-butanedione and is chemically synthesized from methyl ethyl ketone. It is miscible in water, glycerin, alcohol, and ether, and in very dilute water solution, it has a typical buttery odor and flavor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 368, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or

go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51907, Nov. 15, 1983]

§184.1282 Dill and its derivatives.

(a) Dill (American or European) is the herb and seeds from *Anethum graveolens* L., and dill (Indian) is the herb and seeds from *Anethum sowa*, D.C. Its derivatives include essential oils, oleoresins, and natural extractives obtained from these sources of dill.

(b) Dill oils meet the description and specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 122–123, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) Dill and its derivatives are used as flavoring agents and adjuvants as defined in §170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice.

(e) [Reserved]

(f) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984; 64 FR 1760, Jan. 12, 1999; 81 FR 5595, Feb. 3, 2016]

§184.1287 Enzyme-modified fats.

(a) Enzyme-modified refined beef fat, enzyme-modified butterfat, and enzyme-modified steam-rendered chicken fat are prepared from refined beef fat; butterfat or milkfat; and steam-rendered chicken fat, respectively, with enzymes that are generally recognized as safe (GRAS). Enzyme-modified milk powder may be prepared with GRAS enzymes from reconstituted milk powder, whole milk, condensed or concentrated whole milk, evaporated milk, or milk powder. The lipolysis is maintained at a temperature that is optimal for the action of the enzyme until appropriate acid development is attained. The enzymes are then inactivated. The resulting product is concentrated or dried.

(b) The ingredients must be of a purity suitable for their intended use.

(c) In accordance with §184.1(b)(1), the ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as flavoring agents and adjuvants as defined in §170.3(o)(12) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[52 FR 25976, July 10, 1987, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1293 Ethyl alcohol.

(a) Ethyl alcohol (ethanol) is the chemical C_2H_5OH.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), p. 136, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter on pizza crusts prior to final baking at levels not to exceed 2.0 percent by product weight.

(d) This regulation is issued prior to general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984; 64 FR 1760, Jan. 12, 1999; 81 FR 5595, Feb. 3, 2016]

§ 184.1295 Ethyl formate.

(a) Ethyl formate ($C_3H_6O_2$, CAS Reg. No. 109–94–4) is also referred to as ethyl methanoate. It is an ester of formic acid and is prepared by esterification of formic acid with ethyl alcohol or by distillation of ethyl acetate and formic acid in the presence of concentrated sulfuric acid. Ethyl formate occurs naturally in some plant oils, fruits, and juices but does not occur naturally in the animal kingdom.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 376, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.05 percent in baked goods as defined in §170.3(n)(1) of this chapter; 0.04 percent in chewing gum as defined in §170.3(n)(6), hard candy as defined in §170.3(n)(25), and soft candy as defined in §170.3(n)(38) of this chapter; 0.02 percent in frozen dairy desserts as defined in §170.3(n)(20) of this chapter; 0.03 percent in gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter; and 0.01 percent in all other food categories.

(e) Prior sanctions for ethyl formate different from the uses established in this section do not exist or have been waived.

[45 FR 22915, Apr. 4, 1980, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1296 Ferric ammonium citrate.

(a) Ferric ammonium citrate (iron (III) ammonium citrate) is prepared by the reaction of ferric hydroxide with citric acid, followed by treatment with ammonium hydroxide, evaporating, and drying. The resulting product occurs in two forms depending on the stoichiometry of the initial reactants.

(1) Ferric ammonium citrate (iron (III) ammonium citrate, CAS Reg. No. 1332–98–5) is a complex salt of undetermined structure composed of 16.5 to 18.5 percent iron, approximately 9 percent ammonia, and 65 percent citric acid and occurs as reddish brown or garnet red scales or granules or as a brownish-yellowish powder.

(2) Ferric ammonium citrate (iron (III) ammonium citrate, CAS Reg. No. 1333–00–2) is a complex salt of undetermined structure composed of 14.5 to 16 percent iron, approximately 7.5 percent ammonia, and 75 percent citric acid and occurs as thin transparent green

scales, as granules, as a powder, or as transparent green crystals.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 116–117 (Ferric ammonium citrate, brown) and p. 117 (Ferric ammonium citrate, green), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredients are used in food as nutrient supplements as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredients may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[53 FR 16864, May 12, 1988]

§ 184.1297 Ferric chloride.

(a) Ferric chloride (iron (III) chloride, $FeC1_3$, CAS Reg. No. 7705–08–0) may be prepared from iron and chlorine or from ferric oxide and hydrogen chloride. The pure material occurs as hydroscopic, hexagonal, dark crystals. Ferric chloride hexahydrate (iron (III) chloride hexahydrate, $FeC1_3 . 6H_20$, CAS Reg. No. 10025–77–1) is readily formed when ferric chloride is exposed to moisture.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1) the ingredient is used in food as a flavoring agent as defined in §170.3(o)(12) of this chapter, with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16864, May 12, 1988, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1298 Ferric citrate.

(a) Ferric citrate (iron (III) citrate, $C_6H_5FeO_7$, CAS Reg. No. 2338–05–8) is prepared from reaction of citric acid with ferric hydroxide. It is a compound of indefinite ratio of citric acid and iron.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16865, May 12, 1988, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1301 Ferric phosphate.

(a) Ferric phosphate (ferric orthophosphate, iron (III) phosphate, $FePO_4 \cdot xH_2O$, CAS Reg. No. 10045–86–0) is an odorless, yellowish-white to buff-colored powder and contains from one to four molecules of water of hydration. It is prepared by reaction of sodium phosphate with ferric chloride or ferric citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 118–120, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/*

code__of__federal__regulations/ibr__locations.html.

(c) In accordance with §184.1(b)(1), the ingredient is used in food as nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16865, May 12, 1988]

§ 184.1304 Ferric pyrophosphate.

(a) Ferric pyrophosphate (iron (III) pyrophosphate, $Fe_4(P_{207})_3 \cdot xH_2O$, CAS Reg. No. 10058–44–3) is a tan or yellowish white colorless powder. It is prepared by reacting sodium pyrophosphate with ferric citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 120, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16865, May 12, 1988; 53 FR 20939, June 7, 1988]

§ 184.1307 Ferric sulfate.

(a) Ferric sulfate (iron (III) sulfate, $Fe_2(SO_4)_3$ CAS Reg. No. 10028–22–5) is a yellow substance that may be prepared by oxidizing iron (II) sulfate or by treating ferric oxide or ferric hydroxide with sulfuric acid.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food as a flavoring agent as defined in §170.3(o)(12) of this chapter, with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16865, May 12, 1988, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1307a Ferrous ascorbate.

(a) Ferrous ascorbate (CAS Reg. No. 24808–52–4) is a reaction product of ferrous hydroxide and ascorbic acid. It is a blue-violet product containing 16 percent iron.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16865, May 12, 1988, as amended at 69 FR 24512, May 4, 2004; 73 FR 8607, Feb. 14, 2008]

§ 184.1307b Ferrous carbonate.

(a) Ferrous carbonate (iron (II) carbonate, $FeCO_3$, CAS Reg. No. 563–71–3) is an odorless, white solid prepared by treating solutions of iron (II) salts with alkali carbonate salts.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Foods, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16865, May 12, 1988, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1307c Ferrous citrate.

(a) Ferrous citrate (iron (II) citrate, ($C_6H_6FeO_7$), CAS Reg. No. 23383–11–1) is a slightly colored powder or white crystals. It is prepared from the reaction of sodium citrate with ferrous sulfate or by direct action of citric acid on iron filings.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1) the ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16866, May 12, 1988, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1307d Ferrous fumarate.

(a) Ferrous fumarate (iron (II) fumarate, ($C_4H_2FeO_4$), CAS Reg. No. 141–01–5) is an odorless, reddish-orange to reddish-brown powder. It may contain soft lumps that produce a yellow streak when crushed. It is prepared by admixing hot solutions of ferrous sulfate and sodium fumarate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 120–122, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with § 184.1(b)(1) the ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)), or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16866, May 12, 1988]

§ 184.1308 Ferrous gluconate.

(a) Ferrous gluconate (iron (II) gluconate dihydrate, $C_{12}H_{22}FeO_{14}{\cdot}2H_2O$, CAS Reg. No. 6047-12-7) is a fine yellowish-gray or pale greenish-yellow powder or granules. It is prepared by reacting hot solutions of barium or calcium gluconate with ferrous sulfate or by heating freshly prepared ferrous carbonate with gluconic acid in aqueous solution.

(b) The ingredient meets the specifications of the Food Chemcials Codex, 3d Ed. (1981), pp. 122–123, which is incorporated by reference. Copies are available from the National Academy Press,

2101 Constitution Avenue NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16866, May 12, 1988; 53 FR 20939, June 7, 1988]

§184.1311 Ferrous lactate.

(a) Ferrous lactate (iron (II) lactate, $C_6H_{10}FeO_6$, CAS Reg. No. 5905–52–2) in the trihydrate form is a greenish-white powder or crystalline mass. It is prepared by reacting calcium lactate or sodium lactate with ferrous sulfate, direct reaction of lactic acid with iron filings, reaction of ferrous chloride with sodium lactate, or reaction of ferrous sulfate with ammonium lactate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 154 to 155, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter and as a color fixative for ripe olives, with no other limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16866, May 12, 1988, as amended at 61 FR 40319, Aug. 2, 1996; 81 FR 5595, Feb. 3, 2016]

§184.1315 Ferrous sulfate.

(a) Ferrous sulfate heptahydrate (iron (II) sulfate heptahydrate, $FeSO_4 \cdot 7H_2O$, CAS Reg. No. 7782–63–0) is prepared by the action of sulfuric acid on iron. It occurs as pale, bluish-green crystals or granules. Progressive heating of ferrous sulfate heptahydrate produces ferrous sulfate (dried). Ferrous sulfate (dried) consists primarily of ferrous sulfate monohydrate (CAS Reg. No. 17375–41–6) with varying amounts of ferrous sulfate tetrahydrate (CAS Reg. No. 20908–72–9) and occurs as a grayish-white to buff-colored powder.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 123 (Ferrous sulfate heptahydrate) and p. 124 (ferrous sulfate, dried), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredients are used in food as nutrient supplements as defined in §170.3(o)(20) of this chapter and as a processing aid as defined in §170.3(o)(24)

of this chapter, with no limitation other than current good manufacturing practice. The ingredients may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[53 FR 16866, May 12, 1988]

§ 184.1316 Ficin.

(a) Ficin (CAS Reg. No. 9001–33–6) is an enzyme preparation obtained from the latex of species of the genus *Ficus*, which include a variety of tropical fig trees. It is a white to off-white powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.22.3).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32910, June 26, 1995, as amended at 78 FR 14666, Mar. 7, 2013]

§ 184.1317 Garlic and its derivatives.

(a) Garlic is the fresh or dehydrated bulb or cloves obtained from *Allium sativum*, a genus of the lily family. Its derivatives include essential oils, oleoresins, and natural extractives obtained from garlic.

(b) Garlic oil meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 132, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) Garlic and its derivatives are used as flavoring agents and adjuvants as defined in §170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice.

(e) [Reserved]

(f) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1318 Glucono delta-lactone.

(a) Glucono delta-lactone ($C_6H_{10}O_6$, CAS Reg. No. 90–80–2), also called *D*-gluconic acid delta-lactone or *D*-glucono-1,5-lactone, is the cyclic 1,5-intramolecular ester of *D*-gluconic acid. It is prepared by direct crystallization from the aqueous solution of gluconic acid. Gluconic acid may be produced by the oxidation of *D*-glucose with bromine water, by the oxidation of *D*-glucose by microorganisms that are nonpathogenic and nontoxicogenic to man or other animals, or by the oxidation of *D*-glucose with enzymes derived from these microorganisms.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 134, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a curing and pickling agent as defined in §170.3(o)(5) of this chapter, leavening agent as defined in §170.3(o)(17) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and sequestrant as defined in §170.3(o)(26) of this chapter.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 33896, Sept. 24, 1986]

§ 184.1321 Corn gluten.

(a) Corn gluten (CAS Reg. No. 66071–96–3), also known as corn gluten meal, is the principal protein component of corn endosperm. It consists mainly of zein and glutelin. Corn gluten is a byproduct of the wet milling of corn for starch. The gluten fraction is washed to remove residual water soluble proteins. Corn gluten is also produced as a byproduct during the conversion of the starch in whole or various fractions of dry milled corn to corn syrups.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter and a texturizer as defined in §170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 8998, Mar. 6, 1985, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1322 Wheat gluten.

(a) Wheat gluten (CAS Reg. No. 8002–80–0) is the principal protein component of wheat and consists mainly of gliadin and glutenin. Wheat gluten is obtained by hydrating wheat flour and mechanically working the sticky mass to separate the wheat gluten from the starch and other flour components. Vital gluten is dried gluten that has retained its elastic properties.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter; a formulation aid as defined in §170.3(o)(14) of this chapter; a nutrient supplement as defined in §170.3(o)(20) of this chapter; a processing aid as defined in §170.3(o)(24) of this chapter; a stabilizer and thickener as defined in §170.3(o)(28) of this chapter; a surface-finishing agent as defined in §170.3(o)(30) of this chapter; and a texturizing agent as defined in §170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 8998, Mar. 6, 1985, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1323 Glyceryl monooleate.

(a) Glyceryl monooleate is prepared by esterification of commerical oleic acid that is derived either from edible sources or from tall oil fatty acids meeting the requirements of § 172.862 of this chapter. It contains glyceryl monooleate ($C_{21}H_{40}O_4$, CAS Reg. No. 25496–72–4) and glyceryl esters of fatty acids present in commercial oleic acid.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter and as a solvent and vehicle as defined in § 170.3(o)(27) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in § 170.3(n)(1) of this chapter; nonalcoholic beverages and beverage bases as defined in § 170.3(n)(3) of this chapter; chewing gum as defined in § 170.3(n)(6) of this chapter; and meat products as defined in § 170.3(n)(29) of this chapter.

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[54 FR 7403 Feb. 21, 1989, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1324 Glyceryl monostearate.

(a) Glyceryl monostearate, also known as monostearin, is a mixture of variable proportions of glyceryl monostearate ($C_{21}H_{42}O_4$, CAS Reg. No. 31566–31–1), glyceryl monopalmitate ($C_{19}H_{38}O_4$, CAS Reg. No. 26657–96–5) and glyceryl esters of fatty acids present in commercial stearic acid. Glyceryl monostearate is prepared by glycerolysis of certain fats or oils that are derived from edible sources or by esterification, with glycerin, of stearic acid that is derived from edible sources.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not not exist or have been waived.

[54 FR 7403 Feb. 21, 1989, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1328 Glyceryl behenate.

(a) Glyceryl behenate is a mixture of glyceryl esters of behenic acid made from glycerin and behenic acid (a saturated C_{22} fatty acid). The mixture contains predominately glyceryl dibehenate.

(b) The ingredient meets the following specifications:

(1) 10 to 20 percent monoglyceride, 47 to 59 percent diglyceride, 26 to 38 percent triglyceride, and not more than 2.5 percent free fatty acids.

(2) *Behenic acid*. Between 80 and 90 percent of the total fatty acid content.

(3) *Acid value*. Not more than 4.

(4) *Saponification value*. Between 145 and 165.

(5) *Iodine number*. Not more than 3.

(6) *Heavy metals (as Pb)*. Not more than 10 parts per million.

(c) In accordance with § 184.1(b)(1) of this chapter, the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient is generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid, as defined in § 170.3(o)(14) of this chapter.

(2) The ingredient is used in excipient formulations for use in tablets at levels

not to exceed good manufacturing practice.

[52 FR 42430, Nov. 5, 1987]

§ 184.1329 Glyceryl palmitostearate.

(a) Glyceryl palmitostearate is a mixture of mono-, di-, and triglyceryl esters of palmitic and stearic acids made from glycerin, palmitic acid, and stearic acid.

(b) The ingredient meets the following specifications:

(1) The substance is a mixture of mono-, di-, and triglycerides of palmitic acid and stearic acid.

(2) Heavy metals (as lead): Not more than 10 parts per million.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid, as defined in §170.3(o)(14) of this chapter.

(2) The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

[60 FR 63621, Dec. 12, 1995]

§ 184.1330 Acacia (gum arabic).

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family Leguminosae.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 7, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Beverages and beverage bases, §170.3(n)(3) of this chapter	2.0	Emulsifier and emulsifier salt, §170.3(o)(8) of this chapter; flavoring agent and adjuvant, §170.3(o)(12) of this chapter; formulation aid, §170.3(o)(14) of this chapter; stabilizer and thickener, §170.3(o)(28) of this chapter.
Chewing gum, §170.3(n)(6) of this chapter	5.6	Flavoring agent and adjuvant, §170.3(o)(12) of this chapter; formulation aid, §170.3(o)(14) of this chapter; humectant, §170.3(o)(16) of this chapter; surface-finishing agent, §170.3(o)(30) of this chapter.
Confections and frostings, §170.3(n)(9) of this chapter	12.4	Formulation aid, §170.3(o)(14) of this chapter; stabilizer and thickener, §170.3(o)(28) of this chapter; surface-finishing agent, §170.3(o)(30) of this chapter.
Dairy product analogs, §170.3(n)(10) of this chapter	1.3	Formulation aid, §170.3(o)(14) of this chapter; stabilizer and thickener, §170.3(o)(28) of this chapter.
Fats and oils, §170.3(n)(12) of this chapter	1.5	Formulation aid, §170.3(o)(14) of this chapter; stabilizer and thickener, §170.3(o)(28) of this chapter.
Gelatins, puddings, and fillings, §170.3(n)(22) of this chapter	2.5	Emulsifier and emulsifier salt, §170.3(o)(8) of this chapter; formulation aid, §170.3(o)(14) of this chapter.; stabilizer and thickener, §170.3(o)(28) of this chapter.
Hard candy and cough drops, §170.3(n)(25) of this chapter	46.5	Flavoring agent and adjuvant, §170.3(o)(12) of this chapter; formulation aid, §170.3(o)(14) of this chapter.
Nuts and nut products, §170.3(n)(32) of this chapter	8.3	Formulation aid, §170.3(o)(14) of this chapter; surface-finishing agent, §170.3(o)(30) of this chapter.
Quiescently frozen confection products	6.0	Formulation aid, §170.3(o)(14) of this chapter; stabilizer and thickener, §170.3(o)(28) of this chapter.
Snack foods, §170.3(n)(37) of this chapter	4.0	Emulsifier and emulsifier salt, §170.3(o)(8) of this chapter; formulation aid, §170.3(o)(14) of this chapter.

MAXIMUM USAGE LEVELS PERMITTED—Continued

Food (as served)	Percent	Function
Soft candy, § 170.3(n)(38) of this chapter	85.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; firming agent, § 170.3(o)(10) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter, humectant, § 170.3(o)(16) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
All other food categories	1.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; processing aid, § 170.3(o)(24) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter; texturizer, § 170.3(o)(32) of this chapter.

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1983; 53 FR 5766, Feb. 26, 1988]

§ 184.1333 Gum ghatti.

(a) Gum ghatti (Indian gum) is an exudate from wounds in the bark of *Anogeissus latifolia*, a large tree found in the dry deciduous forests of India and Ceylon.

(b) The ingredient complies with the following specifications:

(1) *Viscosity of a 1-percent solution*. Not less than the minimum or within the range claimed by the vendor.

(2) *Limits of impurities*—(i) *Arsenic* (*as AL*). Not more than 3 parts per million (0.0003 percent);

(ii) *Ash* (*acid-insoluble*). Not more than 1.75 percent;

(iii) *Ash* (*total*). Not more than 6.0 percent;

(iv) *Heavy metals* (*as Pb*). Not more than 40 parts per million (0.004 percent); and

(v) *Lead*. Not more than 10 parts per million (0.001 percent).

(3) *Loss on drying*. Not more than 14 percent dried at 105 °C for 5 hours.

(4) *Identification test*. Add 0.2 ml of diluted lead acetate as outlined in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 31.178(b), p. 529, under ''Dilute Basic Lead Acetate Standard Solution,'' which is incorporated by reference (Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.), to 5 ml of a cold 1-in-100 aqueous solution of the gum. An immediate, voluminous, opaque precipitate indicates acacia. A small precipitate or clear solution which produces an opaque flocculent precipitate upon the addition of 1 ml of 3 *N* ammonimum hydroxide indicates gum ghatti.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Beverages and beverage bases, nonalcoholic, § 170.3(n)(3) of this chapter.	0.2	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter.
All other food categories	.1	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1339 Guar gum.

(a) Guar gum is the natural substance obtained from the maceration of the seed of the guar plant, *Cyamopsis tetragonoloba* (Linne) Taub., or *Cyamopsis psoraloides* (Lam.) D.C.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 141, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Baked goods and baking mixes, § 170.3(n)(1) of this chapter	0.35	Emulsifier and emulsifier salts, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener; § 170.3(o)(28) of this chapter.
Breakfast cereals, § 170.3(n)(4) of this chapter	1.2	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Cheese, § 170.3(n)(5) of this chapter	.8	Do.
Dairy products analogs, § 170.3(n)(10) of this chapter	1.0	Firming agent, § 170.3(o)(10) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Fats and oils, § 170.3(n)(12) of this chapter	2.0	Do.
Gravies and sauces, § 170.3(n)(24) of this chapter	1.2	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Jams and jellies, commercial, § 170.3(n)(28) of this chapter	1.0	Do.
Milk products, § 170.3(n)(31) of this chapter	.6	Do.
Processed vegetables and vegetable juices, § 170.3(n)(36) of this chapter.	2.0	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Soups and soup mixes, § 170.3(n)(40) of this chapter	.8	Do.
Sweet sauces, toppings and syrups, § 170.3(n)(43) of this chapter.	1.0	Do.
All other food categories	.5	Emulsifier and emulsifier salts, § 170.3(o)(8) of this chapter; firming agent, § 170.3(o)(10) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1343 Locust (carob) bean gum.

(a) Locust (carob) bean gum is primarily the macerated endosperm of the seed of the locust (carob) bean tree, *Ceratonia siliqua* (Linne), a leguminous evergreen tree, with lesser quantities of seed coat and germ.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 174–175, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used at levels not to exceed the following maximum levels:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Baked goods and baking mixes, § 170.3(n)(1) of this chapter.	0.15	Stabilizer and thickener, § 170.3(o)(28) of this chapter.
Beverages and beverage bases, nonalcoholic, § 170.3(n)(3) of this chapter.	.25	Do.
Cheeses, § 170.3(n)(5) of this chapter	.8	Do.
Gelatins, puddings, and fillings, § 170.3(n)(22) of this chapter.	.75	Do.
Jams and jellies, commercial, § 170.3(n)(28) of this chapter.	.75	Do.
All other food categories	.5	Do.

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1349 Karaya gum (sterculia gum).

(a) Karaya gum (sterculia gum) is the dried gummy exudate from the trunk of trees of various species of the genus *Sterculia*.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 157, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Frozen dairy desserts and mixes, § 170.3(n)(20) of this chapter.	0.3	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Milk products, § 170.3(n)(31) of this chapter	.02	Stabilizer and thickener, § 170.3(o)(28) of this chapter.
Soft candy, § 170.3(n)(38) of this chapter	.9	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
All other food categories	.002	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1351 Gum tragacanth.

(a) Gum tragacanth is the exudate from one of several species of *Astragalus gummifier* Labillardiere, a shrub that grows wild in mountainous regions of the Middle East.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 337, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Baked goods and baking mixes, § 170.3(n)(1) of this chapter.	0.2	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Condiments and relishes, § 170.3(n)(8) of this chapter.	.7	Do.
Fats and oils, § 170.3(n)(12) of this chapter	1.3	Do.
Gravies and sauces, § 170.3(n)(24) of this chapter	.8	Do.
Meat products, § 170.3(n)(29) of this chapter	.2	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Processed fruits and fruit juices, § 170.3(n)(35) of this chapter.	.2	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
All other food categories	.1	Do.

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1355 Helium.

(a) Helium (empirical formula He, CAS Reg. No. 7440–59–7) is a colorless, odorless, flavorless, nonflammable, inert gas. It is lighter than air and is produced by the liquefaction and purification of natural gas.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1366 Hydrogen peroxide.

(a) Hydrogen peroxide (H_2O_2, CAS Reg. No. 7722–84–1) is also referred to as hydrogen dioxide. It is made by the electrolytic oxidation of sulfuric acid or a sulfate to persulfuric acid or a persulfuric acid salt with subsequent hydrolysis and distillation of the hydrogen peroxide formed; by decomposition of barium peroxide with sulfuric or phosphoric acid; by hydrogen reduction of 2-ethylanthraquinone, followed by oxidation with air, to regenerate the quinone and produce hydrogen peroxide; or by electrical discharge through a mixture of hydrogen, oxygen, and water vapor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 146–147,[1] which is incorporated by reference.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Food	Maximum treatment level in food (percent)	Functional use
Milk, intended for use during the cheesemaking process as permitted in the appropriate standards of identity for cheese and related cheese products under part 133 of this chapter.	0.05	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter
Whey, during the preparation of modified whey by electrodialysis methods.	0.04	do.
Dried eggs, dried egg whites, and dried egg yolks as in §§ 160.105, 160.145, and 160.185 of this chapter.	Amount sufficient for the purpose.	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter
Tripe	do	Bleaching agent.
Beef feet	Amount sufficient for the purpose. (Hydrogen peroxide may be in the form of a compound salt, sodium carbonate peroxide).	Bleaching agent.
Herring	Amount sufficient for the purpose.	do.
Wine	do	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter.
Starch	0.15	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter, to produce thermophile-free starch; Remove sulfur dioxide from starch slurry following steeping and grinding operations of corn refining.
Instant tea	Amount sufficient for the purpose.	Bleaching agent.
Corn syrup	0.15	Reduce sulfur dioxide levels in the finished corn syrup.
Colored (annatto) cheese whey	0.05	Bleaching agent.
Wine vinegar	Amount sufficient for the purpose.	Remove sulfur dioxide from wine prior to fermentation to produce vinegar.
Emulsifiers containing fatty acid esters	1.25	Bleaching agent.

(d) Residual hydrogen peroxide is removed by appropriate physical and chemical means during the processing of food where it has been used according to paragraph (c) of this section.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[46 FR 44439, Sept. 4, 1981, as amended at 51 FR 27172, July 30, 1986]

§ 184.1370 Inositol.

(a) Inositol, or myo-inositol ($C_6H_{12}O_6$, CAS Reg. No. 87–89–8), is *cis*-1,2,3,5-*trans*-4,6-cyclohexanehexol. It occurs naturally and is prepared from an aqueous (0.2 percent sulfur dioxide) extract of corn kernels by precipitation and hydrolysis of crude phytate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 150, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in special dietary foods as defined in part 105 of this chapter at levels not to exceed current good manufacturing practice. It may also be used in infant formula in accordance with section 412(g) of the Act, or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established by this section do not exist or have been waived.

[47 FR 38278, Aug. 31, 1982]

§ 184.1372 Insoluble glucose isomerase enzyme preparations.

(a) Insoluble glucose isomerase enzyme preparations are used in the production of high fructose corn syrup described in § 184.1866. They are derived from recognized species of precisely classified nonpathogenic and nontoxicogenic microorganisms, including *Streptomyces rubiginosus*, *Actinoplanes missouriensis*, *Streptomyces olivaceus*, *Streptomyces olivochromogenes*, and *Bacillus coagulans*, that have been grown in a pure culture fermentation that produces no antibiotics. They are fixed (rendered insoluble) for batch production with GRAS ingredients or may be fixed for further immobilization with either GRAS ingredients or materials approved under § 173.357 of this chapter.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d Ed. (1981), p. 107, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in § 170.3(o)(9) of this chapter, to convert glucose to fructose.

(2) The ingredient is used in high fructose corn syrup, at levels not to exceed current good manufacturing practice.

[48 FR 5720, Feb. 8, 1983, as amended at 61 FR 43450, Aug. 23, 1996]

§ 184.1375 Iron, elemental.

(a) Iron, elemental (CAS Reg. No. 7439–89–6) is metallic iron obtained by any of the following processes: reduced iron, electrolytic iron, and carbonyl iron.

(1) Reduced iron is prepared by reacting ground ferric oxide with hydrogen or carbon monoxide at an elevated temperature. The process results in a grayish-black powder, all of which should pass through a 100-mesh sieve. It is lusterless or has not more than a slight luster. When viewed under a microscope, it appears as an amorphous powder free from particles having a crystalline structure. It is stable in dry air.

(2) Electrolytic iron is prepared by electrodeposition. It is an amorphous, lusterless, grayish-black powder. It is stable in dry air.

(3) Carbonyl iron is prepared by the decomposition of iron pentacarbonyl. It occurs as a dark gray powder. When viewed under a microscope, it appears as spheres built up with concentric shells. It is stable in dry air.

(b) Iron, elemental (carbonyl, electrolytic, or reduced) meets the specifications of the Food Chemicals Codex, 3d Ed. (1981) (iron, carbonyl, p. 151; iron, electrolytic, pp. 151–152; iron, reduced; pp. 152–153), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with § 184.1(b)(1), the ingredient is used in food as a nutrient supplement as defined in § 170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in accordance with section 412(g) of the Federal Food,

Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(2)).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 16867, May 12, 1988]

§ 184.1386 Isopropyl citrate.

(a) Isopropyl citrate is a mixture of the mono-, di-, and triisopropyl esters of citric acid. It is prepared by esterifying citric acid with isopropanol.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antioxidant as defined in §170.3(o)(3) of this chapter; a sequestrant as defined in §170.3(o)(26) of this chapter; and a solvent and vehicle as defined in §170.3(o)(27) of this chapter.

(2) The ingredient is used in margarine in accordance with §166.110 of this chapter; in nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; and in fats and oils as defined in §170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63896, Dec. 12, 1994, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1387 Lactase enzyme preparation from Candida pseudotropicalis.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic yeast *C. pseudotropicalis*. It contains the enzyme lactase (β-D-galactoside galactohydrolase, EC 3.2.1.23), which converts lactose to glucose and galactose. It is prepared from yeast that has been grown by a pure culture fermentation process.

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), pp. 107–110, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in §170.3(o)(9) of this chapter, to convert lactose to glucose and galactose.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice is limited to use of this ingredient to reduce the lactose content in milk and milk-derived food products where food standards do not preclude such use.

[61 FR 7704, Feb. 29, 1996, as amended at 81 FR 5595, Feb. 3, 2016]

§ 184.1388 Lactase enzyme preparation from Kluyveromyces lactis.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic yeast *Kluyveromyces lactis* (previously named *Saccharomyces lactis)*. It contains the enzyme B-galactoside galactohydrase (CAS Reg. No. CBS 683), which converts lactose to glucose and galactose. It is prepared from yeast that has been grown in a

pure culture fermentation and by using materials that are generally recognized as safe or are food additives that have been approved for this use by the Food and Drug Administration.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d Ed. (1981), p. 107–110, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to convert lactose to glucose and galactose.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice is to use this ingredient in milk to produce lactase-treated milk, which contains less lactose than regular milk, or lactose-reduced milk, which contains at least 70 percent less lactose than regular milk.

[49 FR 47387, Dec. 4, 1984]

§ 184.1400 Lecithin.

(a) Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of othe lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils. Lecithin is bleached, if desired, by hydrogen peroxide and benzoyl peroxide and dried by heating.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 166–167, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51150, Nov. 7, 1983]

§ 184.1408 Licorice and licorice derivatives.

(a)(1) Licorice (glycyrrhiza) root is the dried and ground rhizome and root portions of *Glycyrrhiza glabra* or other species of *Glycyrrhiza*. Licorice extract is that portion of the licorice root that is, after maceration, extracted by boiling water. The extract can be further purified by filtration and by treatment with acids and ethyl alcohol. Licorice extract is sold as a liquid, paste (''block''), or spray-dried powder.

(2) Ammoniated glycyrrhizin is prepared from the water extract of licorice root by acid precipitation followed by neutralization with dilute ammonia. Monoammonium glycyrrhizinate ($C_{42}H_{61}O_{16}NH_45H_2O$, CAS Reg. No. 1407–03–0) is prepared from ammoniated glycyrrhizin by solvent extraction and separation techniques.

(b) The ingredients shall meet the following specifications when analyzed:

(1) *Assay*. The glycyrrhizin content of each flavoring ingredient shall be determined by the method in the Official Methods of Analysis of the Association of Official Analytical Chemists, 13th Ed., §§19.136–19.140, which is incorporated by reference, or by methods 19.CO1 through 19.CO4 in the *Journal of the Association of Official Analytical Chemists*, 65:471–472 (1982), which are also incorporated by reference. Copies of all of these methods are available from the AOAC INTERNATIONAL, 481

North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(2) *Ash*. Not more than 9.5 percent for licorice, 2.5 percent for ammoniated glycyrrhizin, and 0.5 percent for monoammonium glycyrrhizinate on an anhydrous basis as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p. 466, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(3) *Acid unsoluble ash*. Not more than 2.5 percent for licorice on an anhydrous basis as determined by the method in the Food Chemicals Codex, 3d Ed. (1981), p. 466, which is incorporated by reference.

(4) *Heavy metals (as Pb)*. Not more than 40 parts per million as determined by method II in the Food Chemicals Codex, 3d Ed. (1981), p. 512, which is incorporated by reference.

(5) *Arsenic (As)*. Not more than 3 parts per million as determined by the method in the Food Chemicals Codex. 3d Ed. (1981), p. 464, which is incorporated by reference.

(c) In accordance with § 184.1(b)(2), these ingredients are used in food only within the following specific limitations:

Category of food	Maximum level in food (percent glycyrrhizin content of food) (as served)	Functional use
Baked foods, § 170.3(n)(1) of this chapter	0.05	Flavor enhancer, § 170.3(o)(11) of this chapter; flavoring agent, § 170.3(o)(12) of this chapter.
Alcoholic beverages, § 170.3(n)(2) of this chapter	0.1	Flavor enhancer, § 170.3(o)(11) of this chapter; flavoring agent, § 170.3(o)(12) of this chapter; surface-active agent, § 170.3(o)(29) of this chapter.
Nonalcoholic beverages, § 170.3(n)(3) of this chapter	0.15	Do.
Chewing gum, § 170.3(n)(6) of this chapter	1.1	Flavor enhancer, § 170.3(o)(11) of this chapter; flavoring agent, § 170.3(n)(12) of this chapter.
Hard candy, § 170.3(n)(25) of this chapter	16.0	Do.
Herbs and seasonings, § 170.3(n)(26) of this chapter	0.15	Do.
Plant protein products, § 170.3(n)(33) of this chapter	0.15	Do.
Soft candy, § 170.3(n)(38) of this chapter	3.1	Do.
Vitamin or mineral dietary supplements	0.5	Do.
All other foods except sugar substitutes, § 170.3(n)(42) of this chapter. The ingredient is not permitted to be used as a nonnutritive sweetener in sugar substitutes.	0.1	Do.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 21044, May 22, 1985, as amended at 54 FR 24899, June 12, 1989]

§ 184.1409 Ground limestone.

(a) Ground limestone consists essentially (not less than 94 percent) of calcium carbonate ($CaCO_3$) and is prepared by the crushing, grinding, and classifying of naturally occurring limestone.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 173, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or

go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1415 Animal lipase.

(a) Animal lipase (CAS Reg. No. 9001–62–1) is an enzyme preparation obtained from edible forestomach tissue of calves, kids, or lambs, or from animal pancreatic tissue. The enzyme preparation may be produced as a tissue preparation or as an aqueous extract. Its characterizing enzyme activity is that of a triacylglycerol hydrolase (EC 3.1.1.3).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze fatty acid glycerides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995, as amended at 78 FR 14666, Mar. 7, 2013]

§ 184.1420 Lipase enzyme preparation derived from Rhizopus niveus.

(a) Lipase enzyme preparation contains lipase enzyme (CAS Reg. No. 9001–62–1), which is obtained from the culture filtrate resulting from a pure culture fermentation of a nonpathogenic and nontoxigenic strain of *Rhizopus niveus*. The enzyme preparation also contains diatomaceous earth as a carrier. The characterizing activity of the enzyme, which catalyzes the interesterification of fats and oils at the 1- and 3-positions of triglycerides, is triacylglycerol lipase (EC 3.1.1.3).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the monograph on Enzyme Preparations in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 133 and 134, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter for the interesterification of fats and oils.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[63 FR 24419, May 4, 1998, as amended at 81 FR 5595, Feb. 3, 2016]

§ 184.1425 Magnesium carbonate.

(a) Magnesium carbonate (molecular formula approximately $(MgCO_3)_4 \cdot Mg(OH)_2 \cdot 5H_2O$, CAS Reg. No. 39409–82–0) is also known as magnesium carbonate hydroxide. It is a white powder formed either by adding an alkaline carbonate (such as sodium carbonate) to a solution of magnesium sulfate or by carbonation of a slurry of magnesium hydroxide followed by boiling of the resulting magnesium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 177, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking and free-flow agent as defined in §170.3(o)(1) of this chapter; a flour treating agent as defined in §170.3(o)(13) of this chapter; a lubricant and release agent as defined in §170.3(o)(18) of this chapter; a nutrient supplement as defined in §170.3(o)(20) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; a processing aid as defined in §170.3(o)(24) of this chapter; and a synergist as defined in §170.3(o)(31) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13558, Apr. 5, 1985; 50 FR 16080, Apr. 24, 1985]

§ 184.1426 Magnesium chloride.

(a) Magnesium chloride ($MgCl_2 \cdot 6H_2O$, CAS Reg. No. 7786–30–3) is a colorless, deliquescent, crystalline material that occurs naturally as the mineral bischofite. It is prepared by dissolving magnesium oxide, hydroxide, or carbonate in aqueous hydrochloric acid solution and crystallizing out magnesium chloride hexahydrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 177, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter and a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[50 FR 13559, Apr. 5, 1985; 50 FR 16080, Apr. 24, 1985]

§ 184.1428 Magnesium hydroxide.

(a) Magnesium hydroxide ($Mg(OH)_2$, CAS Reg. No. 1309–42–8) occurs naturally as the colorless, crystalline mineral brucite. It is prepared as a white precipitate by the addition of sodium hydroxide to a water soluble magnesium salt or by hydration of reactive grades of magnesium oxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 178, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; and a processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13559, Apr. 5, 1985, as amended at 64 FR 405, Jan. 5, 1999]

§ 184.1431 Magnesium oxide.

(a) Magnesium oxide (MgO, CAS Reg. No. 1309–48–4) occurs naturally as the colorless, crystalline mineral periclase. It is produced either as a bulky white powder (light) or a relatively dense white powder (heavy) by heating magnesium hydroxide or carbonate. Heating these magnesium salts under moderate conditions (400° to 900 °C for a few hours) produces light magnesium oxide. Heating the salts under more rigorous conditions (1200 °C for 12 hours) produces heavy magnesium oxide. Light magnesium oxide is converted to heavy magnesium oxide by sustained heating at high temperatures.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 178, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking and free-flow agent as defined in §170.3(o)(1) of this chapter; a firming agent as defined in §170.3(o)(10) of this chapter; a lubricant and release agent as defined in §170.3(o)(18) of this chapter; a nutrient supplement as defined in §170.3(o)(20) of this chapter; and a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not be exceed current good manufacturing practice. The ingredient also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[50 FR 13559, Apr. 5, 1985]

§ 184.1434 Magnesium phosphate.

(a) Magnesium phosphate includes both magnesium phosphate, dibasic, and magnesium phosphate, tribasic. Magnesium phosphate, dibasic ($MgHPO_4 \cdot 3H_2O$, CAS Reg. No. 7782–0975–094) occurs naturally as the white, crystalline mineral newberyite. It is prepared commercially as a precipitate formed by treating a solution of magnesium sulfate with disodium phosphate under controlled conditions. Magnesium phosphate, tribasic ($Mg_3(PO_4)2 \cdot xH_2O$, CAS Reg. No. 7757–87–1) may contain 4, 5, or 8 molecules of water of hydration. It is produced as a precipitate from a solution of magnesite with phosphoric acid.

(b) Magnesium phosphate, dibasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 179, which is incorporated by reference. Magnesium phosphate, tribasic, meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 180, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter and a pH control agent as defined in § 170.3(o)(23) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985, as amended at 69 FR 24512, May 4, 2004]

§ 184.1440 Magnesium stearate.

(a) Magnesium stearate ($Mg(C_{17}H_{34}COO)_2$, CAS Reg. No. 557–04–0) is the magnesium salt of stearic acid. It is produced as a white precipitate by the addition of an aqueous solution of magnesium chloride to an aqueous solution of sodium stearate derived from stearic acid that is obtained from edible sources and that conforms to the requirements of § 172.860(b)(2) of this chapter.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 182, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a lubricant and release agent as defined in § 170.3(o)(18) of this chapter; a nutrient supplement as defined in § 170.3(o)(20) of this chapter; and a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

§ 184.1443 Magnesium sulfate.

(a) Magnesium sulfate ($MgSO_4 \cdot 7H_2O$, CAS Reg. No. 10034–99–8) occurs naturally as the mineral epsomite. It is prepared by neutralization of magnesium oxide, hydroxide, or carbonate with sulfuric acid and evaporating the solution to crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 183, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in §170.3(o)(11) of this chapter; a nutrient supplement as defined in §170.3(o)(20) of this chapter; and a processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 13560, Apr. 5, 1985]

§ 184.1443a Malt.

(a) Malt is an enzyme preparation obtained from barley which has been softened by a series of steeping operations and germinated under controlled conditions. It is a brown, sweet, and viscous liquid or a white to tan powder. Its characterizing enzyme activities are α-amylase (EC 3.2.1.1.) and β-amylase (EC 3.2.1.2).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze starch or starch-derived polysaccharides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

§ 184.1444 Maltodextrin.

(a) Maltodextrin ($(C_6H_{10}O_5)_n$, CAS Reg. No. 9050–36–6) is a nonsweet nutritive saccharide polymer that consists of D-glucose units linked primarily by α-1-4 bonds and that has a dextrose equivalent (D.E.) of less than 20. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes.

(b)(1) Maltodextrin derived from corn starch must be of a purity suitable for its intended use.

(2) Maltodextrin derived from potato starch meets the specifications of the Food Chemicals Codex, 3d ed., 3d supp. (1992), p. 125, which are incorporated by

reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or at the Division of Petition Control (HFS–217), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*.

(3) Maltodextrin derived from rice starch meets the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 239 and 240, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51911, Nov. 15, 1983, as amended at 60 FR 48893, Sept. 21, 1995; 63 FR 14611, Mar. 26, 1998; 81 FR 5596, Feb. 3, 2016]

§ 184.1445 Malt syrup (malt extract).

(a) Malt is the product of barley (*Hordeum vulgare* L.) germinated under controlled conditions. Malt syrup and malt extract are interchangeable terms for a viscous concentrate of water extract of germinated barley grain, with or without added safe preservative. Malt syrup is usually a brown, sweet, and viscous liquid containing varying amounts of amylolytic enzymes and plant constituents. Barley is first softened after cleaning by steeping operations and then allowed to germinate under controlled conditions. The germinated grain then undergoes processing, such as drying, grinding, extracting, filtering, and evaporating, to produce malt syrup (malt extract) with 75 to 80 percent solids or dried malt syrup with higher solids content.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51613, Nov. 10, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1446 Manganese chloride.

(a) Manganese chloride ($MnCl_2$, CAS Reg. No. 7773–01–5) is a pink, translucent, crystalline product. It is also known as manganese dichloride. It is prepared by dissolving manganous oxide, pyrolusite ore (MnO_2), or reduced manganese ore in hydrochloric acid. The resulting solution is neutralized to precipitate heavy metals, filtered, concentrated, and crystallized.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/*

code__of__federal__regulations/ibr__locations.html.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 19165, May 7, 1985, as amended at 76 FR 59250, Sept. 26, 2011]

§ 184.1449 Manganese citrate.

(a) Manganese citrate ($Mn_3(C_6H_5O_7)_2$, CAS Reg. No. 10024–66–5) is a pale orange or pinkish white powder. It is obtained by precipitating manganese carbonate from manganese sulfate and sodium carbonate solutions. The filtered and washed precipitate is digested first with sufficient citric acid solution to form manganous citrate and then with sodium citrate to complete the reaction.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; fish products as defined in §170.3(n)(13) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; milk products as defined in §170.3(n)(31) of this chapter; and poultry products as defined in §170.3(n)(34) of this chapter. The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 19166, May 7, 1985, as amended at 73 FR 8607, Feb. 14, 2008; 76 FR 59250, Sept. 26, 2011]

§ 184.1452 Manganese gluconate.

(a) Manganese gluconate ($C_{12}H_{22}MnO_{14}\cdot 2H_2O$, CAS Reg. No. 648–0953–0998) is a slightly pink colored powder. It is obtained by reacting manganese carbonate with gluconic acid in aqueous medium and then crystallizing the product.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 186, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed

current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; fish products as defined in §170.3(n)(13) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; milk products as defined in §170.3(n)(31) of this chapter; and poultry products as defined in §170.3(n)(34) of this chapter. The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 19166, May 7, 1985]

§ 184.1461 Manganese sulfate.

(a) Manganese sulfate ($MnSO_4 \cdot H_2O$, CAS Reg. No. 7785–0987–097) is a pale pink, granular, odorless powder. It is obtained by reacting manganese compounds with sulfuric acid. It is also obtained as a byproduct in the manufacture of hydroquinone. Other manufacturing processes include the action of sulfur dioxide on a slurry of manganese dioxide in sulfuric acid, and the roasting of pyrolusite (MnO_2) ore with solid ferrous sulfate and coal, followed by leaching and crystallization.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 188, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; fish products as defined in §170.3(n(13) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; milk products as defined in §170.3(n)(31) of this chapter; and poultry products as defined in §170.3(n)(34) of this chapter.

The ingredient may be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 19166, May 7, 1985]

§ 184.1472 Menhaden oil.

(a) *Menhaden oil.* (1) Menhaden oil is prepared from fish of the genus *Brevoortia,* commonly known as menhaden, by cooking and pressing. The resulting crude oil is then refined using the following steps: Storage (winterization), degumming (optional), neutralization, bleaching, and deodorization. Winterization may separate the oil and produce a solid fraction.

(2) Menhaden oil meets the following specifications:

(i) *Color and state.* Yellow liquid to white solid.

(ii) *Odor.* Odorless to slightly fishy.

(iii) *Saponification value.* Between 180 and 200 as determined by the American Oil Chemists' Society Official Method Cd 3–25—''Saponification Value'' (reapproved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this publication are available from the Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or available for inspection at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(iv) *Iodine number*. Not less than 120 as determined by the American Oil Chemists' Society Recommended Practice Cd 1d–92—''Iodine Value of Fats and Oils, Cyclohexane—Acetic Acid Method,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(v) *Unsaponifiable matter*. Not more than 1.5 percent as determined by the American Oil Chemists' Society Official Method Ca 6b–53—''Unsaponifiable Matter'' (reapproved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(vi) *Free fatty acids*. Not more than 0.1 percent as determined by the American Oil Chemists' Society Official Method Ca 5a–40—''Free Fatty Acids'' (reapproved 1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(vii) *Peroxide value*. Not more than 5 milliequivalents per kilogram of oil as determined by the American Oil Chemists' Society Official Method Cd 8–53—''Peroxide Value, Acetic Acid—Chloroform Method'' (updated 1992) or Recommended Practice Cd 8b–90—''Peroxide Value, Acetic Acid—Isooctane Method'' (updated 1992), which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(viii) *Lead*. Not more than 0.1 part per million as determined by the American Oil Chemists' Society Official Method Ca 18c–91—''Determination of Lead by Direct Graphite Furnace Atomic Absorption Spectrometry'' (revised 1992), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(ix) *Mercury*. Not more than 0.5 part per million as determined by the method entitled ''Biomedical Test Materials Program: Analytical Methods for the Quality Assurance of Fish Oil,'' published in the ''NOAA Technical Memorandum NMFS-SEFC-211,'' F. M. Van Dolah and S. B. Galloway, editors, National Marine Fisheries Service, U. S. Department of Commerce, pages 71–88, November, 1988, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (a)(2)(iii) of this section.

(3) In accordance with §184.1(b)(2), the ingredient may be used in food only within the following specific limitations to ensure that total intake of eicosapentaenoic acid or docosahexaenoic acid does not exceed 3.0 grams/person/day:

Category of food	Maximum level of use in food (as served)
Baked goods, baking mixes, §170.3(n)(1) of this chapter.	5.0 percent
Cereals, §170.3(n)(4) of this chapter	4.0 percent
Cheese products, §170.3(n)(5) of this chapter.	5.0 percent
Chewing gum, §170.3(n)(6) of this chapter ..	3.0 percent
Condiments, §170.3(n)(8) of this chapter	5.0 percent
Confections, frostings, §170.3(n)(9) of this chapter.	5.0 percent
Dairy product analogs, §170.3(n)(10) of this chapter.	5.0 percent
Egg products, §170.3(n)(11) of this chapter	5.0 percent
Fats, oils, §170.3(n)(12) of this chapter, but not in infant formula.	12.0 percent
Fish products, §170.3(n)(13) of this chapter	5.0 percent
Frozen dairy desserts, §170.3(n)(20) of this chapter.	5.0 percent
Gelatins, puddings, §170.3(n)(22) of this chapter.	1.0 percent
Gravies, sauces, §170.3(n)(24) of this chapter.	5.0 percent
Hard candy, §170.3(n)(25) of this chapter	10.0 percent
Jams, jellies, §170.3(n)(28) of this chapter ..	7.0 percent

Category of food	Maximum level of use in food (as served)
Meat products, § 170.3(n)(29) of this chapter	5.0 percent
Milk products, § 170.3(n)(31) of this chapter	5.0 percent
Nonalcoholic beverages, § 170.3(n)(3) of this chapter.	0.5 percent
Nut products, § 170.3(n)(32) of this chapter ..	5.0 percent
Pastas, § 170.3(n)(23) of this chapter	2.0 percent
Plant protein products, § 170.3(n)(33) of this chapter.	5.0 percent
Poultry products, § 170.3(n)(34) of this chapter.	3.0 percent
Processed fruit juices, § 170.3(n)(35) of this chapter.	1.0 percent
Processed vegetable juices, § 170.3(n)(36) of this chapter.	1.0 percent
Snack foods, § 170.3(n)(37) of this chapter ..	5.0 percent
Soft candy, § 170.3(n)(38) of this chapter	4.0 percent
Soup mixes, § 170.3(n)(40) of this chapter ...	3.0 percent
Sugar substitutes, § 170.3(n)(42) of this chapter.	10.0 percent
Sweet sauces, toppings, syrups, § 170.3(n)(43) of this chapter.	5.0 percent
White granulated sugar, § 170.3(n)(41) of this chapter.	4.0 percent

(4) To ensure safe use of the substance, menhaden oil shall not be used in combination with any other added oil that is a significant source of eicosapentaenoic acid or docosahexaenoic acid.

(b) *Hydrogenated and partially hydrogenated menhaden oils.* (1) Partially hydrogenated and hydrogenated menhaden oils are prepared by feeding hydrogen gas under pressure to a converter containing crude menhaden oil and a nickel catalyst. The reaction is begun at 150 to 160 °C and after 1 hour the temperature is raised to 180 °C until the desired degree of hydrogenation is reached. Hydrogenated menhaden oil is fully hydrogenated.

(2) Partially hydrogenated and hydrogenated menhaden oils meet the following specifications:

(i) *Color.* Opaque white solid.

(ii) *Odor.* Odorless.

(iii) *Saponification value.* Between 180 and 200.

(iv) *Iodine number.* Not more than 119 for partially hydrogenated menhaden oil and not more than 10 for fully hydrogenated menhaden oil.

(v) *Unsaponifiable matter.* Not more than 1.5 percent.—

(vi) *Free fatty acids.* Not more than 0.1 percent.

(vii) *Peroxide value.* Not more than 5 milliequivalents per kilogram of oil.

(viii) *Nickel.* Not more than 0.5 part per million.

(ix) *Mercury.* Not more than 0.5 part per million.

(x) *Arsenic (as As).* Not more than 0.1 part per million.

(xi) *Lead.* Not more than 0.1 part per million.

(3) Partially hydrogenated and hydrogenated menhaden oils are used as edible fats or oils, as defined in § 170.3(n)(12) of this chapter, in food at levels not to exceed current good manufacturing practice.

(4) If the fat or oil is fully hydrogenated, the name to be used on the label of a product containing it shall include the term ''hydrogenated,'' or if it is partially hydrogenated, the name shall include the term ''partially hydrogenated,'' in accordance with § 101.4(b)(14) of this chapter.

[62 FR 30756, June 5, 1997, as amended at 70 FR 14531, Mar. 23, 2005; 81 FR 5596, Feb. 3, 2016]

§ 184.1490 Methylparaben.

(a) Methylparaben is the chemical methyl *p*-hydroxybenzoate. It is produced by the methanol esterification of *p*-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 199, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in

this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5612, Feb. 14, 1984]

§ 184.1498 Microparticulated protein product.

(a) Microparticulated protein product is prepared from egg whites or milk protein or a combination of egg whites and milk protein. These protein sources may be used alone or in combination with other safe and suitable ingredients to form the microparticulated product. The mixture of ingredients is high-shear heat processed to achieve a smooth and creamy texture similar to that of fat. Safe and suitable ingredients used in the preparation of the microparticulated protein product must be used in compliance with the limitations of the appropriate regulations in parts 172, 182, and 184 of this chapter.

(b) The ingredient is used in food in accordance with §184.1(b)(2) at levels not to exceed current good manufacturing practice. The affirmation of the use of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following conditions of use:

(1) The ingredient is used in food as a thickener as defined in §170.3(o)(28) of this chapter or as a texturizer as defined in §170.3(o)(32) of this chapter.

(2) The ingredient is used in frozen dessert-type products except that the ingredient may not be used to replace the milk fat required in standardized frozen desserts.

(3) The name of the ingredient used in the ingredient statement on both bulk and packaged food must include the source of the protein (e.g., ''microparticulated egg white protein''), followed by a parenthetical listing of each of the ingredients in the microparticulated protein product, in descending order of predominance. Microparticulated protein product must be used in accordance with this requirement or its addition to food will be considered by FDA to constitute the use of an unapproved food additive (see §184.1(b)(2)).

[55 FR 6391, Feb. 23, 1990]

§ 184.1505 Mono- and diglycerides.

(a) Mono- and diglycerides consist of a mixture of glyceryl mono- and diesters, and minor amounts of triesters, that are prepared from fats or oils or fat-forming acids that are derived from edible sources. The most prevalent fatty acids include lauric, linoleic, myristic, oleic, palmitic, and stearic. Mono- and diglycerides are manufactured by the reaction of glycerin with fatty acids or the reaction of glycerin with triglycerides in the presence of an alkaline catalyst. The products are further purified to obtain a mixture of glycerides, free fatty acids, and free glycerin that contains at least 90 percent-by-weight glycerides.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 201, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a dough strengthener as defined in §170.3(o)(6) of this chapter; an emulsifier and emulsifier salt as defined in §170.3(o)(8) of this chapter; a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; a formulation aid as defined in §170.3(o)(14) of this chapter; a lubricant and release agent as defined in §170.3(o)(18) of this chapter; a solvent and vehicle as defined in §170.3(o)(27) of this chapter; a stabilizer and thickener as defined in §170.3(o)(28) of this chapter; a surface-active agent as defined in §170.3(o)(29) of this chapter; a surface-finishing

agent as defined in §170.3(o)(30) of this chapter; and a texturizer as defined in §170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[54 FR 7403, Feb. 21, 1989, as amended at 57 FR 10616, Mar. 27, 1992]

§ 184.1521 Monosodium phosphate derivatives of mono- and diglycerides.

(a) Monosodium phophate derivatives of mono- and diglycerides are composed of glyceride derivatives formed by reacting mono- and diglycerides that are derived from edible sources with phosphorus pentoxide (tetraphosphorus decoxide) followed by neutralization with sodium carbonate.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an emulsifier and emulsifier salt as defined in §170.3(o)(8) of this chapter, a lubricant and release agent as defined in §170.3(o)(18) of this chapter, and as a surface-active agent as defined in §170.3(o)(29) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: dairy product analogs as defined in §170.3(n)(10) of this chapter and soft candy as defined in §170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[54 FR 7404, Feb. 21, 1989, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1530 Niacin.

(a) Niacin ($C_6H_5NO_2$, CAS Reg. No. 59–67–6) is the chemical 3-pyridinecarboxylic acid (nicotinic acid). It is a non-hygroscopic, stable, white, crystalline solid that sublimes without decomposition at about 230 °C. It is soluble in water and alcohol. It is insoluble in ether.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), p. 264, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52033, Nov. 16, 1983; 48 FR 54336, Dec. 2, 1983, as amended at 64 FR 1760, Jan. 12, 1999; 81 FR 5596, Feb. 3, 2016]

§ 184.1535 Niacinamide.

(a) Niacinamide ($C_6H_6N_2O$, CAS Reg. No. 98–92–0) is the chemical 3-

pyridinecarboxylic acid amide (nicotinamide). It is a white crystalline powder that is soluble in water, alcohol, ether, and glycerol. It melts between 128° and 131 °C.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 205, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52033, Nov. 16, 1983; 48 FR 54336, Dec. 2, 1983]

§184.1537 Nickel.

(a) Elemental nickel (CAS Reg. No. 7440–02–0) is obtained from nickel ore by transforming it to nickel sulfide (Ni_3S_2). The sulfide is roasted in air to give nickel oxide (NiO). The oxide is then reduced with carbon to give elemental nickel.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a catalyst as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in the hydrogenation of fats and oils as defined in §170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice. Current good manufacturing practice includes the removal of nickel from fats and oils following hydrogenation.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51618, Nov. 10, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

§184.1538 Nisin preparation.

(a) Nisin preparation is derived from pure culture fermentations of certain strains of Streptococcus lactis Lancefield Group N. Nisin preparation contains nisin (CAS Reg. No. 1414–45–5), a group of related peptides with antibiotic activity.

(b) The ingredient is a concentrate or dry material that meets the specifications that follow when it is tested as described in ''Specifications for Identity and Purity of Some Antibiotics,'' World Health Organization, FAO Nutrition Meeting Report Series, No. 45A, 1969, which is incorporated by reference. Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(1) Nisin content, not less than 900 international units per milligram.

(2) Arsenic, not more than 1 part per million.

(3) Lead, not more than 2 parts per million.

(4) Zinc, not more than 25 parts per million.

(5) Copper, zinc plus copper not more than 50 parts per million.

(6) Total plate count, not more than 10 per gram.

(7) *Escherichia coli,* absent in 10 grams.

(8) *Salmonella,* absent in 10 grams.

(9) Coagulase positive staphylococci, absent in 10 grams.

(c) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter to inhibit the outgrowth of *Clostridium botulinum* spores and toxin formation in pasteurized cheese spreads and pasteurized process cheese spreads listed in §133.175; pasteurized cheese spread with fruits, vegetables, or meats as defined in §133.176; pasteurized process cheese spread as defined in §133.179; pasteurized process cheese spread with fruits, vegetables, or meats as defined in §133.180 of this chapter.

(d) The ingredient is used at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1) of this chapter. The current good manufacturing practice level is the quantity of the ingredient that delivers a maximum of 250 parts per million of nisin in the finished product as determined by the British Standards Institution Methods, ''Methods for the Estimation and Differentiation of Nisin in Processed Cheese,'' BS 4020 (1974), which is incorporated by reference. Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

[53 FR 11250, Apr. 6, 1988, as amended at 59 FR 14364, Mar. 28, 1994; 68 FR 24879, May 9, 2003]

§ 184.1540 Nitrogen.

(a) Nitrogen (empirical formula N_2, CAS Reg. No. 7727–37–9) is a colorless, odorless, flavorless gas that is produced commercially by the fractionation of liquid air.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in §170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1545 Nitrous oxide.

(a) Nitrous oxide (empirical formula N_2O, CAS Reg. No. 10024–97–2) is also known as dinitrogen monoxide or laughing gas. It is a colorless gas, about 50 percent heavier than air, with a slightly sweet smell. It does not burn but will support combustion. Nitrous oxide is manufactured by the thermal decomposition of ammonium nitrate. Higher oxides of nitrogen are removed by passing the dry gas through a series of scrubbing towers.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in §170.3(o)(25) of this chapter.

(2) The ingredient is used in dairy product analogs as defined in §170.3(n)(10) of this chapter at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983, as amended at 73 FR 8607, Feb. 14, 2008]

§ 184.1553 Peptones.

(a) Peptones are a variable mixture of polypeptides, oligopeptides, and amino acids that are produced by partial hydrolysis of casein, animal tissue, soy protein isolate, gelatin, defatted fatty tissue, egg albumin, or lactalbumin (whey protein). Peptones are produced from these proteins using proteolytic enzymes that either are considered to be generally recognized as safe (GRAS) or are regulated as food additives. Peptones are also produced by denaturing any of the proteins listed in this paragraph with safe and suitable acids or heat.

(b) The ingredients must be of a purity suitable for their intended use.

(c) In accordance with §184.1(b)(1), these ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as GRAS as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) These ingredients are used as nutrient supplements as defined in §170.3(o)(20) of this chapter; as processing aids as defined in §170.3(o)(24) of this chapter; and as surface-active agents as defined in §170.3(o)(29) of this chapter.

(2) These ingredients are used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[49 FR 25430, June 21, 1984, as amended at 50 FR 49536, Dec. 3, 1985; 73 FR 8607, Feb. 14, 2008]

§ 184.1555 Rapeseed oil.

(a) *Fully hydrogenated rapeseed oil.* (1) Fully hydrogenated rapeseed oil is a mixture of triglycerides in which the fatty acid composition is a mixture of saturated fatty acids. The fatty acids are present in the same porportions which result from the full hydrogenation of fatty acids occurring in natural rapeseed oil. The rapeseed oil is obtained from the *napus* and *campestris* varieties of *Brassica* of the family Cruciferae. It is prepared by fully hydrogenating refined and bleached rapeseed oil at 310–375 °F, using a catalyst such as nickel, until the iodine number is 4 or less.

(2) The ingredient meets the following specifications: Acid value not more than 6, arsenic not more than 3 parts per million, free glycerin not more than 7 percent, heavy metals (as Pb) not more than 10 parts per million, iodine number not more than 4, residue on ignition not more than 0.5 percent.

(3) The ingredient is used as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter in peanut butter. The use level of the ingredient is limited by good manufacturing practice (GMP) to the minimum amount required to produce the intended effect. Current good manufacturing practices result in a maximum level of 2 percent in peanut butter.

(b) *Superglycerinated fully hydrogenated rapeseed oil.* (1) Superglycerinated fully hydrogenated rapeseed oil is a mixture of mono- and diglycerides with triglycerides as a minor component. The fatty acid composition is a mixture of saturated fatty acids present in the same proportions as those resulting from the full hydrogenation of fatty acids in natural rapeseed oil. It is made by adding excess glycerol to the fully hydrogenated rapeseed oil and heating, in the presence of a sodium hydroxide catalyst, to 330 °F under partial vacuum and steam sparging agitation.

(2) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 201, relating to mono- and diglycerides, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/*

ibr__locations.html. An additional specification requires the iodine number to be 4 or less.

(3) The ingredient is used as an emulsifier as defined in §170.3(o)(8) of this chapter in shortenings for cake mixes. The use level of the ingredient is limited by good manufacturing practice (GMP) to the minimum amount required to produce the intended effect. Current good manufacturing practices result in a maximum level, as served, of 4 percent of the shortening or 0.5 percent of the total weight of the cake mix.

(c) *Low erucic acid rapeseed oil*. (1) Low erucic acid rapeseed oil, also known as canola oil, is the fully refined, bleached, and deodorized edible oil obtained from certain varieties of *Brassica Napus* or *B. Campestris* of the family *Cruciferae*. The plant varieties are those producing oil-bearing seeds with a low erucic acid content. Chemically, low erucic acid rapeseed oil is a mixture of triglycerides, composed of both saturated and unsaturated fatty acids, with an erucic acid content of no more than 2 percent of the component fatty acids.

(2) Low erucic acid rapeseed oil as defined in paragraph (c)(1) of this section may be partially hydrogenated to reduce the proportion of unsaturated fatty acids. When the partially hydrogenated low erucic acid rapeseed oil is used, it shall be referred to as partially hydrogenated low erucic acid rapeseed oil.

(3) In addition to limiting the content of erucic acid to a level not exceeding 2 percent of the component fatty acids, low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil must be of a purity suitable for their intended use.

(4) Low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil are used as edible fats and oils in food, except in infant formula, at levels not to exceed current good manufacturing practice.

[42 FR 48336, Sept. 23, 1977, as amended at 49 FR 5613, Feb. 14, 1984; 50 FR 3755, Jan. 28, 1985; 53 FR 52682, Dec. 29, 1988; 73 FR 8608, Feb. 14, 2008]

§ 184.1560 Ox bile extract.

(a) Ox bile extract (CAS Reg. No. 8008–63–7), also known as purified oxgall or sodium choleate, is a yellowish green, soft solid, with a partly sweet, partly bitter, disagreeable taste. It is the purified portion of the bile of an ox obtained by evaporating the alcohol extract of concentrated bile.

(b) Food-grade ox bile extract shall meet the specifications of the U.S. Pharmacopeia (USP), XIV, 1950, p. 410.[1]

(c) The ingredient is used as a surfactant as defined in §170.3 (o)(29) of this chapter.

(d) The ingredient is used in food in accordance with §184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.002 percent for cheese as defined in §170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 36064, Aug. 15, 1978. Redesignated and amended at 50 FR 49537, Dec. 3, 1985]

§ 184.1563 Ozone.

(a) Ozone (O_3, CAS Reg. No. 10028–15–6) is an unstable blue gas with a pungent, characteristic odor, which occurs freely in nature, It is produced commercially by passing electrical discharges or ionizing radiation through air or oxygen.

(b) The ingredient must be of a purity suitable for its intended use in accordance with §170.30(h)(1) of this chapter.

(c) In accordance with §184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

[1] Copies may be obtained from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

Category of food	Maximum treatment level in food	Functional use
Bottled water that prior to ozonation meets the microbiological, physical, chemical, and radiological quality standards of § 165.110 (b)(2) through (b)(5) of this chapter.	Not to exceed current good manufacturing practice. Current good manufacturing practice results in a maximum residual level at the time of bottling of 0.4 milligram of ozone per liter of bottled water.	Antimicrobial agent, § 170.3 (o)(2) of this chapter.

[47 FR 50210, Nov. 5, 1982, as amended at 60 FR 57130, Nov. 13, 1995]

§ 184.1583 Pancreatin.

(a) Pancreatin (CAS Reg. No. 8049–47–6) is an enzyme preparation obtained from porcine or bovine pancreatic tissue. It is a white to tan powder. Its characterizing enzyme activity that of a peptide hydrolase (EC 3.4.21.36).

(b) The ingredient meets the general requirements and additional requirements in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995, as amended at 78 FR 14666, Mar. 7, 2013]

§ 184.1585 Papain.

(a) Papain (CAS Reg. No. 9001–73–4) is a proteolytic enzyme derived from *Carica papaya* L. Crude latex containing the enzyme is collected from slashed unripe papaya. The food-grade product is obtained by repeated filtration of the crude latex or an aqueous solution of latex or by precipitation from an aqueous solution of latex. The resulting enzyme preparation may be used in a liquid or dry form.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 107–110, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than currect good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter; processing aid as defined in § 170.3(o)(24) of this chapter; and texturizer as defined in § 170.3(o)(32) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 48806, Oct. 21, 1983]

§ 184.1588 Pectins.

(a) The pectins (CAS Reg. No. 9000–69–5) are a group of complex, high molecular weight polysaccharides found in plants and composed chiefly of partially methylated polygalacturonic acid units. Portions of the carboxly group occur as methyl esters, and the remaining carboxyl groups exist in the form of the free acid or as its ammonium, potassium, or sodium (CAS Reg. No. 9000–59–8) salts, and in some types as the acid amide. Thus, the pectins regulated in this section are the high-ester pectins, low-ester pectins, amidated pectins, pectinic acids, and pectinates. Pectin is produced commercially by extracting citrus peel, apple pomace, or beet pulp with hot dilute acid (pH 1.0 to 3.5, 70° to 90 °C). The extract is filtered, and pectin is then precipitated from the clear extract with ethanol or isopropanol, or as the copper or aluminum salt. The acid extract is sometimes spray- or roller-dried, or it is concentrated to be sold as liquid pectin.

(b) The ingredients meet the specifications of the Food Chemical Codex, 3d Ed. (1981), p. 215, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredients are used in food with no limitation other than current good manufacturing practice. The affirmation of these ingredients as generally recognized as safe (GRAS) as direct human food ingredients is based upon the following current good manufacturing practice conditions of use:

(1) The ingredients are used as emulsifiers as defined in §170.3(o)(8) of this chapter and as stabilizers and thickeners as defined in §170.3(o)(28) of this chapter.

(2) The ingredients are used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[48 FR 51149, Nov. 7, 1983]

§ 184.1595 Pepsin.

(a) Pepsin (CAS Reg. No. 9001–75–6) is an enzyme preparation obtained from the glandular layer of hog stomach. It is a white to light tan powder, amber paste, or clear amber to brown liquid. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.23.1).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995, as amended at 78 FR 14667, Mar. 7, 2013]

§ 184.1610 Potassium alginate.

(a) Potassium alginate (CAS Reg. No. 9005–36–1) is the potassium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Potassium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Confections and frostings, §170.3(n)(9) of this chapter.	0.1	Stabilizer, thickener, §170.3(o)(28) of this chapter
Gelatins and puddings, §170.3(n)(22) of this chapter.	0.7	Do.
Processed fruits and fruit juices, §170.3(n)(35) of this chapter.	0.25	Do.
All other food categories.	0.01	Do.

(d) Prior sanctions for potassium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29951, July 9, 1982]

§ 184.1613 Potassium bicarbonate.

(a) Potassium bicarbonate ($KHCO_3$, CAS Reg. No. 298–14–6) is made by the following processes:

(1) By treating a solution of potassium hydroxide with carbon dioxide;

(2) By treating a solution of potassium carbonate with carbon dioxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in §170.3(o)(14) of this chapter; nutrient supplemlent as defined in §170.3(o)(20) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1619 Potassium carbonate.

(a) Potassium carbonate (K_2CO_3, CAS Reg. No. 584–08–7) is produced by the following methods of manufacture:

(1) By electrolysis of potassium chloride followed by exposing the resultant potassium to carbon dioxide;

(2) By treating a solution of potassium hydroxide with excess carbon dioxide to produce potassium carbonate;

(3) By treating a solution of potassium hydroxide with carbon dioxide to produce potassium bicarbonate, which is then heated to yield potassium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex,

3d Ed. (1981), p. 240, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. the affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; nutrient supplement as defined in §170.3(o)(20) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§184.1622 Potassium chloride.

(a) Potassium chloride (KCl, CAS Reg. No. 7447–40–7) is a white, odorless solid prepared from source minerals by fractional crystallization or flotation. It is soluble in water and glycerol and has a saline taste at low concentration levels.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 241, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in §170.3(o)(11) of this chapter; as a flavoring agent as defined in §170.3(o)(12) of this chapter; as a nutrient supplement as defined in §170.3(o)(20) of this chapter; as a pH control agent as defined in §170.3(o)(23) of this chapter; and as a stabilizer or thickener as defined in §170.3(o)(28) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Potassium chloride may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51614, Nov. 10, 1983]

§184.1625 Potassium citrate.

(a) Potassium citrate ($C_6H_5K_3O_7 \cdot H_2O$, CAS Reg. No. 006100–0905–096) is the potassium salt of citric acid. It is prepared by neutralizing citric acid with potassium hydroxide or potassium carbonate. It occurs as transparent crystals or a white granular powder, is odorless and deliquescent, and contains one mole of water per mole of potassium citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), p. 242, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, and the Center for Food Safety and Applied Nutrition (HFS–200), 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and

Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63896, Dec. 12, 1994]

§ 184.1631 Potassium hydroxide.

(a) Potassium hydroxide (KOH, CAS Reg. No. 1310–58–3) is also known as caustic potash, potash lye, and potassa. The empirical formula is KOH. It is a white, highly deliquescent caustic solid, which is marketed in several forms, including pellets, flakes, sticks, lumps, and powders. Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available from inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in §170.3(o)(14) of this chapter; a pH control agent as defined in §170.3(o)(23) of the chapter; a processing aid as defined in §170.3(o)(24) of this chapter; and a stabilizer and thickener as defined in §170.3(o)(28) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52444, Nov. 18, 1983]

§ 184.1634 Potassium iodide.

(a) Potassium iodide (KI, CAS Reg. No. 7681–11–0) is the potassium salt of hydriodic acid. It occurs naturally in sea water and in salt deposits, but can be prepared by reacting hydriodic acid (HI) with potassium bicarbonate ($KHCO_3$).

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 246–247, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(d) The ingredient is used in table salt in accordance with §184.1(b)(2) of this chapter as a source of dietary iodine at a maximum level of 0.01 percent.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11699, Mar. 21, 1978, as amended at 49 FR 5613, Feb. 14, 1984; 61 FR 14247, Apr. 1, 1996]

§ 184.1635 Potassium iodate.

(a) Potassium iodate (KIO_3, CAS Reg. No. 7758–05–6) does not occur naturally but can be prepared by reacting iodine with potassium hydroxide.

(b) The ingredient meets the specifications of the ''Food Chemicals

Codex,'' 3d Ed. (1981), pp. 245–246, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as a dough strengthener as defined in §170.3(o)(6) of this chapter.

(d) The ingredient is used in the manufacture of bread in accordance with §184.1(b)(2) of this chapter in an amount not to exceed 0.0075 percent based on the weight of the flour.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 11699, Mar. 21, 1978, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1639 Potassium lactate.

(a) Potassium lactate ($C_3H_5O_3K$, CAS Reg. No. 996–31–6) is the potassium salt of lactic acid. It is a hydroscopic, white, odorless solid and is prepared commercially by the neutralization of lactic acid with potassium hydroxide.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. This regulation does not authorize its use in infant foods and infant formulas. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavor enhancer as defined in §170.3(o)(11) of this chapter; a flavoring agent or adjuvant as defined in §170.3(o)(12) of this chapter; a humectant as defined in §170.3(o)(16) of this chapter; and a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[52 FR 10886, Apr. 6, 1987, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1643 Potassium sulfate.

(a) Potassium sulfate (K_2SO_4, CAS Reg. No. 7778–80–5) occurs naturally and consists of colorless or white crystals or crystalline powder having a bitter, saline taste. It is prepared by the neutralization of sulfuric acid with potassium hydroxide or potassium carbonate.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 252, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.015 percent for nonalcoholic beverages as defined in §170.3(n)(3) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1655 Propane.

(a) Propane (empirical formula C_3H_8, CAS Reg. No. 74–98–6) is also known as dimethylmethane or propyl hydrid. It is a colorless, odorless, flammable gas at normal temperatures and pressures. It is easily liquefied under pressure at room temperature and is stored and shipped in the liquid state. Propane is

obtained from natural gas by fractionation following absorption in oil, adsorption to surface-active agents, or refrigeration.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a propellant, aerating agent, and gas as defined in §170.3(o)(25) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57271, Dec. 29, 1983, as amended at 73 FR 8608, Feb. 14, 2008]

§184.1660 Propyl gallate.

(a) Propyl gallate is the *n*-propylester of 3,4,5-trihydroxybenzoic acid ($C_{10}H_{12}O_5$). Natural occurrence of propyl gallate has not been reported. It is commercially prepared by esterification of gallic acid with propyl alcohol followed by distillation to remove excess alcohol.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 257–258, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as an antioxidant as defined in §170.3(o)(3) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with §184.1(b)(1). Good manufacturing practice results in a maximum total content of antioxidants of 0.02 percent of the fat or oil content, including the essential (volatile) oil content, of the food.

(e) Prior sanctions for this ingredient different from the uses established in this section, or different from that stated in part 181 of this chapter, do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 44 FR 52826, Sept. 11, 1979; 49 FR 5613, Feb. 14, 1984]

§184.1666 Propylene glycol.

(a) Propylene glycol ($C_3H_8O_2$, CAS Reg. No. 57–55–6) is known as 1,2-propanediol. It does not occur in nature. Propylene glycol is manufactured by treating propylene with chlorinated water to form the chlorohydrin which is converted to the glycol by treatment with sodium carbonate solution. It is also prepared by heating glycerol with sodium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 255, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as an anticaking agent as defined in §170.3(o)(1) of this chapter; antioxidant as defined in §170.3(o)(3) of this chapter; dough strengthener as defined in §170.3(o)(6) of this chapter; emulsifier as defined in §170.3(o)(8) of this chapter; flavor agent as defined in §170.3(o)(12) of this chapter; formulation aid as defined in §170.3(o)(14) of this chapter; humectant as defined in §170.3(o)(16) of this chapter; processing aid as defined in §170.3(o)(24) of this chapter; solvent and vehicle as defined in §170.3(o)(27) of this chapter; stabilizer and thickener as defined in §170.3(o)(28) of this chapter; surface-active agent as defined in §170.3(o)(29) of

this chapter; and texturizer as defined in §170.3(o)(32) of this chapter.

(d) The ingredient is used in foods at levels not to exceed current good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in maximum levels, as served, of 5 percent for alcoholic beverages, as defined in §170.3(n)(2) of this chapter; 24 percent for confections and frostings as defined in §170.3(n)(9) of this chapter; 2.5 percent for frozen dairy products as defined in §170.3(n)(20) of this chapter; 97 percent for seasonings and flavorings as defined in §170.3(n)(26) of this chapter; 5 percent for nuts and nut products as defined in §170.3(n)(32) of this chapter; and 2.0 percent for all other food categories.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27812, June 25, 1982]

§184.1670 Propylparaben.

(a) Propylparaben is the chemical propyl *p*-hydroxybenzoate. It is produced by the *n*-propanol esterification of *p*-hydroxybenzoic acid in the presence of sulfuric acid, with subsequent distillation.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 258, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice results in a maximum level of 0.1 percent in food.

(e) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984]

§184.1676 Pyridoxine hydrochloride.

(a) Pyridoxine hydrochloride ($C_8H_{11}NO_3 \cdot HCl$, CAS Reg. No. 58–56–0) is the chemical 3-hydroxy–4,5-dihydroxymethy–2-methylpyridine hydrochloride that is prepared by chemical synthesis.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 260, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; nonalcoholic beverages and beverage bases as defined in §170.3(n)(3) of this chapter; breakfast cereals as defined in §170.3(n)(4) of this chapter; dairy product analogs as defined in §170.3(n)(10) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; milk products as defined in §170.3(n)(31) of this chapter; plant protein products as defined in §170.3(n)(33) of this chapter; and snack foods as defined in §170.3(n)(37) of this chapter. Pyridoxine hydrochloride may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and

Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51615, Nov. 10, 1983]

§ 184.1685 Rennet (animal-derived) and chymosin preparation (fermentation-derived).

(a)(1) Rennet and bovine rennet are commercial extracts containing the active enzyme rennin (CAS Reg. No. 9001–98–3), also known as chymosin (International Union of Biochemistry Enzyme Commission (E.C.) 3.4.23.4). Rennet is the aqueous extract prepared from cleaned, frozen, salted, or dried fourth stomachs (abomasa) of calves, kids, or lambs. Bovine rennet is the product from adults of the animals listed above. Both products are called rennet and are clear amber to dark brown liquid preparations or white to tan powders.

(2) Chymosin preparation is a clear solution containing the active enzyme chymosin (E.C. 3.4.23.4). It is derived, via fermentation, from a nonpathogenic and nontoxigenic strain of *Escherichia coli* K–12 containing the prochymosin gene. The prochymosin is isolated as an insoluble aggregate that is acid-treated to destroy residual cellular material and, after solubilization, is acid-treated to form chymosin. It must be processed with materials that are generally recognized as safe, or are food additives that have been approved by the Food and Drug Administration for this use.

(3) Chymosin preparation is a clear solution containing the active enzyme chymosin (E.C. 3.4.23.4). It is derived, via fermentation, from a nonpathogenic and nontoxigenic strain of *Kluyveromyces marxianus* variety *lactis*, containing the prochymosin gene. The prochymosin is secreted by cells into fermentation broth and converted to chymosin by acid treatment. All materials used in the processing and formulating of chymosin must be either generally recognized as safe (GRAS), or be food additives that have been approved by the Food and Drug Administration for this use.

(4) Chymosin preparation is a clear solution containing the active enzyme chymosin (E.C. 3.4.23.4). It is derived, via fermentation, from a nonpathogenic and nontoxigenic strain of *Aspergillus niger* van Tieghem variety *awamori* (Nakazawa) Al-Musallam (synonym *A. awamori* Nakazawa) containing the prochymosin gene. Chymosin is recovered from the fermentation broth after acid treatment. All materials used in the processing and formulating of chymosin preparation must be either generally recognized as safe (GRAS) or be food additives that have been approved by the Food and Drug Administration for this use.

(b) Rennet and chymosin preparation meet the general and additional requirements for enzyme preparations of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 107–110, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Avenue NW., Washington, DC 20418, or are available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter; a processing aid as defined in §170.3(o)(24) of this chapter; and a stabilizer and thickener as defined in §170.3(o)(28) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: In cheeses as defined in §170.3(n)(5) of this chapter; frozen dairy desserts and mixes as defined in §170.3(n)(20) of this chapter; gelatins, puddings, and fillings

as defined in §170.3(n)(22) of this chapter; and milk products as defined in §170.3(n)(31) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[55 FR 10935, Mar. 23, 1990, as amended at 57 FR 6479, Feb. 25, 1992; 58 FR 27202, May 7, 1993]

§ 184.1695 Riboflavin.

(a) Riboflavin ($C_{17}H_{20}N_4O_6$, CAS Reg. No. 83–88–5) occurs as yellow to orange-yellow needles that are crystallized from 2*N* acetic acid, alcohol, water, or pyridine. It may be prepared by chemical synthesis, biosynthetically by the organism *Eremothecium ashbyii*, or isolated from natural sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 262, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51148, Nov. 7, 1983]

§ 184.1697 Riboflavin–5′-phosphate (sodium).

(a) Riboflavin-5′-phosphate (sodium) ($C_{17}H_{20}N_4O_9PNa{\cdot}2H_2O$, CAS Reg. No 130–40–5) occurs as the dihydrate in yellow to orange-yellow crystals. It is prepared by phosphorylation of riboflavin with chlorophosphoric acid, pyrophosphoric acid, metaphosphoric acid, or pyrocatechol cyclic phosphate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 263, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in milk products, as defined in §170.3(n)(31) of this chapter, at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formulas in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51148, Nov. 7, 1983]

§ 184.1698 Rue.

(a) Rue is the perennial herb of several species of *Ruta* (*Ruta montana* L., *Ruta graveolens* L., *Ruta bracteosa* L., and *Ruta calepensis* L.). The leaves, buds, and stems from the top of the plant are gathered, dried, and then crushed in preparation for use, or left whole.

(b) The ingredient is used in all categories of food in accordance with § 184.1(b)(2) of this chapter at concentrations not to exceed 2 parts per million.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 3705, Jan. 27, 1978]

§ 184.1699 Oil of rue.

(a) Oil of rue is the natural substance obtained by steam distillation of the fresh blossoming plants of rue, the perennial herb of several species of *Ruta*—*Ruta montana* L., *Ruta graveolens* L., *Ruta bracteosa* L., and *Ruta calepensis* L.

(b) Oil of rue meets the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 342–343, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Parts per million	Function
Baked goods and baking mixes, § 170.3(n)(1), of this chapter.	10	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter.
Frozen dairy desserts and mixes, § 170.3 (n)(20) of this chapter.	10	Do.
Soft candy, § 170.3(n)(38) of this chapter	10	Do.
All other food categories	4	Do.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984; 64 FR 1760, Jan. 12, 1999; 81 FR 5596, Feb. 3, 2016]

§ 184.1702 Sheanut oil.

(a) Sheanut oil is produced from sheanuts derived from the Shea tree *Butyrospermum parkii* and is composed principally of triglycerides containing an oleic acid moiety at the 2-position and saturated fatty acids, usually stearic or palmitic acids, at the 1- and 3-positions.

(b) The ingredient meets the following specifications when tested using any appropriate validated methodology:

(1) Saponification value of 185 to 195,

(2) Iodine value of 28 to 43,

(3) Unsaponifiable matter not to exceed 1.5 percent,

(4) Free fatty acids not more than 0.1 percent as oleic acid,

(5) Peroxide value not more than 10 milliequivalents/equivalent (meq/eq),

(6) Lead not more than 0.1 part per million (ppm),

(7) Copper not more than 0.1 ppm.

(c) In accordance with § 184.1(b)(3), the ingredient is used in the following food categories at levels not to exceed current good manufacturing practice, except that the ingredient may not be used in a standardized food unless permitted by the standard of identity: Confections and frostings as defined in § 170.3(n)(9) of this chapter, coatings of soft candy as defined in § 170.3(n)(38) of

this chapter, and sweet sauces and toppings as defined in §170.3(n)(43) of this chapter.

[63 FR 28895, May 27, 1998]

§ 184.1721 Sodium acetate.

(a) Sodium acetate ($C_2H_3O_2Na$, CAS Reg. No. 127–09–3 or $C_2H_3O_2Na·3H_2O$, CAS Reg. No. 6131–90–4) is the sodium salt of acetic acid and occurs naturally in plant and animal tissues. Sodium acetate may occur in either the anhydrous or trihydrated form. It is produced synthetically by the neutralization of acetic acid with sodium carbonate or by treating calcium acetate with sodium sulfate and sodium bicarbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 272, 273 which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; and as a pH control agent as defined in §170.3(o)(23) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.007 percent for breakfast cereals as defined in §170.3(n)(4) of this chapter; 0.5 percent for fats and oils as defined in §170.3(n)(12) of this chapter; 0.6 percent for grain products and pastas as defined in §170.3(n)(23) of this chapter and snack foods as defined in §170.3(n)(37) of this chapter; 0.15 percent for hard candy as defined in §170.3(n)(25) of this chapter; 0.12 percent for jams and jellies as defined in §170.3(n)(28) of this chapter and meat products as defined in §170.3(n)(29) of this chapter; 0.2 percent for soft candy as defined in §170.3(n)(38) of this chapter; 0.05 percent for soups and soup mixes as defined in §170.3(n)(40) of this chapter and sweet sauces as defined in §170.3(n)(43) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27815, June 25, 1982]

§ 184.1724 Sodium alginate.

(a) Sodium alginate (CAS Reg. No. 9005–38–3) is the sodium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Sodium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 274, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(2), the ingredient is used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Condiments and relishes, §170.3(n)(8) of this chapter, except pimento ribbon for stuffed olives.	1.0	Texturizer, §170.3(o)(32) of this chapter, formulation aid §170.3(o)(14) of this chapter, stabilizer, thickener, §170.3(o)(28) of this chapter.
Pimento ribbon for stuffed olives	6.0	Do.
Confections and frostings, §170.3(n)(9) of this chapter	0.3	Stabilizer, thickener, §170.3(o)(28) of this chapter.

Category of food	Maximum level of use in food (as served) (percent)	Functional use
Gelatins and puddings, § 170.3(n)(22) of this chapter	4.0	Firming agent, § 170.3(o)(10) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter; stabilizer, thickener, § 170.3(o)(28) of this chapter.
Hard candy, § 170.3(n)(25) of this chapter	10.0	Stabilizer, thickener, § 170.3(o)(28) of this chapter.
Processed fruits and fruit juices, § 170.3(n)(35) of this chapter.	2.0	Formulation aid, § 170.3(o)(14) of this chapter; texturizer, § 170.3(o)(32) of this chapter.
All other food categories	1.0	Emulsifier, § 170.3(o)(8) of this chapter; firming agent, § 170.3(o)(10) of this chapter; flavor enhancer, § 170.3(o)(11) of this chapter; flavor adjuvant, § 170.3(o)(12) of this chapter; processing aid, § 170.3(o)(24) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter; surface active agent, § 170.3(o)(29) of this chapter.

(d) Prior sanctions for sodium alginate different from the uses established in this section do not exist or have been waived.

[47 FR 29951, July 9, 1982, as amended at 48 FR 52448, Nov. 18, 1983]

§ 184.1733 Sodium benzoate.

(a) Sodium benzoate is the chemical benzoate of soda ($C_7H_5NaO_2$), produced by the neutralization of benzoic acid with sodium bicarbonate, sodium carbonate, or sodium hydroxide. The salt is not found to occur naturally.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 278, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter, and as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.1 percent in food. (The Food and Drug Administration has not determined whether significally different conditions of use would be GRAS.)

(e) Prior sanctions for this ingredient different from the uses established in this section, or different from that set forth in part 181 of this chapter, do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1736 Sodium bicarbonate.

(a) Sodium bicarbonate ($NaHCO_3$, CAS Reg. No. 144–55–8) is prepared by treating a sodium carbonate or a sodium carbonate and sodium bicarbonate solution with carbon dioxide. As carbon dioxide is absorbed, a suspension of sodium bicarbonate forms. The slurry is filtered, forming a cake which is washed and dried.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 278, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983]

§ 184.1742 Sodium carbonate.

(a) Sodium carbonate (Na_2CO_3, CAS Reg. No. 497–19–8) is produced (1) from purified trona ore that has been calcined to soda ash; (2) from trona ore calcined to impure soda ash and then purified; or (3) synthesized from limestone by the Solvay process.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 280, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an antioxidant as defined in §170.3(o)(3) of this chapter; curing and pickling agent as defined in §170.3(o)(5) of this chapter; flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; pH control agent as defined in §170.3(o)(23) of this chapter; and processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52442, Nov. 18, 1983, as amended at 50 FR 49536, Dec. 3, 1985]

§ 184.1751 Sodium citrate.

(a) Sodium citrate ($C_6H_5Na_3O_7 \cdot 2H_2O$, CAS Reg. No. 68–0904–092) is the sodium salt of citric acid. It is prepared by neutralizing citric acid with sodium hydroxide or sodium carbonate. The product occurs as colorless crystals or a white crystalline powder. It may be prepared in an anhydrous state or may contain two moles of water per mole of sodium citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 283–284, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, and the Center for Food Safety and Applied Nutrition (HFS–200), 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63896, Dec. 12, 1994]

§ 184.1754 Sodium diacetate.

(a) Sodium diacetate ($C_4H_7O_4Na \cdot xH_2O$, CAS Reg. No. 126–96–5) is a molecular compound of acetic acid, sodium acetate, and water of hydration. The technical grade is prepared synthetically by reacting sodium carbonate with acetic acid. Special grades are produced by reacting anhydrous sodium acetate and acetic acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 284, which is incorporated by reference. Copies are available from the National Academy Press,

2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter; flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; and pH control agent as defined in §170.3(o)(23) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with §184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, 0.4 percent for baked goods as defined in §170.3(n)(1) of this chapter; 0.1 percent for fats and oils as defined in §170.3(n)(12) of this chapter, meat products as defined in §170.3(n)(29) of this chapter and soft candy as defined in §170.3(n)(38) of this chapter; 0.25 percent for gravies and sauces as defined in §170.3(n)(24) of this chapter; and 0.05 percent for snack foods as defined in §170.3(n)(37) of this chapter and soups and soup mixes as defined in §170.3(n)(40) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27815, June 25, 1982]

§ 184.1763 Sodium hydroxide.

(a) Sodium hydroxide (NaOH, CAS Reg. No. 1310–73–2) is also known as sodium hydrate, soda lye, caustic soda, white caustic, and lye. The empirical formula is NaOH. Sodium hydroxide is prepared commercially by the electrolysis of sodium chloride solution and also by reacting calcium hydroxide with sodium carbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a pH control agent as defined in §170.3(o)(23) of this chapter and as a processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52444, Nov. 18, 1983]

§ 184.1764 Sodium hypophosphite.

(a) Sodium hypophosphite (NaH_2PO_2, CAS Reg. No. 7681–53–0) is a white, odorless, deliquescent granular powder with a saline taste. It is also prepared as colorless, pearly crystalline plates. It is soluble in water, alcohol, and glycerol. It is prepared by neutralization of hypophosphorous acid or by direct aqueous alkaline hydrolysis of white phosphorus.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier or stabilizer, as defined in §§170.3(o)(8) and 170.3(o)(28) of this chapter.

(2) The ingredient is used in cod-liver oil emulsions at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been waived.

[47 FR 38277, Aug. 31, 1982, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1768 Sodium lactate.

(a) Sodium lactate ($C_3H_5O_3N_a$, CAS Reg. No. 72–17–3) is the sodium salt of lactic acid. It is prepared commercially by the neutralization of lactic acid with sodium hydroxide.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. This regulation does not authorize its use in infant foods and infant formulas. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier as defined in §170.3(o)(8) of this chapter; a flavor enhancer as defined in §170.3(o)(11) of this chapter; a flavoring agent or adjuvant as defined in §170.3(o)(12) of this chapter; a humectant as defined in §170.3(o)(16) of this chapter; and a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[52 FR 10886, Apr. 6, 1987, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1769a Sodium metasilicate.

(a) Sodium metasilicate (CAS Reg. No. 6834–92–0) is a strongly alkaline white powder. It does not occur naturally but rather is synthesized by melting sand with sodium carbonate at 1400 °C. The commercially available forms of sodium metasilicate are the anhydrous form (Na_2SiO_3), the pentahydrate ($Na_2SiO_3 \cdot 5H_2O$), and the nonahydrate ($Na_2SiO_3 \cdot 9H_2O$).

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a processing aid as defined in §170.3(o)(24) of this chapter.

(2) The ingredient is used to treat the following foods at levels not to exceed current good manufacturing practice: for use in washing and lye peeling of fruits, vegetables, and nuts when used in accordance with §173.315 of this chapter; for use as a denuding agent in tripe; for use as a hog scald agent in removing hair; and for use as a corrosion preventative in canned and bottled water when used in accordance with §165.110 of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 38781, Sept. 25, 1985; 50 FR 42011, Oct. 17, 1985, as amended at 72 FR 10357, Mar. 8, 2007; 73 FR 8608, Feb. 14, 2008]

§ 184.1784 Sodium propionate.

(a) Sodium propionate ($C_3H_5NaO_2$, CAS Reg. No. 137–40–6) is the sodium salt of propionic acid. It occurs as colorless, transparent crystals or a granular crystalline powder. It is odorless, or has a faint acetic-butyric acid odor, and is deliquescent. It is prepared by neutralizing propionic acid with sodium hydroxide.

(b) The ingredients meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 296, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no

limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter and a flavoring agent as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods as defined in §170.3(n)(1) of this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; cheeses as defined in §170.3(n)(5) of this chapter; confections and frostings as defined in §170.3(n)(9) of this chapter; gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter; jams and jellies as defined in §170.3(n)(28) of this chapter; meat products as defined in §170.3(n)(29) of this chapter; and soft candy as defined in §170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 13142, Apr. 3, 1984]

§ 184.1792 Sodium sesquicarbonate.

(a) Sodium sesquicarbonate ($Na_2CO_3 \cdot NaHCO_3 \cdot 2H_2O$, CAS Reg. No. 533–96–0) is prepared by: (1) Partial carbonation of soda ash solution followed by crystallization, centrifugation, and drying; (2) double refining of trona ore, a naturally occurring impure sodium sesquicarbonate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 299, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in cream at levels not to exceed current good manufacturing practice. Current good manufacturing practice utilizes a level of the ingredient sufficient to control lactic acid prior to pasteurization and churning of cream into butter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52443, Nov. 18, 1983]

§ 184.1801 Sodium tartrate.

(a) Sodium tartrate ($C_4H_4Na_2O_6 \cdot 2H_2O$, CAS Reg. No. 868–18–8) is the disodium salt of l−(+)−tartaric acid. It occurs as transparent, colorless, and odorless crystals. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 303, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier as defined in §170.3(o)(8) of this

chapter and as a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: cheeses as defined in§170.3(n)(5) of this chapter; fats and oils as defined in §170.3(n)(12) of this chapter; and jams and jellies as defined in §170.3(n)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52447, Nov. 18, 1983]

§ 184.1804 Sodium potassium tartrate.

(a) Sodium potassium tartrate ($C_4H_4KNaO_6 \cdot 4H_2O$, CAS Reg. No. 304–59–6) is the sodium potassium salt of l−(+)−tartaric acid and is also called the Rochelle salt. It occurs as colorless crystals or as a white, crystalline powder and has a cooling saline taste. It is obtained as a byproduct of wine manufacture.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 296, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier as defined in §170.3(o)(8) of this chapter and as a pH control agent as defined in §170.3(o)(23) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: cheeses as defined in §170.3(n)(5) of this chapter and jams and jellies as defined in §170.3(n)(28) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52447, Nov. 18, 1983]

§ 184.1807 Sodium thiosulfate.

(a) Sodium thiosulfate ($Na_2S_2O_3 \cdot 5H_2O$, CAS Reg. No. 010102–0917–097) is also known as sodium hyposulfite. It is prepared synthetically by the reaction of sulfides and sulfur dioxide (SO_2), the reaction of sulfur and sulfite, or the oxidation of metal sulfides and hydrosulfides.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 304, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as a formulation aid as defined in §170.3(o)(14) of this chapter and reducing agent as defined in §170.3(o)(22) of this chapter.

(d) The ingredient is used in alcoholic beverages and table salt in accordance with §184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.00005 percent for alcoholic beverages as defined in §170.3(n)(2) of this chapter and 0.1 percent for table salt as defined in §170.3(n)(26) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 22938, May 30, 1978, as amended at 49 FR 5613, Feb. 4, 1984]

§ 184.1835 Sorbitol.

(a) Sorbitol is the chemical 1,2,3,4,5,6-hexanehexol ($C_6H_{14}O_6$), a hexahydric alcohol, differing from mannitol principally by having a different optical rotation. Sorbitol is produced by the electrolytic reduction, or the transition metal catalytic hydrogenation of sugar solutions containing glucose or fructose.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), p. 308, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as an anticaking agent and free-flow agent as defined in §170.3(o)(1) of this chapter, curing and pickling agent as defined in §170.3(o)(5) of this chapter, drying agent as defined in §170.3(o)(7) of this chapter, emulsifier and emulsifier salt as defined in §170.3(o)(8) of this chapter, firming agent as defined in §170.3(o)(10) of this chapter, flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter, formulation aid as defined in §170.3(o)(14) of this chapter, humectant as defined in §170.3(o)(16) of this chapter, lubricant and release agent as defined in §170.3(o)(18) of this chapter, nutritive sweetener as defined in §170.3(o)(21) of this chapter, sequestrant as defined in §170.3(o)(26) of this chapter, stabilizer and thickener as defined in §170.3(o)(28) of this chapter, surface-finishing agent as defined in §170.3(o)(30) of this chapter, and texturizer as defined in §170.3(o)(32) of this chapter.

(d) The ingredient is used in food at levels not to exceed good manufacturing practices. Current good manufacturing practice in the use of sorbitol results in a maximum level of 99 percent in hard candy and cough drops as defined in §170.3(n)(25) of this chapter, 75 percent in chewing gum as defined in §170.3(n)(6) of this chapter, 98 percent in soft candy as defined in §170.3(n)(38) of this chapter, 30 percent in nonstandardized jams and jellies, commercial, as defined in §170.3(n)(28) of this chapter, 30 percent in baked goods and baking mixes as defined in §170.3(n)(1) of this chapter, 17 percent in frozen dairy desserts and mixes as defined in §170.3(n)(20) of this chapter, and 12 percent in all other foods.

(e) The label and labeling of food whose reasonably foreseeable consumption may result in a daily ingestion of 50 grams of sorbitol shall bear the statement: ''Excess consumption may have a laxative effect.''

(f) Prior sanctions for this ingredient different from the uses established in this regulation do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 49 FR 5613, Feb. 14, 1984]

§ 184.1845 Stannous chloride (anhydrous and dihydrated).

(a) Stannous chloride is anhydrous or contains two molecules of water of hydration. Anhydrous stannous chloride ($SnCl_2$, CAS Reg. No. 7772–99–8) is the chloride salt of metallic tin. It is prepared by reacting molten tin with either chlorine or gaseous tin tetrachloride. Dihydrated stannous chloride ($SnCl_2{\cdot}2H_2O$, CAS Reg. No. 10025–69–1) is the chloride salt of metallic tin that contains two molecules of water. It is prepared from granulated tin suspended in water and hydrochloric acid or chlorine.

(b) Both forms of the ingredient meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 312, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) The ingredient is used as an antioxidant as defined in §170.3(o)(3) of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with §184.(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.0015 percent or less; calculated as tin, for all food categories.

(e) Prior sanctions for this ingredient different from those uses established in this section do not exist or have been waived.

[47 FR 27816, June 25, 1982, as amended at 76 FR 59250, Sept. 26, 2011]

§ 184.1848 Starter distillate.

(a) Starter distillate (butter starter distillate) is a steam distillate of the culture of any or all of the following species of bacteria grown on a medium consisting of skim milk usually fortified with about 0.1 percent citric acid: *Streptococcus lactis, S. cremoris, S. lactis subsp. diacetylactis, Leuconostoc citrovorum,* and *L. dextranicum.* The ingredient contains more than 98 percent water, and the remainder is a mixture of butterlike flavor compounds. Diacetyl is the major flavor component, constituting as much as 80 to 90 percent of the mixture of organic flavor compounds. Besides diacetyl, starter distillate contains minor amounts of acetaldehyde, ethyl formate, ethyl acetate, acetone, ethyl alcohol, 2-butanone, acetic acid, and acetoin.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51907, Nov. 15, 1983, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1851 Stearyl citrate.

(a) Stearyl citrate is a mixture of the mono-, di-, and tristearyl esters of citric acid. It is prepared by esterifying citric acid with stearyl alcohol.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antioxidant as defined in §170.3(o)(3) of this chapter; an emulsifier and emulsifier salt as defined in §170.3(o)(8) of this chapter; a sequestrant as defined in §170.3(o)(26) of this chapter; and a surface-active agent as defined in §170.3(o)(29) of this chapter.

(2) The ingredient is used in margarine in accordance with §166.110 of this chapter; in nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; and in fats and oils as defined in §170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63897, Dec. 12, 1994, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1854 Sucrose.

(a) Sucrose ($C_{12}H_{22}O_{11}$, CAS Reg. No. 57–50–11–1) sugar, cane sugar, or beet sugar is the chemical β-D-fructofuranosyl-α-D-glucopyranoside. Sucrose is obtained by crystallization from sugar cane or sugar beet juice that has been extracted by pressing or diffusion, then clarified and evaporated.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[53 FR 44876, Nov. 7, 1988; 54 FR 228, Jan. 4, 1989, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1857 Corn sugar.

(a) Corn sugar ($C_6H_{12}O_6$, CAS Reg. No. 50–99–7), commonly called D-glucose or dextrose, is the chemical α-D-glucopyranose. It occurs as the anhydrous or the monohydrate form and is produced by the complete hydrolysis of corn starch with safe and suitable acids or enzymes, followed by refinement and crystallization from the resulting hydrolysate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 97–98 under the heading ''Dextrose,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 1. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 44876, Nov. 7, 1988]

§ 184.1859 Invert sugar.

(a) Invert sugar (CAS Reg. No. 8013–17–0) is an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash. The solution is colorless, odorless, and flavorless, except for sweetness. It is produced by the hydrolysis or partial hydrolysis of sucrose with safe and suitable acids or enzymes.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 44876, Nov. 7, 1988; 54 FR 228, Jan. 4, 1989, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1865 Corn syrup.

(a) Corn syrup, commonly called ''glucose sirup'' or ''glucose syrup,'' is obtained by partial hydrolysis of corn starch with safe and suitable acids or enzymes. It may also occur in the dehydrated form (dried glucose sirup). Depending on the degree of hydrolysis, corn syrup may contain, in addition to glucose, maltose and higher saccharides.

(b) The ingredient meets the specifications as defined and determined in §168.120(b) or §168.121(a) of this chapter, as appropriate.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[53 FR 44876, Nov. 7, 1988, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1866 High fructose corn syrup.

(a) High fructose corn syrup, a sweet, nutritive saccharide mixture containing either approximately 42 or 55 percent fructose, is prepared as a clear aqueous solution from high dextrose-equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose using an insoluble glucose isomerase enzyme preparation described in §184.1372. The product containing more than 50 percent fructose (dry weight) is prepared through concentration of the fructose portion of the mixture containing less than 50 percent fructose.

(b) The ingredient shall conform to the identity and specifications listed in the monograph entitled ''High-Fructose Corn Syrup'' in the Food Chemicals Codex, 4th ed. (1996), pp. 191–192,

which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

[61 FR 43450, Aug. 23, 1996, as amended at 78 FR 14667, Mar. 7, 2013; 81 FR 5596, Feb. 3, 2016]

§ 184.1875 Thiamine hydrochloride.

(a) Thiamine hydrochloride ($C_{12}H_{17}C1N_4OS{\cdot}HCl$, CAS Reg. No. 67–03–8) is the chloride-hydrochloride salt of thiamine. It occurs as hygroscopic white crystals or a white crystalline powder. The usual method of preparing this substance is by linking the preformed thiazole and pyrimidine ring systems.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 324, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter or as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Thiamine hydrochloride may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 55124, Dec. 9, 1983]

§ 184.1878 Thiamine mononitrate.

(a) Thiamine mononitrate ($C_{12}H_{17}N_5O_4S$, CAS Reg. No. 532–43–4) is the mononitrate salt of thiamine. It occurs as white crystals or a white crystalline powder and is prepared from thiamine hydrochloride by dissolving the hydrochloride salt in alkaline solution followed by precipitation of the nitrate half-salt with a stoichiometric amount of nitric acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 325, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Thiamine mononitrate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 55124, Dec. 9, 1983]

§ 184.1890 α-Tocopherols.

(a) The α-tocopherols that are the subject of this GRAS affirmation regulation are limited to the following:

(1) *d*-α-Tocopherol (CAS Reg. No. 59–02–9) is the chemical [2R,4′R,8′R]-2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyltridecyl)-6-chromanol. It occurs commercially as a concentrate and is a red, nearly odorless, viscous oil. It is obtained by vacuum steam distillation of edible vegetable oil products.

(2) *dl*-α-Tocopherol (CAS Reg. No. 10191–41–0) is a mixture of stereoisomers of 2,5,7,8-tetramethyl-2-(4′,8′,12′-trimethyl-tridecyl)-6-chromanol. It is chemically synthesized by condensing racemic isophytol with trimethyl hydroquinone. It is a pale yellow viscous oil at room temperature.

(b) The ingredients meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 330–331, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(3), the affirmation of the ingredients as generally recognized as safe is limited to the following conditions of use while the agency concludes the general evaluation of all food uses of tocopherols:

(1) The ingredients are used as inhibitors of nitrosamine formation.

(2) The ingredients are used in pump-cured bacon at levels not to exceed current good manufacturing practice.

[49 FR 13348, Apr. 4, 1984]

§ 184.1901 Triacetin.

(a) Triacetin (C_8 $H_{14}O_6$, CAS Reg. No. 102–76–1), also known as 1,2,3,-propanetriol triacetate or glyceryl triacetate, is the triester of glycerin and acetic acid. Triacetin can be prepared by heating glycerin with acetic anhydride alone or in the presence of finely divided potassium hydrogen sulfate. It can also be prepared by the reaction of oxygen with a liquid-phase mixture of allyl acetate and acetic acid using a bromide salt as a catalyst.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 337–338, as revised by the First Supplement to the 3d Ed., which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2102 Constitution Ave., NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; a formulation aid as defined in §170.3(o)(14) of this chapter; and humectant as defined in §170.3(o)(16) of this chapter; and a solvent and vehicle as defined in §170.3(o)(27) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in §170.3(n)(1) of this chapter, alcoholic beverages as defined in

§170.3(n)(2) of this chapter; nonalcoholic beverages and beverage bases as defined in §170.3(n)(3) of this chapter; chewing gum as defined in §170.3(n)(6) of this chapter; confections and frostings as defined in §170.3(n)(9) of this chapter; frozen dairy dessert and mixes as defined in §170.3(n)(20) of this chapter; gelatins, puddings, and fillngs as defined in §170.3(n)(22) of this chapter; hard candy as defined in §170.3(n)(25) of this chapter; and soft candy as defined in §170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[54 FR 7404, Feb. 21, 1989]

§ 184.1903 Tributyrin.

(a) Tributyrin ($C_{15}H_{26}O_6$, CAS Reg. No. 60–01–5), also known as butyrin or glyceryl tributyrate, is the triester of glycerin and butyric acid. It is prepared by esterification of glycerin with excess butyric acid.

(b) The ingredient meets the specification of the Food Chemicals Codex, 3d Ed. (1981), p. 416, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generaly recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice; baked goods as defined in §170.3(n)(1) of this chapter; alcoholic beverages as defined in §170.3(n)(2) of this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; fats and oils as defined in §170.3(n)(12) of this chapter; frozen dairy desserts and mixes as defined in §170.3(n)(20) of this chapter; gelatins, puddings and fillngs as defined in §170.3(n)(22) of this chapter; and soft candy as defined in §170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[54 FR 7404, Feb. 21, 1989; 54 FR 10482, Mar. 13, 1989]

§ 184.1911 Triethyl citrate.

(a) Triethyl citrate ($C_{12}H_{20}O_7$, CAS Reg. No. 77–93–0) is the triethyl ester of citric acid. It is prepared by esterifying citric acid with ethyl alcohol and occurs as an odorless, practically colorless, oily liquid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), p. 339, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, and the Center for Food Safety and Applied Nutrition (HFS–200), 5001 Campus Dr., College Park, MD 20740, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent as defined in §170.3(o)(12) of this chapter; a solvent and vehicle as defined in §170.3(o)(27) of this chapter; and a surface-active agent as defined in §170.3(o)(29) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63897, Dec. 12, 1994]

§ 184.1914 Trypsin.

(a) Trypsin (CAS Reg. No. 9002–07–7) is an enzyme preparation obtained from purified extracts of porcine or bovine pancreas. It is a white to tan amorphous powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.21.4).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995, as amended at 78 FR 14667, Mar. 7, 2013]

§ 184.1923 Urea.

(a) Urea ($CO(NH_2)_2$, CAS Reg. No. 57–13–6) is the diamide of carbonic acid and is also known as carbamide. It is a white, odorless solid and is commonly produced from CO_2 by ammonolysis or from cyanamide by hydrolysis.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in §170.3(o)(14) of this chapter and as a fermentation aid.

(2) The ingredient is used in yeast-raised bakery products; in alcoholic beverages as defined in §170.3(n)(2) of this chapter; and in gelatin products.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51616, Nov. 10, 1983, as amended at 49 FR 19816, May 10, 1984; 73 FR 8608, Feb. 14, 2008]

§ 184.1924 Urease enzyme preparation from Lactobacillus fermentum.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic bacterium *Lactobacillus fermentum*. It contains the enzyme urease (CAS Reg. No. 9002–13–5), which facilitates the hydrolysis of urea to ammonia and carbon dioxide. It is produced by a pure culture fermentation process and by using materials that are generally recognized as safe (GRAS) or are food additives that have been approved for this use by the Food and Drug Administration (FDA).

(b) The ingredient meets the general and additional requirements for enzyme preparations in the ''Food Chemicals Codex,'' 3d ed. (1981), pp. 107–110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the

National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in wine, as defined in 27 CFR 1.10 and 4.10, as an enzyme as defined in §170.3(o)(9) of this chapter to convert urea to ammonia and carbon dioxide.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice is limited to use of this ingredient in wine to inhibit formation of ethyl carbamate.

[57 FR 60473, Dec. 21, 1992, as amended at 85 FR 72907, Nov. 16, 2020]

§ 184.1930 Vitamin A.

(a)(1) Vitamin A (retinol; CAS Reg. No. 68–26–8) is the alcohol 9,13-dimethyl-7-(1,1,5-trimethyl-6-cyclohexen-5-yl)-7,9,11,13-nonatetraen-15-ol. It may be nearly odorless or have a mild fishy odor. Vitamin A is extracted from fish liver oils or produced by total synthesis from β-ionone and a propargyl halide.

(2) Vitamin A acetate (retinyl acetate; CAS Reg. No. 127–47–9) is the acetate ester of retinol. It is prepared by esterifying retinol with acetic acid.

(3) Vitamin A palmitate (retinyl palmitate; CAS Reg. No. 79–81–2) is the palmitate ester of retinol. It is prepared by esterifying retinol with palmitic acid.

(b) The ingredient meets the specifications for vitamin A in the Food Chemicals Codex, 3d Ed. (1981), p. 342, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. Vitamin A may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51610, Nov. 10, 1983]

§ 184.1945 Vitamin B_{12}.

(a) Vitamin B_{12}, also known as cyanocobalamin ($C_{63}H_{88}CoN_{14}O_{14}P$, CAS Reg. No. 68–0919–099), is produced commercially from cultures of *Streptomyces griseus.*

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 343, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon

the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in §170.3(o)(20) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Vitamin B_{12} also may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 6341, Feb. 15, 1985]

§ 184.1950 Vitamin D.

(a) Vitamin D is added to food as the following food ingredients:

(1) Crystalline vitamin D_2 ($C_{28}H_{44}O$, CAS Reg. No. 50–14–6), also known as ergocalciferol, is the chemical 9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol. The ingredient is produced by ultraviolet irradiation of ergosterol isolated from yeast and related fungi and is purified by crystallization.

(2) Crystalline vitamin D_3 ($C_{27}H_{44}O$, CAS Reg. No. 67–97–0), also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E,)-5,7,10(19)-cholestatrien-3-ol. Vitamin D_3 occurs in, and is isolated from, fish liver oils. It is also manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol. It is purified by crystallization. Vitamin D_3 is the vitamin D form that is produced endogenously in humans through sunlight activation of 7-dehydrocholesterol in the skin.

(3) Vitamin D_2 resin and vitamin D_3 resin are the concentrated forms of irradiated ergosterol (D_2) and irradiated 7-dehydrocholesterol (D_3) that are separated from the reacting materials in paragraphs (a)(1) and (2) of this section. The resulting products are sold as food sources of vitamin D without further purification.

(b) Vitamin D_2 and vitamin D_3 as crystals meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 344 and 345, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Vitamin D_2 resin and vitamin D_3 resin must be of a purity suitable for their intended use.

(c)(1) In accordance with §184.1(b)(2), the ingredients are used in food as the sole source of added vitamin D only within the following specific limitations:

Category of food	Maximum levels in food (as served)	Functional use
Breakfast cereals, §170.3(n)(4) of this chapter.	350 (IU/100 grams).	Nutrient supplement, §170.3(o)(20) of this chapter.
Grain products and pastas, §170.3(n)(23) of this chapter.	90(IU/100 grams)	Do.
Milk, §170.3(n)(30) of this chapter.	42 (IU/100 grams)	Do.
Milk products, §170.3(n)(31) of this chapter.	89 (IU/100 grams)	Do.

(2) Vitamin D may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(3) Vitamin D may be used in margarine in accordance with §166.110 of this chapter.

(d) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

[50 FR 30152, July 24, 1985, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1973 Beeswax (yellow and white).

(a) Beeswax (CAS Reg. No. 8012–89–3) is a secretory product of honey bees used as a structural material in honeycombs. Beeswax is prepared from honeycombs after removal of the honey by draining or centrifuging. The combs are melted in hot water or steam or with solar heat, and strained. The wax is refined by melting in hot water to which sulfuric acid or alkali may be added to extract impurities. The resulting wax is referred to as yellow

beeswax. White beeswax is produced by bleaching the constituent pigments of yellow beeswax with peroxides, or preferably it is bleached by sun light.

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 3d Ed. (1981), pp. 34–35, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter, as a lubricant as defined in §170.3(o)(18) of this chapter, and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(d) The ingredient is used in food, in accordance with §184.1(b)(1) of this chapter, at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of: 0.065 percent for chewing gum as defined in §170.3(n)(6) of this chapter; 0.005 percent for confections and frostings as defined in §170.3(n)(9) of this chapter; 0.04 percent for hard candy as defined in §170.3(n)(25) of this chapter; 0.1 percent for soft candy as defined in §170.3(n)(38) of this chapter; and 0.002 percent or less for all other food categories.

[43 FR 14644, Apr. 7, 1978, as amended at 49 FR 5613, Feb. 14, 1984; 50 FR 49536, Dec. 3, 1985]

§ 184.1976 Candelilla wax.

(a) Candelilla wax (CAS Reg. No. 8006–44–8) is obtained from the candelilla plant. It is a hard, yellowish-brown, opaque-to-translucent wax. Candelilla wax is prepared by immersing the plants in boiling water containing sulfuric acid and skimming off the wax that rises to the surface. It is composed of about 50 percent hydrocarbons with smaller amounts of esters and free acids.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 67, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a lubricant as defined in §170.3(o)(18) of this chapter and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: in chewing gum as defined in §170.3(n)(6) of this chapter and in hard candy as defined in §170.3(n)(25) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51617, Nov. 10, 1983]

§ 184.1978 Carnauba wax.

(a) Carnauba wax (CAS Reg. No. 008–015–869) is obtained from the leaves and buds of the Brazilian wax palm *Copernicia cerifera* Martius. The wax is hard, brittle, sparingly soluble in cold organic solvents and insoluble in water. It is marketed in five grades designated No. 1 through No. 5. Grades No. 4 and No. 5 represent the bulk of the commercial trade volume. These commercial grades consist chiefly of C_{24} to C_{32} normal saturated monofunctional fatty acids and normal saturated monofunctional primary alcohols.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 73, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an anticaking agent as defined §170.3(o)(1) of this chapter; as a formulation aid as defined in §170.3(o)(14) of this chapter; as a lubricant and release agent as defined in §170.3(o)(18) of this chapter; and as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in §170.3(n)(1) of this chapter; chewing gun as defined in §170.3(n)(6) of this chapter; confections and frostings as defined in §170.3(n)(9) of this chapter; fresh fruits and fruit juices as defined in §170.3(n)(16) of this chapter; gravies and sauces as defined in §170.3(n)(24) of this chapter; processed fruits and fruit juices as defined in §170.3(n)(35) of this chapter; and soft candy as defined in §170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51147, Nov. 7, 1983]

§ 184.1979 Whey.

(a)(1) *Whey*. Whey is the liquid substance obtained by separating the coagulum from milk, cream, or skim milk in cheesemaking. Whey obtained from a procedure, in which a significant amount of lactose is converted to lactic acid, or from the curd formation by direct acidification of milk, is known as acid whey. Whey obtained from a procedure in which there is insignificant conversion of lactose to lactic acid is known as sweet whey. Sweet whey has a maximum titratable acidity of not more than 0.16 percent, calculated as lactic acid, and an alkalinity of ash of not more than 225 milliliters of 0.1*N* hydrochloric acid per 100 grams. The acidity of whey, sweet or acid, may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(2) *Concentrated whey*. Concentrated whey is the liquid substance obtained by the partial removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(3) *Dry or dried whey*. Dry or dried whey is the dry substance obtained by the removal of water from whey, while leaving all other constituents in the same relative proportions as in whey.

(b) The ingredients meet the following specifications:

(1) The analysis of whey, concentrated whey, and dry (dried) whey, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(i) Protein content, 10 to 15 percent—as determined by the methods prescribed in section 16.036 (liquid sample),

entitled ''Total Nitrogen—Official Final Action'' under the heading ''Total Solids,'' or in section 16.193 (dry sample), entitled ''Kjeldahl Method'' under the heading ''Protein—Official Final Action.''

(ii) Fat content, 0.2 to 2.0 percent—as determined by the methods prescribed in section 16.059 (liquid sample), ''Reese-Gottlieb Method [Reference Method] (11)—Official Final Action'' under the heading ''Fat,'' or in section 16.199 (dry sample), entitled ''Fat in Dried Milk (45)—Official Final Action.''

(iii) Ash content, 7 to 14 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled ''Ash (5)—Official Final Action'' under the heading ''Total Solids,'' or in section 16.196 (dry sample), entitled ''Ash—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(iv) Lactose content, 61 to 75 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled ''Gravimetric Method—Official Final Action'' under the heading ''Lactose,'' or in section 31.061 (dry sample), entitled ''Lane-Eynon General Volumetric Method'' under the heading ''Lactose—Chemical Methods—Official Final Action.''

(v) Moisture content, 1 to 8 percent—as determined by the methods prescribed in section 16.192, entitled ''Moisture (41)—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled ''Method I—Official Final Action'' under the heading ''Total Solids.''

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled ''Acidity (2)—Official Final Action'' under the heading ''Milk,'' or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent) as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(3) The whey must be derived from milk that has been pasteurized, or the whey and modified whey product must be subjected to pasteurization techniques or its equivalent before use in food.

(c) Whey, concentrated whey, and dry (dried) whey may be used in food in accordance with good manufacturing practice as indicated in §184.1(b)(1).

(d) The label on the whey form sold to food manufacturers shall read as follows:

(1) For whey: ''(Sweet or acid) whey'' or ''whey (____% titratable acidity).

(2) For concentrated whey: ''Concentrated (sweet or acid) whey, ____% solids'' or ''Concentrated whey (____% titratable acidity), ____% solids''.

(3) For dry (dried) whey: ''Dry (dried) (sweet or acid) whey'' or ''dry (dried) whey, (____% titratable acidity)''.

(e) Whey, concentrated whey, or dry (dried) whey in a finished food product shall be listed as ''whey.''

[46 FR 44439, Sept. 4, 1981; 47 FR 7410, Feb. 19, 1982, as amended at 54 FR 24899, June 12, 1989; 64 FR 1760, Jan. 12, 1999; 81 FR 5596, Feb. 3, 2016]

§184.1979a Reduced lactose whey.

(a) Reduced lactose whey is the substance obtained by the removal of lactose from whey. The lactose content of the finished dry product shall not exceed 60 percent. Removal of the lactose is accomplished by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced lactose whey can be used as a fluid, concentrate, or a dry product form. The acidity of reduced lactose whey may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(b) The reduced lactose whey meets the following specifications:

(1) The analysis of reduced lactose whey, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(i) Protein content, 16 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled ''Total Nitrogen—Official Final Action'' under the heading ''Total Solids,'' or in section 16.193 (dry sample), entitled ''Kjeldahl Method'' under the heading ''Protein—Official Final Action.''

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in section 16.059 (liquid sample), ''Reese-Gottlieb Method [Reference Method] (11)—Official Final Action'' under the heading ''Fat,'' or in section 16.199 (dry sample), entitled ''Fat in Dried Milk (45)—Official Final Action.''

(iii) Ash content, 11 to 27 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled ''Ash (5)—Official Final Action'' under the heading ''Total Solids,'' or in section 16.196 (dry sample), entitled ''Ash—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(iv) Lactose content, not more than 60 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled ''Gravimetric Method—Official Final Action'' under the heading ''Lactose,'' or in section 31.061 (dry sample), entitled ''Lane-Eynon General Volumetric Method'' under the heading ''Lactose—Chemical Methods—Official Final Action.''

(v) Moisture content, 1 to 6 percent—as determined by the method prescribed in section 16.192, entitled ''Moisture (41)—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled ''Method I—Official Final Action'' under the heading ''Total Solids.''

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled ''Acidity (2)—Official Final Action'' under the heading ''Milk,'' or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(3) The reduced lactose whey shall be derived from milk that has been pasteurized, or the reduced lactose whey shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) Reduced lactose whey may be used in food in accordance with good manufacturing practice as indicated in §184.1(b)(1).

(d) The percent of lactose present on a dry product basis, i.e., ''reduced lactose whey (____% lactose),'' shall be declared on the label of the package sold

to food manufacturers. The percent of lactose may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of lactose in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of reduced lactose whey in a finished food product shall be listed as ''reduced lactose whey.''

[46 FR 44440, Sept. 4, 1981, as amended at 54 FR 24899, June 12, 1989; 64 FR 1760, Jan. 12, 1999; 81 FR 5596, Feb. 3, 2016]

§ 184.1979b Reduced minerals whey.

(a) Reduced minerals whey is the substance obtained by the removal of a portion of the minerals from whey. The dry product shall not contain more than 7 percent ash. Reduced minerals whey is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, reduced minerals whey can be used as a fluid, concentrate, or a dry product form. The acidity of reduced minerals whey may be adjusted by the additional of safe and suitable pH-adjusting ingredients.

(b) The reduced minerals whey meets the following specifications:

(1) The analysis of reduced minerals whey, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(i) Protein content, 10 to 24 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled ''Total Nitrogen—Official Final Action'' under the heading ''Total Solids,'' or in section 16.193 (dry sample), entitled ''Kjeldahl Method'' under the heading ''Protein—Official Final Action.''

(ii) Fat content, 1 to 4 percent—as determined by the methods prescribed in section 16.059 (liquid sample), ''Reese-Gottlieb Method [Reference Method] (11)—Official Final Action'' under the heading ''Fat,'' or in section 16.199 (dry sample), entitled ''Fat in Dried Milk (45)—Official Final Action.''

(iii) Ash content, maximum 7 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled ''Ash (5)—Official Final Action'' under the heading ''Total Solids,'' or in section 16.196 (dry sample), entitled ''Ash—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(iv) Lactose content, maximum 85 percent—as determined by the methods prescribed in section 16.057 (liquid sample), entitled ''Gravimetric Method—Official Final Action'' under the heading ''Lactose,'' or in section 31.061 (dry sample), entitled ''Lane-Eynon General Volumetric Method'' under the heading ''Lactose—Chemical Methods—Official Final Action.''

(v) Moisture content, 1 to 6 percent—as determined by the methods prescribed in section 16.192, entitled ''Moisture (41)—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled ''Method I—Official Final Action'' under the heading ''Total Solid.''

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled ''Acidity (2)—Official Final Action'' under the heading ''Milk,'' or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated

by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(3) The reduced minerals whey shall be derived from milk that has been pasteurized, or the reduced minerals whey shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) The reduced minerals whey may be used in food in accordance with good manufacturing practice as indicated in § 184.1(b)(1).

(d) The percent of minerals present on a dry product basis, i.e., ''reduced minerals whey (____% minerals),'' shall be declared on the label of the package sold to food manufacturers. The percent of minerals may be declared in 2-percent increments expressed as a multiple of 2, not greater than the actual percentage of minerals in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of reduced minerals whey in a finished food product shall be listed as ''reduced minerals whey''.

[46 FR 44441, Sept. 4, 1981, as amended at 54 FR 24899, June 12, 1989; 64 FR 1761, Jan. 12, 1999; 81 FR 5596, Feb. 3, 2016]

§ 184.1979c Whey protein concentrate.

(a) Whey protein concentrate is the substance obtained by the removal of sufficient nonprotein constituents from whey so that the finished dry product contains not less than 25 percent protein. Whey protein concentrate is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, whey protein concentrate can be used as a fluid, concentrate, or dry product form. The acidity of whey protein concentrate may be adjusted by the addition of safe and suitable pH-adjusting ingredients.

(b) The whey protein concentrate meets the following specifications:

(1) The analysis of whey protein concentrate, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(i) Protein content, minimum 25 percent—as determined by the methods prescribed in section 16.036 (liquid sample), entitled ''Total Nitrogen—Officials Final Action'' under the heading ''Total Solids,'' or in section 16.193 (dry sample), entitled ''Kjeldahl Method'' under the heading ''Protein—Official Final Action.''

(ii) Fat content, 1 to 10 percent—as determined by the methods prescribed in section 16.059 (liquid sample), ''Reese-Gottlieb Method [Reference Method] (11)—Official Final Action'' under the heading ''Fat,'' or in section 16.199 (dry sample), entitled ''Fat in Dried Milk (45)—Official Final Action.''

(iii) Ash content, 2 to 15 percent—as determined by the methods prescribed in section 16.035 (liquid sample), entitled ''Ash (5)—Official Final Action'' under the heading ''Total Solids,'' or in section 16.196 (dry sample), entitled ''Ash—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(iv) Lactose content, maximum 60 percent—as determined by the methods

prescribed in section 16.057 (liquid sample), entitled ''Gravimetric Method—Official Final Action'' under the heading ''Lactose,'' or in section 31.061 (dry sample), entitled ''Lane-Eynon General Volumetric Method'' under the heading ''Lactose—Chemical Methods—Official Final Action.''

(v) Moisture content, 1 to 6 percent—as determined by the methods prescribed in section 16.192, entitled ''Moisture (41)—Official Final Action'' under the heading ''Dried Milk, Nonfat Dry Milk, and Malted Milk.''

(vi) Solids content, variable—as determined by the methods prescribed in section 16.032, entitled ''Method I—Official Final Action'' under the heading ''Total Solids.''

(vii) Titratable Acidity, variable—as determined by the methods prescribed in section 16.023, entitled ''Acidity (2)—Official Final Action'' under the heading ''Milk,'' or by an equivalent potentiometric method.

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address *http://www.nap.edu*), or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(3) The whey protein concentrate shall be derived from milk that has been pasteurized, or the whey protein concentrate shall be subjected to pasteurization techniques or its equivalent before use in food.

(c) The whey protein concentrate may be used in food in accordance with good manufacturing practice as indicated in §184.1(b)(1).

(d) The percent of protein present on a dry product basis, i.e., ''whey protein concentrate (____% protein),'' shall be declared on the label of the package sold to food manufacturers. The percent of protein may be declared in 5-percent increments, expressed as a multiple of 5, not greater than the actual percentage of protein in the product, or as an actual percentage provided that an analysis of the product on which the actual percentage is based is supplied to the food manufacturer.

(e) The presence of whey protein concentrate in a finished food product shall be listed as ''whey protein concentrate''.

[46 FR 44441, Sept. 4, 1981, as amended at 54 FR 24899, June 12, 1989; 64 FR 1761, Jan. 12, 1999; 81 FR 5596, Feb. 3, 2016]

§ 184.1983 Bakers yeast extract.

(a) Bakers yeast extract is the food ingredient resulting from concentration of the solubles of mechanically ruptured cells of a selected strain of yeast, *Saccharomyces cerevisiae*. It may be concentrated or dried.

(b) The ingredient meets the following specifications on a dry weight basis: Less than 0.4 part per million (ppm) arsenic, 0.13 ppm cadmium, 0.2 ppm lead, 0.05 ppm mercury, 0.09 ppm selenium, and 10 ppm zinc.

(c) The viable microbial content of the finished ingredient as a concentrate or dry material is:

(1) Less than 10,000 organisms/gram by aerobic plate count.

(2) Less than 10 yeasts and molds/gram.

(3) Negative for *Salmonella*, *E. coli*, coagulase positive *Staphylococci*, *Clostridium perfringens*, *Clostridium botulinum*, or any other recognized microbial pathogen or any harmful microbial toxin.

(d) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter at a level not to exceed 5 percent in food.

(e) This regulation is issued prior to general evaluation of use of this ingredient in order to affirm as GRAS the specific use named.

§ 184.1984 Zein.

(a) Zein (CAS Reg. No. 9010–66–6) is one of the components of corn gluten. It is produced commercially by extraction from corn gluten with alkaline aqueous isopropyl alcohol containing sodium hydroxide. The extract is then cooled, which causes the zein to precipitate.

(b) The ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a surface-finishing agent as defined in §170.3(o)(30) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[50 FR 8999, Mar. 6, 1985, as amended at 73 FR 8608, Feb. 14, 2008]

§ 184.1985 Aminopeptidase enzyme preparation derived from lactococcus lactis.

(a) Aminopeptidase enzyme preparation is derived from the nonpathogenic and nontoxicogenic bacterium *Lactococcus lactis* (previously named *Streptococcus lactis*). The preparation contains the enzyme aminopeptidase (CAS Reg. No. 9031–94–1; EC 3.4.11.1) and other peptidases that hydrolyze milk proteins. The preparation is produced by pure culture fermentation.

(b) The ingredient meets the specifications for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), pp. 107–110, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1200, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in §170.3(o)(9) of this chapter, as an optional ingredient for flavor development in the manufacture of cheddar cheese, in accordance with §133.113 of this chapter, and in the preparation of protein hydrolysates.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

[60 FR 54193, Oct. 20, 1995, as amended at 78 FR 14667, Mar. 7, 2013]

states prominently, ''Caution—Contains new color additive—For investigational use only.'' No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Subpart A—Foods

Sec.

Subpart B—Drugs

Subpart C—Cosmetics

Subpart D—Medical Devices

AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

SOURCE: 42 FR 15643, Mar. 22, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 73 appear at 66 FR 66742, Dec. 27, 2001.

Subpart A—Foods

§ 73.1 Diluents in color additive mixtures for food use exempt from certification.

The following substances may be safely used as diluents in color additive mixtures for food use exempt from certification, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. If a specification for a particular diluent is not set forth in this part 73, the material shall be of a purity consistent with its intended use.

(a) *General use.* (1) Substances that are generally recognized as safe under the conditions set forth in section 201(s) of the act.

(2) Substances meeting the definitions and specifications set forth under subchapter B of this chapter, and which are used only as prescribed by such regulations.

(3) The following:

Substances	Definitions and specifications	Restrictions
Calcium disodium EDTA (calcium disodium ethyl- enediamine- tetraacetate).	Contains calcium disodium ethyl- enediamine- tetraacetate dihydrate (CAS Reg. No. 6766–87–6) as set forth in the Food Chemicals Codex, 3d ed., p. 50, 1981.	May be used in aqueous solutions and aqueous dispersions as a preservative and sequestrant in color additive mixtures intended only for ingested use; the color additive mixture (solution or dispersion) may contain not more than 1 percent by weight of the diluent (calculated as anhydrous calcium disodium ethyl- enediamine-tetraacetate).
Castor oil	As set forth in U.S.P. XVI	Not more than 500 p.p.m. in the finished food. Labeling of color additive mixtures containing castor oil shall bear adequate directions for use that will result in a food meeting this restriction.
Dioctylsodium sulfosuccinate	As set forth in sec. 172.810 of this chapter.	Not more than 9 p.p.m. in the finished food. Labeling of color additive mixtures containing dioctylsodium sulfosuccinate shall bear adequate directions for use that will result in a food meeting this restriction.
Disodium EDTA (disodium ethyl- enediamine- tetraacetate).	Contains disodium ethyl- enediamine- tetraacetate dihydrate (CAS Reg. No. 6381–92–6) as set forth in the Food Chemicals Codex, 3d ed., p. 104, 1981.	May be used in aqueous solutions and aqueous dispersions as a preservative and sequestrant in color additive mixtures intended only for ingested use; the color additive mixture (solution or dispersion) may contain not more than 1 percent by weight of the diluent (calculated as anhydrous disodium ethyl- enediamine- tetraacetate).

(b) *Special use*—(1) *Diluents in color additive mixtures for marking food*—(i) *Inks for marking food supplements in tablet form, gum, and confectionery*. Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, SDA–3A	As set forth in 26 CFR pt. 212	No residue.
n-Butyl alcohol		Do.
Cetyl alcohol	As set forth in N.F. XI	Do.
Cyclohexane		Do.
Ethyl cellulose	As set forth in sec. 172.868 of this chapter.	
Ethylene glycol monoethyl ether		Do.
Isobutyl alcohol		Do.
Isopropyl alcohol		Do.
Polyoxyethylene sorbitan monooleate (polysorbate 80).	As set forth in sec. 172.840 of this chapter.	
Polyvinyl acetate	Molecular weight, minimum 2,000.	
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	
Rosin and rosin derivatives	As set forth in sec. 172.615 of this chapter.	
Shellac, purified	Food grade.	

(ii) *Inks for marking fruit and vegetables*. Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Acetone	As set forth in N.F. XI	No residue.
Alcohol, SDA–3A	As set forth in 26 CFR pt. 212	Do.
Benzoin	As set forth in U.S.P. XVI.	
Copal, Manila	.	
Ethyl acetate	As set forth in N.F. XI	Do.
Ethyl cellulose	As set forth in sec. 172.868 of this chapter.	
Methylene chloride		Do.
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	
Rosin and rosin derivatives	As set forth in sec. 172.615 of this chapter.	

Substances	Definitions and specifications	Restrictions
Silicon dioxide	As set forth in sec. 172.480 of this chapter.	Not more than 2 pct of the ink solids.
Terpene resins, natural	As set forth in sec. 172.615 of this chapter.	
Terpene resins, synthetic	Polymers of α- and β-pinene.	

(2) *Diluents in color additive mixtures for coloring shell eggs.* Items listed in paragraph (a) of this section and the following, subject to the condition that there is no penetration of the color additive mixture or any of its components through the eggshell into the egg:

Alcohol, denatured, formula 23A (26 CFR part 212), Internal Revenue Service.
Damar gum (resin).
Diethylene glycol distearate.
Dioctyl sodium sulfosuccinate.
Ethyl cellulose (as identified in §172.868 of this chapter).
Ethylene glycol distearate.
Japan wax.
Limed rosin.
Naphtha.
Pentaerythritol ester of fumaric acid-rosin adduct.
Polyethylene glycol 6000 (as identified in §172.820 of this chapter).
Polyvinyl alcohol.
Rosin and rosin derivatives (as identified in §172.615 of this chapter).

(3) *Miscellaneous special uses.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	In or as food-tablet coatings; limit, not more than 0.1 pct in the finished food; labeling of color additive mixtures containing polyvinylpyrrolidone shall bear adequate directions for use that will result in a food meeting this restriction.

[42 FR 15643, Mar. 22, 1977, as amended at 57 FR 32175, July 21, 1992; 69 FR 24511, May 4, 2004]

§ 73.30 Annatto extract.

(a) *Identity.* (1) The color additive annatto extract is an extract prepared from annatto seed, *Bixa orellana* L., using any one or an appropriate combination of the food-grade extractants listed in paragraph (a)(1) (i) and (ii) of this section:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this section. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto extract may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead as Pb, not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this section are used, annatto extract shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Annatto extract may be safely used for coloring

foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this section.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.35 Astaxanthin.

(a) *Identity.* (1) The color additive astaxanthin is 3, 3′-dihydroxy-β, β-carotene-4, 4′-dione.

(2) Astaxanthin may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with astaxanthin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Astaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.
0.05 percent solution in chloroform, complete and clear.
Absorption maximum wavelength 484–493 nanometers (in chloroform).
Residue on ignition, not more than 0.1 percent.
Total carotenoids other than astaxanthin, not more than 4 percent.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals, not more than 10 parts per million.
Assay, minimum 96 percent.

(c) *Uses and restrictions.* Astaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of color additive in feed is such that the color additive shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin shall be declared in accordance with §§ 101.22(k)(2) and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[60 FR 18738, Apr. 13, 1995]

§ 73.37 Astaxanthin dimethyldisuccinate.

(a) *Identity.* (1) The color additive astaxanthin dimethyldisuccinate is 3,3′-bis(4-methoxy-1,4-dioxobutoxy)-β,β-carotene–4,4′-dione.

(2) Astaxanthin dimethyldisuccinate may be added to the fish feed only as a component of a stabilized mixture. Color additive mixtures for fish feed use made with astaxanthin dimethyldisuccinate may contain only those diluents that are suitable and are listed in this subpart as safe for use in

color additive mixtures for coloring foods.

(b) *Specifications.* Astaxanthin dimethyldisuccinate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

(1) Physical state, solid.

(2) 0.05 percent solution in chloroform, complete and clear.

(3) Absorption maximum wavelength 484–493 nanometers (in chloroform).

(4) Residue on ignition, not more than 0.1 percent.

(5) Total carotenoids other than astaxanthin dimethyldisuccinate, not more than 4 percent.

(6) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million).

(7) Arsenic, not more than 2 mg/kg (2 parts per million).

(8) Mercury, not more than 1 mg/kg (1 part per million).

(9) Heavy metals, not more than 10 mg/kg (10 parts per million).

(10) Assay including astaxanthin dimethyldisuccinate, astaxanthin monomethylsuccinate, and astaxanthin, minimum 96 percent.

(c) *Uses and restrictions.* Astaxanthin dimethyldisuccinate may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin dimethyldisuccinate in the finished feed, when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 110 milligrams per kilogram (mg/kg), which is equivalent to 80 mg/kg astaxanthin (72 grams per ton).

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin dimethyldisuccinate shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[74 FR 57251, Nov. 5, 2009]

§ 73.40 Dehydrated beets (beet powder).

(a) *Identity.* (1) The color additive dehydrated beets is a dark red powder prepared by dehydrating sound, mature, good quality, edible beets.

(2) Color additive mixtures made with dehydrated beets may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive shall conform to the following specifications:

Volatile matter, not more than 4 percent.
Acid insoluble ash, not more than 0.5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Dehydrated beets may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.50 Ultramarine blue.

(a) *Identity.* The color additive ultramarine blue is a blue pigment obtained by calcining a mixture of kaolin, sulfur, sodium carbonate, and carbon at temperatures above 700 °C. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfo-silicate having the approximate formula $Na_7Ai_6Si_6O_{24}S_3$.

(b) *Specifications.* Ultramarine blue shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The color additive ultramarine blue may be safely used for coloring salt intended for animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5 percent by weight of the salt.

(d) *Labeling requirements.* The color additive shall be labeled in accordance with the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.70 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white powder consisting essentially of calcium carbonate ($CaCO_3$) prepared either by grinding naturally occurring limestone or synthetically, by precipitation.

(2) Color additive mixtures for food use made with calcium carbonate may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive meets the specifications of the Food Chemicals Codex, 10th ed. (2016), pp. 213–214 (calcium carbonate) and p. 754 (limestone, ground), which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color soft and hard candies and mints, and in inks used on the surface of chewing gum, except that it may not be used to color chocolate for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes must conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and, therefore, batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[82 FR 51557, Nov. 7, 2017]

§ 73.75 Canthaxanthin.

(a) *Identity.* (1) The color additive canthaxanthin is β-carotene-4,4′-dione.

(2) Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Canthaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Physical state, solid.
1 percent solution in chloroform, complete and clear.
Melting range (decomposition), 207 °C. to 212 °C. (corrected).
Loss on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Total carotenoids other than trans-canthaxanthin, not more than 5 percent.
Lead, not more than 10 parts per million.
Arsenic, not more than 3 parts per million.
Mercury, not more than 1 part per million.
Assay, 96 to 101 percent.

(c) *Use and restrictions.* (1) The color additive canthaxanthin may be safely used for coloring foods generally subject to the following restrictions:

(i) The quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food; and

(ii) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(2) Canthaxanthin may be safely used in broiler chicken feed to enhance the yellow color of broiler chicken skin in accordance with the following conditions: The quantity of canthaxanthin incorporated in the feed shall not exceed 4.41 milligrams per kilogam (4 grams per ton) of complete feed to supplement other known sources of xanthophyll and associated carotenoids to accomplish the intended effect.

(3) Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(i) Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture;

(ii) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and

(iii) The quantity of color additive in feed shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(2) For purposes of coloring fish, the labeling of the color additive and any premixes prepared therefrom shall bear expiration dates (established through generally accepted stability testing methods) for the sealed and open container, other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c)(3) of this section.

(3) The presence of the color additive in finished fish feed prepared according to paragraph (c)(3) of this section shall be declared in accordance with § 501.4 of this chapter.

(4) The presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 50 FR 47534, Nov. 19, 1985; 63 FR 14817, Mar. 27, 1998]

§ 73.85 Caramel.

(a) *Identity.* (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:

Dextrose.
Invert sugar.
Lactose.
Malt sirup.
Molasses.
Starch hydrolysates and fractions thereof.
Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) Acids:

Acetic acid.
Citric acid.
Phosphoric acid.
Sulfuric acid.
Sulfurous acid.

(ii) Alkalis:

Ammonium hydroxide.
Calcium hydroxide U.S.P.
Potassium hydroxide.
Sodium hydroxide.

(iii) Salts: Ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in §172.854 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Caramel shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 0.1 part per million.

(c) *Uses and restrictions.* Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.90 β-Apo-8′-carotenal.

(a) *Identity.* (1) The color additive is β-apo-8′-carotenal.

(2) Color additive mixtures for food use made with β-apo-8′-carotenal may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* β-Apo-8′-carotenal shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Melting point (decomposition), 136 °C.–140 °C. (corrected).
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Assay (spectrophotometric), 96–101 percent.

(c) *Uses and restrictions.* The color additive β-apo-8′-carotenal may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β-apo-8′-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.95 β-Carotene.

(a) *Identity.* (1) The color additive is β-carotene prepared synthetically or obtained from natural sources.

(2) Color additive mixtures for food use made with β-carotene may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* β-carotene shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Assay (spectrophotometric), 96–101 percent.

(c) *Uses and restrictions.* The color additive β-carotene may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color those foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.100 Cochineal extract; carmine.

(a) *Identity.* (1) The color additive cochineal extract is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic extract of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)). The coloring principle is chiefly carminic acid.

(2) The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)).

(3) Color additive mixtures for food use made with cochineal extract or carmine may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Cochineal extract shall conform to the following specifications:

pH, not less than 5.0 and not more than 5.5 at 25 °C.
Protein (N × 6.25), not more than 2.2 percent.
Total solids, not less than 5.7 and not more than 6.3 percent.
Methyl alcohol, not more than 150 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 1.8 percent.

(2) Carmine shall conform to the following specifications:

Volatile matter (at 135 °C. for 3 hours), not more than 20.0 percent.
Ash, not more than 12.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 50.0 percent.

Carmine and cochineal extract shall be pasteurized or otherwise treated to destroy all viable Salmonella microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine and cochineal extract free of viable Salmonella microorganisms, which substances are not food additives as defined in section 201(s) of the act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the act.

(c) *Uses and restrictions.* Carmine and cochineal extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards

of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* (1) The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) The label of food products intended for human use, including butter, cheese, and ice cream, that contain cochineal extract or carmine shall specifically declare the presence of the color additive by listing its respective common or usual name, ''cochineal extract'' or ''carmine,'' in the statement of ingredients in accordance with § 101.4 of this chapter.

(e) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 74 FR 216, Jan. 5, 2009]

§ 73.125 Sodium copper chlorophyllin.

(a) *Identity.* (1) The color additive sodium copper chlorophyllin is a green to black powder prepared from chlorophyll by saponification and replacement of magnesium by copper. Chlorophyll is extracted from alfalfa (*Medicago sativa*) using any one or a combination of the solvents acetone, ethanol, and hexane.

(2) Color additive mixtures made with sodium copper chlorophyllin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Sodium copper chlorophyllin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

(1) Moisture, not more than 5.0 percent.

(2) Solvent residues (acetone, ethanol, and hexane), not more than 50 parts per million, singly or, in combination.

(3) Total copper, not less than 4 percent and not more than 6 percent.

(4) Free copper, not more than 200 parts per million.

(5) Lead (as Pb), not more than 10 parts per million.

(6) Arsenic (as As), not more than 3 parts per million.

(7) Mercury (as Hg), not more than 0.5 part per million.

(8) Ratio of absorbance at 405 nanometers (nm) to absorbance at 630 nm, not less than 3.4 and not more than 3.9.

(9) Total copper chlorophyllins, not less than 95 percent of the sample dried at 100 °C for 1 hour.

(c) *Uses and restrictions.* Sodium copper chlorophyllin may be safely used to color citrus-based dry beverage mixes in an amount not exceeding 0.2 percent in the dry mix.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[67 FR 35431, May 20, 2002]

§ 73.140 Toasted partially defatted cooked cottonseed flour.

(a) *Identity.* (1) The color additive toasted partially defatted cooked cottonseed flour is a product prepared as follows: Food quality cottonseed is delinted and decorticated; the meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown.

(2) Color additive mixtures for food use made with toasted partially defatted cooked cottonseed flour may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Toasted partially defatted cooked cottonseed flour shall conform to the following specifications:

Arsenic: It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

Lead (as Pb), not more than 10 parts per million.

Free gossypol content, not more than 450 parts per million.

(c) *Uses and restrictions.* The color additive toasted partially defatted cooked cottonseed flour may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.160 Ferrous gluconate.

(a) *Identity.* The color additive ferrous gluconate is the ferrous gluconate defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 122–123, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(b) *Specifications.* Ferrous gluconate shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a) of this section.

(c) *Uses and restrictions.* Ferrous gluconate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 49 FR 10089, Mar. 19, 1984]

§ 73.165 Ferrous lactate.

(a) *Identity.* The color additive ferrous lactate is the ferrous lactate defined in § 184.1311 of this chapter.

(b) *Specifications.* Ferrous lactate shall meet the specifications given in the Food Chemicals Codex, 4th ed. (1996), pp. 154 to 155, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(c) *Uses and restrictions.* Ferrous lactate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act (the act).

[61 FR 40319, Aug. 2, 1996, as amended at 66 FR 66742, Dec. 27, 2001; 81 FR 5590, Feb. 3, 2016]

§ 73.169 Grape color extract.

(a) *Identity.* (1) The color additive grape color extract is an aqueous solution of anthocyanin grape pigments made from Concord grapes or a dehydrated water soluble powder prepared from the aqueous solution. The aqueous solution is prepared by extracting the pigments from precipitated lees produced during the storage of Concord grape juice. It contains the common components of grape juice, namely anthocyanins, tartrates, malates, sugars, and minerals, etc., but not in the same proportion as found in grape juice. The dehydrated water soluble powder is prepared by spray drying the aqueous solution containing added malto-dextrin.

(2) Color additive mixtures for food use made with grape color extract may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Grape color extract shall conform to the following specifications: Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act. Lead (as Pb), not more than 10 parts per million. Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions.* Grape color extract may be safely used for the coloring of nonbeverage food, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches are exempt from the certification requirements of section 721(c) of the Act.

[46 FR 47532, Sept. 29, 1981]

§ 73.170 Grape skin extract (enocianina).

(a) *Identity.* (1) The color additive grape skin extract (enocianina) is a purplish-red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes have been pressed to produce grape juice or wine. It contains the common components of grape juice; namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the steeping process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol. The extract is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulphur dioxide may be present.

(2) Color additive mixtures for food use made with grape skin extract (enocianina) may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Grape skin extract (enocianina) shall conform to the following specifications:

Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions.* Grape skin extract (enocianina) may be safely used for the coloring of still and carbonated drinks and ades, beverage bases, and alcoholic beverages subject to the following restrictions:

(1) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless artificial color is authorized by such standards.

(2) Its use in alcoholic beverages shall be in accordance with the provisions of parts 4 and 5, title 27 CFR.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. The common or usual name of the color additive is ''grape

skin extract'' followed, if desired, by ''(enocianina)''.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.185 Haematococcus algae meal.

(a) *Identity.* (1) The color additive haematococcus algae meal consists of the comminuted and dried cells of the alga *Haematococcus pluvialis*.

(2) Haematococcus algae meal may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with haematococcus algae meal may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Haematococcus algae meal shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals (as Pb), not more than 10 parts per million.
Astaxanthin, not less than 1.5 percent.

(c) *Uses and restrictions.* Haematococcus algae meal may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing haematococcus algae meal shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[65 FR 41584, July 6, 2000]

§ 73.200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for food use made with synthetic iron oxide may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Synthetic iron oxide for human food use shall conform to the following specifications:

Arsenic (as As), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million (ppm)).
Lead (as Pb), not more than 5 mg/kg (5 ppm).
Mercury (as Hg), not more than 1 mg/kg (1 ppm).

(2) Synthetic iron oxide for dog and cat food use shall conform to the following specifications:

Arsenic (as As), not more than 5 parts per million.
Lead (as Pb), not more than 20 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* (1) Synthetic iron oxide may be safely used for

human food use subject to the following restrictions:

(i) In sausage casings intended for human consumption in an amount not exceeding 0.10 percent by weight of the finished food.

(ii) In soft and hard candy, mints, and chewing gum at levels consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

(iii) In dietary supplement tablets and capsules, including coatings and printing inks, such that the total amount of elemental iron per day for labeled dosages does not exceed 5 milligrams.

(2) Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25 percent by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 59 FR 10578, Mar. 7, 1994; 80 FR 14842, Mar. 20, 2015; 83 FR 54872, Nov. 1, 2018]

§ 73.250 Fruit juice.

(a) *Identity.* (1) The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 60 FR 52629, Oct. 10, 1995]

§ 73.260 Vegetable juice.

(a) *Identity.* (1) The color additive vegetable juice is prepared either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the dried vegetable. The color additive may be concentrated or dried. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to

color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 60 FR 52629, Oct. 10, 1995]

§ 73.275 Dried algae meal.

(a) *Identity.* The color additive dried algae meal is a dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth), molasses, cornsteep liquor, and a maximum of 0.3 percent ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum.*

(b) *Uses and restrictions.* The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (b)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(c) *Labeling.* The label of the color additives and any premixes prepared therefrom shall bear in addition to the information required by § 70.25 of this chapter.

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this section.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.295 Tagetes (Aztec marigold) meal and extract.

(a) *Identity.* (1) The color additive tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (*Tagetes erecta* L.) mixed with not more than 0.3 percent ethoxyquin.

(2) The color additive tagetes (Aztec marigold) extract is a hexane extract of the flower petals of the Aztec marigold (*Tagetes erecta* L.). It is mixed with an edible vegetable oil, or with an edible vegetable oil and a hydrogenated edible vegetable oil, and not more than 0.3 percent ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

(b) *Specifications.* (1) Tagetes (Aztec marigold) meal is free from admixture with other plant material from *Tageteserecta* L. or from plant material or flowers of any other species of plants.

(2) Tagetes (Aztec marigold) extract shall be prepared from tagetes (Aztec marigold) petals meeting the specifications set forth in paragraph (b)(1) of this section and shall conform to the following additional specifications:

Melting point	53.5–55.0 °C.
Iodine value	132–145.
Saponification value	175–200.
Acid value	0.60–1.20.
Titer	35.5–37.0 °C.
Unsaponifiable matter	23.0 percent–27.0 percent.
Hexane residue	Not more than 25 p.p.m.

All determinations, except the hexane residue, shall be made on the initial extract of the flower petals (after drying in a vacuum oven at 60 °C. for 24 hours) prior to the addition of the oils and ethoxyquin. The hexane determination shall be made on the color additive after the addition of the vegetable oils, hydrogenated vegetable oils, and ethoxyquin.

(c) *Uses and restrictions.* The color additives tagetes (Aztec marigold) meal and extract may be safely used in

chicken feed in accordance with the following prescribed conditions:

(1) The color additives are used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additives incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(d) *Labeling requirements.* The label of the color additives and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter:

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this section.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.300 Carrot oil.

(a) *Identity.* (1) The color additive carrot oil is the liquid or the solid portion of the mixture or the mixture itself obtained by the hexane extraction of edible carrots (*Daucus carota* L.) with subsequent removal of the hexane by vacuum distillation. The resultant mixture of solid and liquid extractives consists chiefly of oils, fats, waxes, and carrotenoids naturally occurring in carrots. The definition of carrot oil in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for carrot oil or carrot oleoresin under section 401 of the act.

(2) Color additive mixtures for food use made with carrot oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Carrot oil shall contain no more than 25 parts per million of hexane.

(c) *Uses and restrictions.* Carrot oil may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless the use of added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.315 Corn endosperm oil.

(a) *Identity.* (1) The color additive corn endosperm oil is a reddish-brown liquid composed chiefly of glycerides, fatty acids, sitosterols, and carotenoid pigments obtained by isopropyl alcohol and hexane extraction from the gluten fraction of yellow corn grain. The definition of corn endosperm oil in this paragraph is for the purpose of definition as a color additive only and shall not be construed as a food standard of identity under section 401 of the act.

(2) Color additive mixtures for food use made with corn endosperm oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Corn endosperm oil conforms to the following specifications:

Total fatty acids, not less than 85 percent.
Iodine value, 118 to 134.
Saponification value, 165 to 185.
Unsaponifiable matter, not more than 14 percent.
Hexane, not more than 25 parts per million.
Isopropyl alcohol, not more than 100 parts per million.

(c) *Uses and restrictions.* The color additive corn endosperm oil may be safely used in chicken feed in accordance

with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section.

(d) *Labeling requirements.* The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required by §70.25 of this chapter, a statement of the concentration of xanthophyll contained therein.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.340 Paprika.

(a) *Identity.* (1) The color additive paprika is the ground dried pod of mild capsicum (*Capsicum annuum* L.). The definition of paprika in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for paprika under section 401 of the act.

(2) Color additive mixtures made with paprika may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Paprika may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of §70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.345 Paprika oleoresin.

(a) *Identity.* (1) The color additive paprika oleoresin is the combination of flavor and color principles obtained from paprika (*Capsicum annuum* L.) by extraction, using any one or a combination of the following solvents:

Acetone	Isopropyl alcohol
Ethyl alcohol	Methyl alcohol
Ethylene dichloride	Methylene chloride
Hexane	Trichloroethylene

The definition of paprika oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for paprika oleoresin under section 401 of the act.

(2) Color additive mixtures made with paprika oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Paprika oleoresin shall contain no more residue of the solvents listed in paragraph (a)(1) of this section than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Paprika oleoresin may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not

necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.350 Mica-based pearlescent pigments.

(a) *Identity.* (1) The color additive is formed by depositing titanium salts onto mica, followed by heating to produce titanium dioxide on mica. Mica used to manufacture the color additive shall conform in identity to the requirements of § 73.1496(a)(1).

(2) Color additive mixtures for food use made with mica-based pearlescent pigments may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring food.

(b) *Specifications.* Mica-based pearlescent pigments shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead (as Pb), not more than 4 parts per million (ppm).

(2) Arsenic (as As), not more than 3 ppm.

(3) Mercury (as Hg), not more than 1 ppm.

(c) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be safely used as a color additive in food as follows:

(i) In amounts up to 1.25 percent, by weight, in the following foods: Cereals, confections and frostings, gelatin desserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum.

(ii) In amounts up to 0.07 percent, by weight, in the following:

(A) Distilled spirits containing not less than 18 percent and not more than 25 percent alcohol by volume.

(B) Cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, and cocktails.

(C) Non-alcoholic cocktail mixes and mixers, such as margarita mix, Bloody Mary mix, and daiquiri mix, but excluding eggnog, tonic water, and beverages that are typically consumed without added alcohol (*e.g.*, fruit juices, fruit juice drinks, and soft drinks).

(iii) In egg decorating kits used for coloring the shells of eggs in amounts consistent with good manufacturing practice.

(2) The color additive may not be used to color foods for which standards of identity have been issued under section 401 of the act, unless the use of the added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[71 FR 31929, June 2, 2006, as amended at 78 FR 35117, June 12, 2013; 80 FR 32307, June 8, 2015; 80 FR 58602, Sept. 30, 2015]

§ 73.352 Paracoccus pigment.

(a) *Identity.* (1) The color additive paracoccus pigment consists of the heat-killed, dried cells of a nonpathogenic and nontoxicogenic strain of the bacterium *Paracoccus carotinifaciens* and may contain added calcium carbonate to adjust the astaxanthin level.

(2) Color additive mixtures for fish feed use made with paracoccus pigment may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Paracoccus pigment shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such impurities may be avoided by good manufacturing practice:

(1) Physical state, solid.

(2) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million (ppm)).

(3) Arsenic, not more than 2 mg/kg (2 ppm).

(4) Mercury, not more than 1 mg/kg (1 ppm).

(5) Heavy metals (as Pb), not more than 10 mg/kg (10 ppm).

(6) Astaxanthin, not less than 1.75 percent.

(c) *Uses and restrictions.* Paracoccus pigment may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from paracoccus pigment when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 mg/kg (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing paracoccus pigment shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore, batches thereof are exempt from the certification requirements of section 721(c) of the act.

[74 FR 58845, Nov. 16, 2009]

§ 73.355 Phaffia yeast.

(a) *Identity.* (1) The color additive phaffia yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast *Phaffia rhodozyma.*

(2) Phaffia yeast may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with phaffia yeast may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Phaffia yeast shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals (as Pb), not more than 10 parts per million.
Astaxanthin, not less than 0.4 percent.

(c) *Uses and restrictions.* Phaffia yeast may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from phaffia yeast when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing phaffia yeast shall be declared in accordance with §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[65 FR 41587, July 6, 2000]

§ 73.450 Riboflavin.

(a) *Identity.* (1) The color additive riboflavin is the riboflavin defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 262–263, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(2) Color additive mixtures made with riboflavin may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* Riboflavin shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this section.

(c) *Uses and restrictions.* Riboflavin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice; except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Act.

[42 FR 15643, Mar. 22, 1977, as amended at 47 FR 947, Jan. 8, 1982; 49 FR 10089, Mar. 19, 1984]

§ 73.500 Saffron.

(a) *Identity.* (1) The color additive saffron is the dried stigma of Crocus sativus L. The definition of saffron in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for saffron under section 401 of the act.

(2) Color additive mixtures made with saffron may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Saffron may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.520 Soy leghemoglobin.

(a) *Identity.* (1) The color additive soy leghemoglobin is a stabilized product of controlled fermentation of a nonpathogenic and non-toxicogenic strain of the yeast, *Pichia pastoris*, genetically engineered to express soy leghemoglobin protein. Soy leghemoglobin protein is the principal coloring component of the color additive and imparts a reddish-brown color.

(2) Color additive mixtures made with soy leghemoglobin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Soy leghemoglobin shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such impurities may be avoided by good manufacturing practice:

(1) Soy leghemoglobin protein purity on protein basis (weight/weight), not less than 65 percent, as determined by sodium dodecyl sulfate-polyacrylamide gel electrophoresis.

(2) Lead, not more than 0.4 milligrams per kilogram (mg/kg) (0.4 parts per million (ppm)).

(3) Arsenic, not more than 0.05 mg/kg (0.05 ppm).

(4) Mercury, not more than 0.05 mg/kg (0.05 ppm).

(5) Cadmium, not more than 0.2 mg/kg (0.2 ppm).

(c) *Uses and restrictions.* Soy leghemoglobin may be safely used in ground beef analogue products such that the amount of soy leghemoglobin protein does not exceed 0.8 percent by weight of the uncooked ground beef analogue product.

(d) *Labeling.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes must conform to § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[84 FR 37576, Aug. 1, 2019]

§ 73.530 Spirulina extract.

(a) *Identity.* (1) The color additive spirulina extract is prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis.* The color additive contains phycocyanins as the principal coloring components.

(2) Color additive mixtures for food use made with spirulina extract may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Spirulina extract must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead, not more than 2 milligrams per kilogram (mg/kg) (2 part per million (ppm));

(2) Arsenic, not more than 2 mg/kg (2 ppm);

(3) Mercury, not more than 1 mg/kg (1 ppm); and

(4) Negative for microcystin toxin.

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring confections (including candy and chewing gum), frostings, ice cream and frozen desserts, dessert coatings and toppings, beverage mixes and powders, yogurts, custards, puddings, cottage cheese, gelatin, breadcrumbs, ready-to-eat cereals (excluding extruded cereals), coating formulations applied to dietary supplement tablets and capsules, at levels consistent with good manufacturing practice, and to seasonally color the shells of hard-boiled eggs, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes must conform to § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[78 FR 49120, Aug. 13, 2013, as amended at 79 FR 20098, May 13, 2014; 80 FR 50765, Aug. 21, 2015; 82 FR 30734, July 3, 2017]

§ 73.575 Titanium dioxide.

(a) *Identity.* (1) The color additive titanium dioxide is synthetically prepared TiO_2, free from admixture with other substances.

(2) Color additive mixtures for food use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods, and the following: Silicon dioxide, SiO_2 and/or aluminum oxide, $Al_2 O_3$, as dispersing aids—not more than 2 percent total.

(b) *Specifications.* Titanium dioxide shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Antimony (as Sb), not more than 2 parts per million.

Mercury (as Hg), not more than 1 part per million.
Loss on ignition at 800 °C. (after drying for 3 hours at 105 °C.), not more than 0.5 percent.
Water soluble substances, not more than 0.3 percent.
Acid soluble substances, not more than 0.5 percent.
TiO_2, not less than 99.0 percent after drying for 3 hours at 105 °C.

Lead, arsenic, and antimony shall be determined in the solution obtained by boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1 percent by weight of the food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.585 Tomato lycopene extract; tomato lycopene concentrate.

(a) *Identity.* (1) The color additive tomato lycopene extract is a red to dark brown viscous oleoresin extracted with ethyl acetate from tomato pulp followed by removal of the solvent by evaporation. The pulp is produced from fresh, edible varieties of the tomato by removing the liquid. The main coloring component is lycopene.

(2) The color additive tomato lycopene concentrate is a powder prepared from tomato lycopene extract by removing most of the tomato lipids with ethyl acetate and then evaporating off the solvent.

(3) Color additive mixtures made with tomato lycopene extract or tomato lycopene concentrate may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring food.

(b) *Specifications.* (1) Tomato lycopene extract shall conform to the following specification: Lycopene, not less than 5.5 percent of oleoresin as determined by the method entitled ''Qualitative Analysis of Lycopene, Its Isomers and Other Carotenoids in Different Concentrations of Lyc-O-Mato® (Tomato Oleoresin) and in Tomato Pulp by High Performance Liquid Chromatography (HPLC),'' S.O.P. number : Lab/119/01, Revision 01, dated May 30, 2001, published by LycoRed Natural Products Industries, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the method from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. You may inspect a copy at theFood and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*

(2) Tomato lycopene concentrate shall conform to the following specification: Lycopene, not less than 60 percent of oleoresin as determined by the method identified in paragraph (b)(1) of this section.

(c) *Uses and restrictions.* Tomato lycopene extract and tomato lycopene concentrate may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been issued under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not

necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[70 FR 43045, July 26, 2005, as amended at 81 FR 5590, Feb. 3, 2016; 81 FR 49895, July 29, 2016]

§ 73.600 Turmeric.

(a) *Identity.* (1) The color additive turmeric is the ground rhizome of Curcuma longa L. The definition of turmeric in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric under section 401 of the act.

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.615 Turmeric oleoresin.

(a) *Identity.* (1) The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (Curcuma longa L.) by extraction using any one or a combination of the following solvents:

Acetone	Isopropyl alcohol
Ethyl alcohol	Methyl alcohol
Ethylene dichloride	Methylene chloride
Hexane	Trichloroethylene

The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under section 401 of the act.

(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this section than is permitted for the corresponding solvents in spice oleoresins under applicable food additive regulation in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Subpart B—Drugs

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. Such listing of diluents is not to be construed as superseding any of

74.2334 D&C Red No. 34.
74.2336 D&C Red No. 36.
74.2340 FD&C Red No. 40.
74.2602 D&C Violet No. 2.
74.2602a Ext. D&C Violet No. 2.
74.2705 FD&C Yellow No. 5.
74.2706 FD&C Yellow No. 6.
74.2707 D&C Yellow No. 7.
74.2707a Ext. D&C Yellow No. 7.
74.2708 D&C Yellow No. 8.
74.2710 D&C Yellow No. 10.
74.2711 D&C Yellow No. 11.

Subpart D—Medical Devices

74.3045 [Phthalocyaninato(2-)] copper.
74.3054 D&C Black No. 4.
74.3102 FD&C Blue No. 2.
74.3106 D&C Blue No. 6.
74.3206 D&C Green No. 6.
74.3230 D&C Red No. 17.
74.3602 D&C Violet No. 2.
74.3708 D&C Yellow No. 8.
74.3710 D&C Yellow No. 10.

AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

SOURCE: 42 FR 15654, Mar. 22, 1977, unless otherwise noted.

Subpart A—Foods

§ 74.101 FD&C Blue No. 1.

(a) *Identity.* (1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[*p*-[ethyl (*m*-sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene] - 2,5 -cyclohexadien - 1 - ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl [4-[*p*-[ethyl(*p*-sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl [4-[*p*-[ethyl (*o*-sulfobenzyl) amino] - α - (*o* -sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*o*-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Blue No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of *o*-, *m*-, and *p*-sulfobenzaldehydes, not more than 1.5 percent.
N-Ethyl,*N*-(*m*-sulfobenzyl)sulfanilic acid, not more than 0.3 percent.
Subsidiary colors, not more than 6.0 percent.
Chromium (as Cr), not more than 50 parts per million.
Manganese (as Mn), not more than 100 parts per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Blue No. 1 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 58 FR 17511, Apr. 5, 1993]

§ 74.102 FD&C Blue No. 2.

(a) *Identity.* (1) The color additive FD&C Blue No. 2 is principally the disodium salt of 2-(1,3-dihydro-3-oxo-5-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 860–22–0) with smaller amounts of the disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 54947–75–0) and the sodium salt of 2-(1,3-dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 605–18–5). Additionally, FD&C Blue No.

2 is obtained by heating indigo (or indigo paste) in the presence of sulfuric acid. The color additive is isolated and subjected to purification procedures. The indigo (or indigo paste) used above is manufactured by the fusion of *N*-phenylglycine (prepared from aniline and formaldehyde) in a molten mixture of sodamide and sodium and potassium hydroxides under ammonia pressure. The indigo is isolated and subjected to purification procedures prior to sulfonation.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 2 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive FD&C Blue No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

5-Sulfoanthranilic acid, not more than 0.2 percent.

Disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid, not more than 18 percent.

Sodium salt of 2-(1,3-dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid, not more than 2 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive FD&C Blue No. 2 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 5260, Feb. 4, 1983]

§ 74.203 FD&C Green No. 3.

(a) *Identity.* (1) The color additive FD&C Green No. 3 is principally the inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide (CAS Reg. No. 2353–45–9); with smaller amounts of the isomeric inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl] amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide; of *N*-ethyl-*N*-[4-[[4-[ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide and of *N*-ethyl-*N*-[4-[[4-[ethyl[(2-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide. Additionally, FD&C Green No. 3 is manufactured by the acid catalyzed condensation of one molecule of 2-formyl-5-hydroxybenzenesulfonic acid with two molecules from a mixture consisting principally of 3-[(ethylphenylamino)methyl]

benzensulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl]

benzenesulfonic acid and 2-[(ethylphenylamino)methyl]

benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid or with dichromate and acid to form the dye. The intermediate 2-formyl-5-

hydroxybenzenesulfonic acid is prepared by the potassium permanganate oxidation of 2,2′-(1,2-ethenediyl)-bis(5-aminobenzenesulfonic acid) to sodium 5-amino-2-formylbenzenesulfonate. This amine is diazotized and the resulting diazonium salt is hydrolyzed to the desired 2-formyl-5-hydroxybenzenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Green No. 3 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring food.

(b) *Specifications.* The color additive FD&C Green No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of 2-,3-,4-formylbenzenesulfonic acids, sodium salts, not more than 0.5 percent.
Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl] benzenesulfonic acid, disodium salts, not more than 0.3 percent.
2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5 percent.
Subsidiary colors, not more than 6 percent.
Chromium (as Cr), not more than 50 parts per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 52143, Nov. 19, 1982; 47 FR 56489, Dec. 17, 1982]

§ 74.250 Orange B.

(a) *Identity.* (1) The color additive Orange B is principally the disodium salt of 1-(4-sulfophenyl)-3-ethylcarboxy-4-(4-sulfonaphthylazo)-5-hydro-xypyrazole.

(2) The diluents in color additive mixtures for food use containing Orange B are limited to those listed in part 73 of this chapter as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Orange B shall conform to the following specifications:

Volatile matter (at 135 °C.), not more than 6.0 percent.
Chlorides and sulfates (calculated as the sodium salts), not more than 7.0 percent.
Water insoluble matter, not more than 0.2 percent.
1-(4-Sulfophenyl)-3-ethylcarboxy-5-hydroxypyrazolone and 1-(4-sulfophenyl)-3-carboxy-5-hydroxypyrazolone, not more than 0.7 percent.
Naphthionic acid, not more than 0.2 percent.
Phenylhydrazine-*p*-sulfonic acid, not more than 0.2 percent.
The trisodium salt of 1-(4-sulfophenyl)-3-carboxy-4-(4-sulfonaphthylazo)-5-hydroxypyrazole, not more than 6.0 percent.
Other subsidiary dyes, not more than 1.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* Orange B may be safely used for coloring the casings or surfaces of frankfurters and sausages subject to the restriction that the quantity of the color additive does not exceed 150 parts per million by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Orange B shall be certified in accordance with

regulations promulgated under part 80 of this chapter.

§ 74.302 Citrus Red No. 2.

(a) *Identity.* (1) The color additive Citrus Red No. 2 is principally 1–(2,5–dimethoxyphenylazo)-2-naphthol.

(2) The following diluents may be used in aqueous suspension, in the percentages specified, to facilitate application to oranges in accordance with paragraph (c)(1) of this section:

(i) Suitable diluents used in accordance with § 73.1(a) of this chapter.

(ii) Volatile solvents that leave no residue after application to the orange.

(iii) Salts of fatty acids meeting the requirements of § 172.863 of this chapter.

(iv) Sodium tripolyphosphate, not more than 0.05 percent.

(b) *Specifications.* Citrus Red No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100 °C.), not more than 0.5 percent.
Water-soluble matter, not more than 0.3 percent.
Matter insoluble in carbon tetrachloride, not more than 0.5 percent.
Uncombined intermediates, not more than 0.05 percent.
Subsidiary dyes, not more than 2.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Total color, not less than 98 percent.

(c) *Uses and restrictions.* (1) Citrus Red No. 2 shall be used only for coloring the skins of oranges that are not intended or used for processing (or if so used are designated in the trade as *Packinghouse elimination*) and that meet minimum maturity standards established by or under the laws of the States in which the oranges are grown.

(2) Oranges colored with Citrus Red No. 2 shall bear not more than 2.0 parts per million of such color additive, calculated on the basis of the weight of the whole fruit.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. To meet the requirements of § 70.25 (b) and (c) of this chapter the label shall bear:

(1) The statement (or its equivalent) ''To be used only for coloring skins of oranges.''

(2) Directions for use to limit the amount of the color additive to not more than 2.0 parts per million, calculated on the basis of the weight of the whole fruit.

(e) *Certification.* All batches of Citrus Red No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.303 FD&C Red No. 3.

(a) *Identity.* (1) The color additive FD&C Red No. 3 is principally the monohydrate of 9 (*o*- carboxyphenyl)-6-hydroxy - 2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower imdinated fluoresceins.

(2) Color additive mixtures for food use made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Red No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135 °C.) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
Unhalogenated intermediates, total not more than 0.1 percent.
Sodium iodide, not more than 0.4 percent.
Triiodoresorcinol, not more than 0.2 percent.
2(2′,4′-Dihydroxy-3′, 5′-diiodobenzoyl) benzoic acid, not more than 0.2 percent.
Monoiodofluoresceins not more than 1.0 percent.
Other lower iodinated fluoresceins, not more than 9.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring

foods generally (including dietary supplements) in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.340 FD&C Red No. 40.

(a) *Identity.* (1) The color additive FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Red No. 40 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(3) The listing of this color additive includes lakes prepared as described in § 82.51 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 of this chapter.

(b) *Specifications.* FD&C Red No. 40 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C.) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl) azo] -8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, not more than 1.0 percent.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3 percent.

4-Amino-5-methoxy-*o*- toluenesulfonic acid, not more than 0.2 percent.

Disodium salt of 6,6′-oxybis (2-naphthalenesulfonic acid), not more than 1.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 40 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.705 FD&C Yellow No. 5.

(a) *Identity.* (1) The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[4-sulfophenyl-azo]-1*H*-pyrazole-3-carboxylic acid (CAS Reg. No. 1934–21–0). To manufacture the additive, 4-amino-benzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(2) Color additive mixtures for food use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be

avoided by good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
4,4′-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.
4-[(4′,5-Disulfo[1,1′-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.
Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.
4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.
4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.
4,4′-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.
4-Aminoazobenzene, not more than 75 parts per billion.
4-Aminobiphenyl, not more than 5 parts per billion.
Aniline, not more than 100 parts per billion.
Azobenzene, not more than 40 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions.* FD&C Yellow No. 5 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) Foods for human use that contain FD&C Yellow No. 5, including butter, cheese, and ice cream, shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive as FD&C Yellow No. 5 among the list of ingredients.

(e) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979, as amended at 44 FR 37220, June 26, 1979; 51 FR 24519, July 7, 1986]

§ 74.706 FD&C Yellow No. 6.

(a) *Identity.* (1) The color additive FD&C Yellow No. 6 is principally the disodium salt of 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid (CAS Reg. No. 2783–94–0). The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid (CAS Reg. No. 50880–65–4) may be added in small amounts. The color additive is manufactured by diazotizing 4-aminobenzenesulfonic acid using hydrochloric acid and sodium nitrite or sulfuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulfonic acid. The dye is isolated as the sodium salt and dried. The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid which may be blended with the principal color is prepared in the same manner except the diazo benzenesulfonic acid is coupled with 3-hydroxy-2,7-naphthalenedisulfonic acid.

(2) Color additive mixtures for food use made with FD&C Yellow No. 6 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive FD&C Yellow No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such

other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water insoluble matter, not more than 0.2 percent.
Sodium salt of 4-aminobenzenesulfonic acid, not more than 0.2 percent.
Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3 percent.
Disodium salt of 6,6′-oxybis[2-naphthalenesulfonic acid], not more than 1 percent.
Disodium salt of 4,4′-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1 percent.
Sum of the sodium salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid, not more than 1 percent.
Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries, not more than 5 percent.
4-Aminoazobenzene, not more than 50 parts per billion.
4-Aminobiphenyl, not more than 15 parts per billion.
Aniline, not more than 250 parts per billion.
Azobenzene, not more than 200 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
1-(Phenylazo)-2-naphthalenol, not more than 10 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions.* The color additive FD&C Yellow No. 6 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) [Reserved]

(e) *Certification.* All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986, as amended at 52 FR 21508, June 8, 1987; 53 FR 49138, Dec. 6, 1988]

Subpart B—Drugs

§ 74.1101 FD&C Blue No. 1

(a) *Identity.* (1) For ingested drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of § 74.101(a)(1).

(2) For externally applied drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of § 74.2101(a).

(3) Color additive mixtures for drug use made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* (1) The color additive FD&C Blue No. 1 for use in coloring drugs generally shall conform in specifications to the requirements of § 74.101(b).

(2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) FD&C Blue No. 1 may be safely used for coloring drugs, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Blue No. 1 Aluminum Lake may be safely used for coloring drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice, subject to the restrictions on the use of color additives in § 70.5(b) and (c) of this chapter.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

Subpart B—Requirements for Specific Standardized Milk and Cream

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14360, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 131 appear at 63 FR 14035, Mar. 24, 1998.

Subpart A—General Provisions

§ 131.3 Definitions.

(a) *Cream* means the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

(b) *Pasteurized* when used to describe a dairy product means that every particle of such product shall have been heated in properly operated equipment to one of the temperatures specified in the table of this paragraph and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature	Time
145 °F [1]	30 minutes
161 °F [1]	15 seconds
191 °F	1 second
204 °F	0.05 second
212 °F	0.01 second

[1] If the dairy ingredient has a fat content of 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5 °F.

(c) *Ultra-pasteurized* when used to describe a dairy product means that such product shall have been thermally processed at or above 280 °F for at least 2 seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

§ 131.25 Whipped cream products containing flavoring or sweetening.

The unqualified name ''whipped cream'' should not be applied to any product other than one made by whipping the cream that complies with the standards of identity for whipping cream (§§ 131.150 and 131.157 of this chapter). If flavoring and/or sweetening is added, the resulting product is a flavored and/or sweetened whipped cream, and should be so identified.

Subpart B—Requirements for Specific Standardized Milk and Cream

§ 131.110 Milk.

(a) *Description.* Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8¼ percent milk solids not fat and not less than 3¼ percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

(b) *Vitamin addition* (Optional). (1) If added, vitamin A shall be present in such quantity that each quart of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each

quart of the food contains 400 International Units thereof within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavorings.

(d) *Methods of analysis.* Referenced methods are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—''Fat, Roese-Gottlieb Method—Official Final Action,'' section 16.059.

(2) Milk solids not fat content—Calculated by subtracting the milk fat content from the total solids content as determined by the method ''Total Solids, Method I—Official Final Action,'' section 16.032.

(3) Vitamin D content—''Vitamin D—Official Final Action,'' sections 43.195–43.208.

(e) *Nomenclature.* The name of the food is ''milk''. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in §101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) If vitamins are added, the phrase ''vitamin A'' or ''vitamin A added'', or ''vitamin D'' or ''vitamin D added'', or ''vitamin A and D'' or ''vitamins A and D added'', as is appropriate. The word ''vitamin'' may be abbreviated ''vit.''.

(ii) The word ''ultra-pasteurized'' if the food has been ultra-pasteurized.

(2) The following terms may appear on the label:

(i) The word ''pasteurized'' if the food has been pasteurized.

(ii) The word ''homogenized'' if the food has been homogenized.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11822, Mar. 19, 1982; 49 FR 10090, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.111 Acidified milk.

(a) *Description.* Acidified milk is the food produced by souring one or more of the optional dairy ingredients specified in pargaph (c) of this section with one or more of the acidifying ingredients specified in paragraph (d) of this section, with or without the addition of characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (e) of this section may also be added. When one or more of the ingredients specified in paragraph (e)(1) of this section are used, they shall be included in the souring process. All ingredients used are safe and suitable. Acidified milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the microbial culture and, when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains

400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Optional acidifying ingredients.* Acetic acid, adipic acid, citric acid, fumaric acid, glucono-*delta*- lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.

(e) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulalting that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

(f) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—As determined by the method prescribed in section 16.059, ''Roese-Gottlieb Method (Reference Method) (11)—Official Final Action,'' under the heading ''Fat.''

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, ''Method I—Official Final Action,'' under the heading ''Total Solids.''

(3) Titratable acidity—As determined by the method prescribed in section 16.023, ''Acidity (2)—Official Final Action,'' or by an equivalent potentiometric method.

(g) *Nomenclature.* The name of the food is ''acidified milk''. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients when used, e.g., ''acidified kefir milk'', ''acidified acidophilus milk'', or when characterizing ingredients such as those in paragraphs (e) (6), (7), (8), and (9) of this section are used, the food may be named ''acidified buttermilk''.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase ''vitamin A'' or ''vitamin A added'', or ''vitamin D'' or ''vitamin D added'', or ''vitamins A and D added'', as appropriate. The word ''vitamin'' may be abbreviated ''vit.''.

(ii) The word ''sweetened'' if nutritive carbohydrate sweetener is added

without the addition of characterizing flavoring.

(2) The term ''homogenized'' may appear on the label if the dairy ingredients used are homogenized.

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[46 FR 9934, Jan. 30, 1981, as amended at 47 FR 11822, Mar. 19, 1982; 47 FR 41523, Sept. 21, 1982; 48 FR 24869, June 3, 1983; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.112 Cultured milk.

(a) *Description.* Cultured milk is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Cultured milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition to the microbial culture, and when applicable, the addition of flakes or granules of butterfat or milkfat.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided*, That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of milkfat or butterfat.

(5) Stabilizers.

(6) Butterfat or milkfat, which may or may not contain color additives, in the form of flakes or granules.

(7) Aroma- and flavor-producing microbial culture.

(8) Salt.

(9) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

(e) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—section 16.059, ''Roese-Gottlieb Method (Reference Method) (11)—Official Final Action,'' under the heading ''Fat.''

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as

determined by the method prescribed in section 16.032, ''Method I—Official Final Action,'' under the heading ''Total Solids.''

(3) Titratable acidity—As determined by the methods prescribed in section 16.023 ''Acidity (2)—Official Final Action,'' or by an equivalent potentiometric method.

(f) *Nomenclature.* The name of the food is ''cultured milk''. The full name of the food shall appear on the principal display panel in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients, e.g., ''kefir cultured milk'', ''acidophilus cultured milk'', or when characterizing ingredients such as those in paragraphs (d) (6), (7), (8), and (9) of this section, and lactic acid-producing organisms are used the food may be named ''cultured buttermilk''.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The phrase ''vitamin A'' or ''vitamin A added'', or ''vitamin D'' or ''vitamin D added'', or ''vitamin A and D added'', as appropriate. The word ''vitamin'' may be abbreviated ''vit.''.

(ii) The word ''sweetened'' if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(2) The term ''homogenized'' may appear on the label if the dairy ingredients used are homogenized.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[46 FR 9934, Jan. 30, 1981, as amended at 47 FR 11822, Mar. 19, 1982; 47 FR 41523, Sept. 21, 1982; 48 FR 24869, June 3, 1983; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.115 Concentrated milk.

(a) *Description.* Concentrated milk is the liquid food obtained by partial removal of water from milk. The milkfat and total milk solids contents of the food are not less than 7.5 and 25.5 percent, respectively. It is pasteurized, but is not processed by heat so as to prevent spoilage. It may be homogenized.

(b) *Vitamin addition* (Optional). If added, vitamin D shall be present in such quantity that each fluid ounce of the food contains 25 International Units thereof, within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Carrier for vitamin D.

(2) Characterizing flavoring ingredients, with or without coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* Referenced methods are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—''Fat—Official Final Action,'' section 16.172.

(2) Total milk solids—''Total Solids—Official Final Action,'' section 16.169.

(3) Vitamin D content—''Vitamin D in Milk—Official Final Action,'' sections 43.195–43.208.

(e) *Nomenclature.* The name of the food is ''Concentrated milk'' or alternatively ''Condensed milk''. If the food contains added vitamin D, the phrase ''vitamin D'' or ''vitamin D added'' shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the

height of the letters used in such name. The word ''homogenized'' may appear on the label if the food has been homogenized. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11822, Mar. 19, 1982; 48 FR 13024, Mar. 29, 1983; 49 FR 10090, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.120 Sweetened condensed milk.

(a) *Description.* Sweetened condensed milk is the food obtained by partial removal of water only from a mixture of milk and safe and suitable nutritive carbohydrate sweeteners. The finished food contains not less than 8 percent by weight of milkfat, and not less than 28 percent by weight of total milk solids. The quantity of nutritive carbohydrate sweetener used is sufficient to prevent spoilage. The food is pasteurized and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable characterizing flavoring ingredients, with or without coloring and nutritive carbohydrate sweeteners, may be used:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 16.185, under ''Fat—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(d) *Nomenclature.* The name of the food is ''Sweetened condensed milk.'' The word ''homogenized'' may appear on the label if the food has been homogenized. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[43 FR 21670, May 19, 1978, as amended at 47 FR 11823, Mar. 19, 1982; 49 FR 10091, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.125 Nonfat dry milk.

(a) *Description.* Nonfat dry milk is the product obtained by removal of water only from pasteurized skim milk. It contains not more than 5 percent by weight of moisture, and not more than 1½ percent by weight of milkfat unless otherwise indicated.

(b) *Optional ingredients.* Safe and suitable characterizing flavoring ingredients (with or without coloring and nutritive carbohydrate sweetener) as follows:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavorings.

(c) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(1) Milkfat content—''Fat in Dried Milk—Official Final Action,'' sections 16.199–16.200.

(2) Moisture content—''Moisture—Official Final Action,'' section 16.192.

(d) *Nomenclature.* The name of the food is ''Nonfat dry milk''. If the fat

content is over 1½ percent by weight, the name of the food on the principal display panel or panels shall be accompanied by the statement ''Contains __% milkfat'', the blank to be filled in with the percentage to the nearest one-tenth of 1 percent of fat contained, within limits of good manufacturing practice. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(e) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 43 FR 19836, May 9, 1978; 47 FR 11823, Mar. 19, 1982; 49 FR 10091, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.127 Nonfat dry milk fortified with vitamins A and D.

(a) *Description*. Nonfat dry milk fortified with vitamins A and D conforms to the standard of identity for nonfat dry milk, except that vitamins A and D are added as prescribed by paragraph (b) of this section.

(b) *Vitamin addition*. (1) Vitamin A is added in such quantity that, when prepared according to label directions, each quart of the reconstituted product contains 2000 International Units thereof.

(2) Vitamin D is added in such quantity that, when prepared according to label directions, each quart of the reconstituted product contains 400 International Units thereof.

(3) The requirements of this paragraph will be deemed to have been met if reasonable overages, within limits of good manufacturing practice, are present to ensure that the required levels of vitamins are maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) *Optional ingredients*. The following safe and suitable optional ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Characterizing flavoring ingredients, with or without coloring and nutritive carbohydrate sweetener, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavorings.

(d) *Methods of analysis*. The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(1) Milkfat content—''Fat in Dried Milk—Official Final Action,'' sections 16.199–16.200.

(2) Moisture content—''Moisture—Official Final Action,'' section 16.192.

(3) Vitamin D content—''Vitamin D—Official Final Action,'' sections 43.195–43.208.

(e) *Nomenclature*. The name of the food is ''Nonfat dry milk fortified with vitamins A and D''. If the fat content is over 1½ percent by weight, the name of the food on the principal display panel or panels shall be accompanied by the statement ''Contains __% milkfat'', the blank to be filled in to the nearest one-tenth of 1 percent with the percentage of fat contained within limits of good manufacturing practice. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(f) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 43 FR 19836, May 9, 1978; 43 FR 29769, July 11, 1978; 43 FR 36622, Aug. 18, 1978; 47 FR 11823, Mar. 19, 1982; 49 FR 10091, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.130 Evaporated milk.

(a) *Description.* Evaporated milk is the liquid food obtained by partial removal of water only from milk. It contains not less than 6.5 percent by weight of milkfat, not less than 16.5 percent by weight of milk solids not fat, and not less than 23 percent by weight of total milk solids. Evaporated milk contains added vitamin D as prescribed by paragraph (b) of this section. It is homogenized. It is sealed in a container and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) *Vitamin addition.* (1) Vitamin D shall be present in such quantity that each fluid ounce of the food contains 25 International Units thereof within limits of good manufacturing practice.

(2) Addition of vitamin A is optional, If added, vitamin A shall be present in such quantity that each fluid ounce of the food contains not less than 125 International Units thereof within limits of good maufacturing practice.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Emulsifiers.

(3) Stabilizers, with or without dioctyl sodium sulfosuccinate (when permitted by and complying with the provisions of § 172.810 of this chapter) as a solubilizing agent.

(4) Characterizing flavoring ingredients, with or without coloring and nutritive carbohydrate sweeteners, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—''Fat—Official Final Action,'' section 16.172.

(2) Total milk solids—''Total Solids—Official Final Action,'' section 16.169.

(3) Vitamin D content—''Vitamin D in Milk—Official Final Action,'' sections 43.195–43.208.

(e) *Nomenclature.* The name of the food is ''Evaporated milk.'' The phrase ''vitamin D'' or ''vitamin D added'', or ''vitamins A and D'' or ''vitamins A and D added'', as is appropriate, shall immediately precede or follow the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name. The name of the food shall include a declaration of a the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[43 FR 21670, May 19, 1978, as amended at 47 FR 11823, Mar. 19, 1982; 49 FR 10091, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993; 59 FR 17691, Apr. 14, 1994]

§ 131.147 Dry whole milk.

(a) *Description.* Dry whole milk is the product obtained by removal of water only from pasteurized milk, as defined in § 131.110(a), which may have been homogenized. Alternatively, dry whole milk may be obtained by blending fluid, condensed, or dried nonfat milk with liquid or dried cream or with fluid, condensed, or dried milk, as appropriate, provided the resulting dry whole milk is equivalent in composition to that obtained by the method described in the first sentence of this paragraph. It contains the lactose, milk proteins, milkfat, and milk minerals in the same relative proportions as the milk from which it was made. It contains not less than 26 percent but less than 40 percent by weight of milkfat on an as is basis. It contains not more than 5 percent by weight of moisture on a milk solids not fat basis.

(b) *Vitamin addition.* (1) Addition of vitamin A is optional. If added, vitamin A shall be present in such quantity

that, when prepared according to label directions, each quart of the reconstituted product shall contain not less than 2,000 International Units thereof.

(2) Addition of vitamin D is optional. If added, vitamin D shall be present in such quantity that, when prepared according to label directions, each quart of the reconstituted product shall contain 400 International Units thereof.

(3) The requirements of this paragraph will be met if reasonable overages, within limits of good manufacturing practice, are present to ensure that the required levels of vitamins are maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Carriers for vitamins A and D.

(2) Emulsifiers.

(3) Stabilizers.

(4) Anticaking agents.

(5) Antioxidants.

(6) Characterizing flavoring ingredients (with or without coloring and nutritive carbohydrate sweetener) as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—''Fat in Dried Milk—Official Final Action,'' sections 16.199–16.200.

(2) Moisture content—''Moisture—Official Final Action,'' section 16.192.

(3) Vitamin D content—''Vitamin D—Official Final Action,'' sections 43.195–43.208.

(e) *Nomenclature.* The name of the food is ''Dry whole milk.'' The name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter. The following phrases in type size not less than one-half the height of the type size used in such name shall accompany the name of the food wherever it appears on the principal display panel or panels.

(1) The phrase ''Contains __% milkfat'', the blank to be filled in with the whole number closest to the actual fat content of the food.

(2) If vitamins are ''added'', the phrase ''vitamin A'', or ''vitamin A added'', or ''vitamin D'', or ''vitamin D added'', or ''vitamins A and D'', or ''vitamins A and D added'', as appropriate. The word ''vitamin'' may be abbreviated ''vit.''

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[43 FR 19836, May 9, 1978, as amended at 47 FR 11824, Mar. 19, 1982; 49 FR 10092, Mar. 19, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.149 Dry cream.

(a) *Description.* Dry cream is the product obtained by removal of water only from pasteurized milk or cream or a mixture thereof, which may have been homogenized. Alternatively, dry cream may be obtained by blending dry milks as defined in §§ 131.125(a) and 131.147(a) with dry cream as appropriate: *Provided,* That the resulting product is equivalent in composition to that obtained by the method described in the first sentence of this paragraph. It contains not less than 40 percent but less than 75 percent by weight of milkfat on an as is basis. It contains not more than 5 percent by weight of moisture on a milk solids not fat basis.

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Anticaking agents.

(4) Antioxidants.

(5) Nutritive carbohydrate sweeteners.

(6) Characterizing flavoring ingredients, with or without coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(1) Milkfat content—''Fat in Dried Milk—Official Final Action,'' sections 16.199–16.200.

(2) Moisture content—''Moisture—Official Final Action,'' section 16.192.

(d) *Nomenclature.* The name of the food is ''Dry cream.'' The name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in §101.22 of this chapter. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label, in letters not less than one-half of the height of the letters used in such name:

(1) The phrase ''Contains __% milkfat'', the blank to be filled in with the whole number closest to the actual fat content of the food.

(2) The word ''sweetened'' if no characterizing flavoring ingredients are used but nutritive carbohydrate sweetener is added.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[43 FR 19836, May 9, 1978, as amended at 44 FR 3965, Jan. 19, 1979; 47 FR 11824, Mar. 19, 1982; 48 FR 13024, Mar. 29, 1983; 49 FR 10092, Mar. 19, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993; 61 FR 59002, Nov. 20, 1996]

§ 131.150 Heavy cream.

(a) *Description.* Heavy cream is cream which contains not less than 36 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), sections 16.156 and 16.059, under ''Fat, Roese-Gottlieb Method—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(d) *Nomenclature.* (1) The name of the food is ''Heavy cream'' or alternatively ''Heavy whipping cream''. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in §101.22 of this chapter. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) The word ''ultra-pasteurized'' if the food has been ultra-pasteurized.

(ii) The word ''sweetened'' if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word ''pasteurized'' if the food has been pasteurized.

(ii) The word ''homogenized'' if the food has been homogenized.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11824, Mar. 19, 1982; 49 FR 10092, Mar. 19, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.155 Light cream.

(a) *Description.* Light cream is cream which contains not less than 18 percent but less than 30 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Stabilizers.

(2) Emulsifiers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), sections 16.156 and 16.059, under ''Fat, Roese-Gottlieb Method—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(d) *Nomenclature.* The name of the food is ''Light cream'', or alternatively ''Coffee cream'' or ''Table cream''. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) The word ''ultra-pasteurized'' if the food has been ultra-pasteurized.

(ii) The word ''sweetened'' if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word ''pasteurized'' if the food has been pasteurized.

(ii) The word ''homogenized'' if the food has been homogenized.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11824, Mar. 19, 1982; 49 FR 10092, Mar. 1, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.157 Light whipping cream.

(a) *Description.* Light whipping cream is cream which contains not less than 30 percent but less than 36 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980),

sections 16.156 and 16.059, under ''Fat, Roese-Gottlieb Method—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(d) *Nomenclature.* The name of the food is ''Light whipping cream'' or alternatively ''Whipping cream''. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in §101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) The word ''ultra-pasteurized'' if the food has been ultra-pasteurized.

(ii) The word ''sweetened'' if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word ''pasteurized'' if the food has been pasteurized.

(ii) The word ''homogenized'' if the food has been homogenized.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11824, Mar. 19, 1982; 49 FR 10092, Mar. 19, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.160 Sour cream.

(a) *Description.* Sour cream results from the souring, by lactic acid producing bacteria, of pasteurized cream. Sour cream contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) *Optional ingredients.* (1) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

(2) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.

(3) Rennet.

(4) Safe and suitable nutritive sweeteners.

(5) Salt.

(6) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Safe and suitable natural and artificial food flavoring.

(c) *Methods of analysis.* Referenced methods in paragraph (c) (1) and (2) of this section are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(1) Milkfat content—''Fat—Official Final Action,'' section 16.172.

(2) Titratable acidity—''Acidity—Official Final Action,'' section 16.023.

(d) *Nomenclature.* The name of the food is ''Sour cream'' or alternatively ''Cultured sour cream''. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in §101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of

characterizing flavoring, the name of the food shall be preceded by the word ''sweetened''.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11824, Mar. 19, 1982; 49 FR 10092, Mar. 19, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.162 Acidified sour cream.

(a) *Description.* Acidified sour cream results from the souring of pasteurized cream with safe and suitable acidifiers, with or without addition of lactic acid producing bacteria. Acidified sour cream contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Acidified sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) *Optional ingredients.* (1) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

(2) Rennet.

(3) Safe and suitable nutritive sweeteners.

(4) Salt.

(5) Flavoring ingredients, with or without safe and suitable coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Safe and suitable natural and artificial food flavoring.

(c) *Methods of analysis.* Referenced methods in paragraphs (c) (1) and (2) of this section are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—''Fat—Official Final Action,'' section 16.172.

(2) Titratable acidity—''Acidity—Official Final Action,'' section 16.023.

(d) *Nomenclature.* The name of the food is ''Acidified sour cream''. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in § 101.22 of this chapter. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word ''sweetened''.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11825, Mar. 19, 1982; 49 FR 10092, Mar. 19, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.170 Eggnog.

(a) *Description.* Eggnog is the food containing one or more of the optional dairy ingredients specified in paragraph (b), one or more of the optional egg yolk-containing ingredients specified in paragraph (c) of this section, and one or more of the optional nutritive carbohydrate sweeteners specified in paragraph (d) of this section. One or more of the optional ingredients specified in paragraph (e) of this section may also be added. All ingredients used are safe and suitable. Eggnog contains not less than 6 percent milkfat and not less than 8.25 percent milk solids not fat. The egg yolk solids content is not less than 1 percent by weight of the finished food. The food shall be pasteurized or ultra-pasteurized and may be homogenized. Flavoring ingredients and color additives may be added after the food is pasteurized or ultra-pasteurized.

(b) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(c) *Egg yolk-containing ingredients.* Liquid egg yolk, frozen egg yolk, dried egg yolk, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one or more of the foregoing ingredients with liquid egg white or frozen egg white.

(d) *Nutritive carbohydrate sweeteners.* Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(e) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Salt.

(3) Flavoring ingredients.

(4) Color additives that do not impart a color simulating that of egg yolk, milkfat, or butterfat.

(5) Stabilizers.

(f) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—As determined by the method prescribed in section 16.059, ''Roese-Gottlieb Method (Reference Method) (11)—Official Final Action,'' under the heading ''Fat.''

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, ''Method I—Official Final Action,'' under the heading ''Total Solids.''

(g) *Nomenclature.* The name of the food is ''eggnog''. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter. If the food is ultra-pasteurized, the phrase ''ultra-pasteurized'' shall accompany the name of the food wherever it appears on the label in letters not less than one-half of the height of the letters used in the name. The following terms may accompany the name of the food on the label:

(1) The word ''pasteurized'' if the food has been pasteurized.

(2) The word ''homogenized'' if the food has been homogenized.

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[46 FR 9938, Jan. 30, 1981, as amended at 47 FR 11825, Mar. 19, 1982; 47 FR 41524, Sept. 21, 1982; 47 FR 49638, Nov. 2, 1982; 48 FR 24869, June 3, 1983; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.180 Half-and-half.

(a) *Description.* Half-and-half is the food consisting of a mixture of milk and cream which contains not less than 10.5 percent but less than 18 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Emulsifiers.

(2) Stabilizers.

(3) Nutritive sweeteners.

(4) Characterizing flavoring ingredients (with or without coloring) as follows:

(i) Fruit and fruit juice (including concentrated fruit and fruit juice).

(ii) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), in sections 16.156 and 16.059, under ''Fat, Roese-Gottlieb Method—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(d) *Nomenclature.* The name of the food is ''Half-and-half''. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(i) The word ''ultra-pasteurized'' if the food has been ultra-pasteurized.

(ii) The word ''sweetened'' if no characterizing flavor ingredients are used, but nutritive sweetener is added.

(2) The following terms may appear on the label:

(i) The word ''pasteurized'' if the food has been pasteurized.

(ii) The word ''homogenized'' if the food has been homogenized.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11825, Mar. 19, 1982; 49 FR 10092, Mar. 19, 1984; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.200 Yogurt.

(a) *Description.* Yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Yogurt, before the addition of bulky flavors, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of current good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose

corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers.

(e) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—As determined by the method prescribed in section 16.059 ''Roese-Gottlieb Method (Reference Method) (11)—Official Final Action,'' under the heading ''Fat.''

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, ''Method I—Official Final Action,'' under the heading ''Total Solids.''

(3) Titratable acidity—As determined by the method prescribed in section 16.023, ''Acidity (2)—Official Final Action,'' or by an equivalent potentiometric method.

(f) *Nomenclature.* The name of the food is ''yogurt''. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word ''sweetened'' if nutritive carbohydrate sweetener is added without the addition of characterizing flavor.

(ii) The parenthetical phrase ''(heat-treated after culturing)'' shall follow the name of the food if the dairy ingredients have been heat-treated after culturing.

(iii) The phrase ''vitamin A'' or ''vitamin A added'', or ''vitamin D'' or ''vitamin D added'', or ''vitamins A and D added'', as appropriate. The word ''vitamin'' may be abbreviated ''vit''.

(2) The term ''homogenized'' may appear on the label if the dairy ingredients used are homogenized.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[46 FR 9939, Jan. 30, 1981, as amended at 47 FR 11825, Mar. 19, 1982; 47 FR 41524, Sept. 21, 1982; 48 FR 24869, June 3, 1983; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.203 Lowfat yogurt.

(a) *Description.* Lowfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus.* One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Lowfat yogurt, before the addition of bulky flavors, contains not less than 0.5 percent nor more than 2 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, lowfat yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of current good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose, maltose sirup, dried maltose sirup; malt extract, dried malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers.

(e) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877 or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(1) Milkfat content—As determined by the method prescribed in section 16.059 ''Roese-Gottlieb Method (Reference Method) (11)—Official Final Action,'' under the heading ''Fat.''

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, ''Method I—Official Final Action,'' under the heading ''Total Solids.''

(3) Titratable acidity—As determined by the method prescribed in section 16.023, ''Acidity (2)—Official Final Action,'' or by an equivalent potentiometric method.

(f) *Nomenclature.* The name of the food is ''lowfat yogurt''. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name.

(i) The phrase ''__% milkfat'', the blank to be filled in with the fraction ½ or multiple thereof closest to the actual fat content of the food.

(ii) The word ''sweetened'' if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(iii) The parenthetical phrase ''(heat-treated after culturing)'' shall follow the name of the food if the dairy ingredients have been heat-treated after culturing.

(iv) The phrase ''vitamin A'' or ''vitamin A added'', or ''vitamin D'' or ''vitamin D added'', or ''vitamins A and D added'', as appropriate. The word ''vitamin'' may be abbreviated ''vit''.

(2) The term ''homogenized'' may appear on the label if the dairy ingredients used are homogenized.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the

applicable sections of parts 101 and 130 of this chapter.

[46 FR 9939, Jan. 30, 1981, as amended at 47 FR 11825, Mar. 19, 1982; 47 FR 41524, Sept. 21, 1982; 48 FR 24869, June 3, 1983; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

§ 131.206 Nonfat yogurt.

(a) *Description.* Nonfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Nonfat yogurt, before the addition of bulky flavors, contains less than 0.5 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, nonfat yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

(b) *Vitamin addition (optional).* (1) If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units thereof, within limits of good manufacturing practice.

(2) If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.

(c) *Optional dairy ingredients.* Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

(d) *Other optional ingredients.* (1) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: *Provided,* That the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

(2) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup, dried maltose sirup; malt extract, dired malt extract; malt sirup, dried malt sirup; honey; maple sugar; or any of the sweeteners listed in part 168 of this chapter, except table sirup.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers.

(e) *Methods of analysis.* The following referenced methods of analysis are from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Milkfat content—As determined by the method prescribed in section 16.059, ''Roese-Gottlieb Method (Reference Method) (11)—Official Final Action,'' under the heading ''Fat.''

(2) Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method prescribed in section 16.032, ''Method I—Official Final Action,'' under the heading ''Total Solids.''

(3) Titratable acidity—As determined by the method prescribed in section 16.023, ''Acidity (2)—Official Final Action,'' or by an equivalent potentiometric method.

(f) *Nomenclature.* The name of the food is ''nonfat yogurt''. The full name

of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in §101.22 of this chapter.

(1) The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word ''sweetened'' if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(ii) The parenthetical phrase ''(heat-treated after culturing)'' shall follow the name of the food if the dairy ingredients have been heat-treated after culturing.

(iii) The phrase ''vitamin A'' or ''vitamin A added'', or ''vitamin D'' or ''vitamin D added'', or ''vitamins A and D added'', as appropriate. The word ''vitamin'' may be abbreviated ''vit''.

(2) The term ''homogenized'' may appear on the label if the dairy ingredients used are homogenized.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[46 FR 9940, Jan. 30, 1981, as amended at 47 FR 11825, Mar. 19, 1982; 47 FR 41524, Sept. 21, 1982; 48 FR 24869, June 3, 1983; 54 FR 24893, June 12, 1989; 58 FR 2891, Jan. 6, 1993]

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

Subpart A—General Provisions

Sec.

Subpart B—Requirements for Specific Standardized Cheese and Related Products

§ 133.10 Notice to manufacturers, packers, and distributors of pasteurized blended cheese, pasteurized process cheese, cheese food, cheese spread, and related foods.

(a) Definitions and standards of identity have recently been promulgated under the authority of the Federal Food, Drug, and Cosmetic Act for a number of foods made in part from cheese, including pasteurized process cheese; pasteurized process cheese with fruits, vegetables, or meats; pasteurized blended cheese; pasteurized process cheese food; pasteurized process cheese spread, and related foods. These standards prescribe the name for each such food. The act requires that this name appear on the label. Many of these names consist of several words. In the past it has been the practice of some manufacturers to subordinate the words ''pasteurized,'' ''blended,'' ''process,'' ''food,'' and ''spread'' to give undue prominence to the word ''cheese'' and to words naming the variety of cheese involved.

(b) When placing the names of these foods on labels so as to comply with the requirements of section 403 (a), (f), and (g) of the act, all the words forming the name specified by a definition and standard of identity should be given equal prominence. This can readily be accomplished by printing the specified name of the food in letters of the same size, color, and style of type, and with the same background.

(c) Where the names of optional ingredients are required to appear on the label, the designations of all such ingredients should be given equal prominence. The names of the optional ingredients should appear prominently and conspicuously but should not be displayed with greater prominence than the name of the food. The word ''contains'' may precede the names of the optional ingredients, and when so used will not be considered as intervening printed matter between name of food and name of optional ingredients required to be placed on the label.

(d) Where a manufacturer elects to include a label statement of fat and moisture content, the declaration should be on the basis of the food as marketed. A fat declaration on a moisture-free basis is likely to be misleading, and should not be used in labeling.

Subpart B—Requirements for Specific Standardized Cheese and Related Products

§ 133.102 Asiago fresh and asiago soft cheese.

(a) Asiago fresh cheese, asiago soft cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 45 percent of moisture, and its solids contain not less than 50 percent of milkfat, as determined by the methods prescribed in § 133.5 (a), (b), and (d). It is cured for not less than 60 days.

(b) Milk which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is cut, stirred, and heated to promote and regulate separation of the whey from the curd. The whey is drained off. When the curd is sufficiently firm it is removed from the kettle or vat, further drained for a short time, packed into hoops, and pressed. The pressed curd is salted in brine and cured in a well-ventilated room. During curing the surface of the cheese is occasionally rubbed with a vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of asiago fresh cheese may be added during the procedure in such quantity that the weight

of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c)(1) For the purposes of this section, the word ''milk'' means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Safe and suitable antimycotic agent(s), the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 48 FR 49013, Oct. 24, 1983; 49 FR 10093, Mar. 19, 1984; 58 FR 2891, Jan. 6, 1993]

§ 133.103 Asiago medium cheese.

Asiago medium cheese conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed by § 133.102 for asiago fresh cheese, except that it contains not more than 35 percent moisture, its solids contain not less than 45 percent of milkfat, and it is cured for not less than 6 months.

[58 FR 2892, Jan. 6, 1993]

§ 133.104 Asiago old cheese.

Asiago old cheese conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed by § 133.102 for asiago fresh cheese, except that it contains not more than 32 percent moisture, its solids contain not less than 42 percent of milk fat, and it is cured for not less than 1 year.

[58 FR 2892, Jan. 6, 1993]

§ 133.106 Blue cheese.

(a) *Description.* (1) Blue cheese is the food prepared by the procedure set forth in paragraph (a)(2), of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It is characterized by the presence of bluish-green mold, *Penicillium roquefortii,* throughout the cheese. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 46 percent by weight, as determined by the methods described in § 133.5. The dairy ingredients used may be pasteurized. Blue cheese is at least 60 days old.

(2) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be homogenized, bleached, warmed, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage. While the curd is being placed in forms, spores of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd, and it is held at a temperature of approximately 50 °F. at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. Antimycotics may be applied to the

surface of the whole cheese. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Blue or green color in an amount to neutralize the natural yellow color of the curd.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages or to the surface of the bulk cheese during curing.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(vi) Vegetable fats or oils, which may be hydrogenated, used as a coating for the rind.

(c) *Nomenclature.* The name of the food is ''blue cheese.''

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[48 FR 2742, Jan. 21, 1983, as amended at 54 FR 32052, Aug. 4, 1989; 58 FR 2892, Jan. 6, 1993]

§ 133.108 Brick cheese.

(a) *Description.* (1) Brick cheese is the food prepared from dairy ingredients and other ingredients specified in this section by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 44 percent by weight, as determined by the methods described in § 133.5. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35 °F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of brick cheese is not more than 5 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section is brought to a temperature of about 88 °F and subjected to the action of a lactic acid-producing bacterial culutre. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into cubes with sides approximately ⅜ inch long, and stirred and heated so that the temperature rises slowly to about 96 °F. The stirring is continued until the curd is sufficiently firm. Part of the whey is then removed, and the mixture diluted with water or salt brine to control the acidity. The curd is transferred to forms, and drained. During drainage it is pressed and turned. After drainage the curd is salted, and the biological curing agents characteristic of brick cheese are applied to the surface. The cheese is then cured to develop the characteristics of brick cheese. One or more of the other optional ingredients specified

in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, the cumulative level of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(c) *Nomenclature.* The name of the food is ''brick cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32052, Aug. 4, 1989; 54 FR 35756, Aug. 29, 1989, as amended at 58 FR 2892, Jan. 6, 1993; 58 FR 17105, Apr. 1, 1993]

§ 133.109 Brick cheese for manufacturing.

Brick cheese for manufacturing conforms to the definition and standard of identity for brick cheese prescribed by §133.108, except that the dairy ingredients are not pasteurized and curing is not required.

[54 FR 32053, Aug. 4, 1989]

§ 133.111 Caciocavallo siciliano cheese.

(a) Caciocavallo siciliano cheese is the food prepared from cow's milk or sheep's milk or goat's milk or mixtures of two or all of these and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has a stringy texture, and is made in oblong shapes. It contains not more than 40 percent of moisture, and its solids contain not less than 42 percent milkfat as determined by the methods prescribed in §133.5 (a), (b), and (d). It is cured for not less than 90 days at a temperature of not less than 35 °F.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut, stirred, and heated so as to promote and regulate the separation of whey from curd. The whey is drained off, and the curd is removed to another vat containing hot whey, in which it is soaked for several hours. This whey is withdrawn, the curd is allowed to mat, and is cut into blocks. These are washed in hot whey until the desired elasticity is obtained. The curd is removed from the vat, drained, pressed into oblong forms, dried, and salted in brine, and cured. It may be paraffined. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of caciocavallo siciliano cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c)(1) For the purposes of this section, the word ''milk'' means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Safe and suitable antimycotic agent(s), the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the cheese during the kneading and stretching process and/or applied to the surface of the cheese.

(e) When caciocavallo siciliano cheese is made solely from cow's milk, the name of such cheese is ''Caciocavallo siciliano cheese''. When made from sheep's milk or goat's milk or mixtures of these, or one or both of these with cow's milk, the name is followed by the words ''made from _____'', the blank being filled in with the name or names of the milks used, in order of predominance by weight.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 42 FR 39102, Aug. 2, 1977; 48 FR 49013, Oct. 24, 1983; 49 FR 10093, Mar. 19, 1984; 58 FR 2892, Jan. 6, 1993]

§ 133.113 Cheddar cheese.

(a) *Description.* (1) Cheddar cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight of the solids, and the maximum moisture content is 39 percent by weight, as determined by the methods described in §133.5. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35 °F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of cheddar cheese is not more than 3 micrograms as determined by the method described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed, treated with hydrogen peroxide/catalase, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by sprinkling or pouring water over them, with free and continuous drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is salted, stirred, further drained, and pressed into forms. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial orgin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(v) Hydrogen peroxide, followed by a sufficient quantity of catalase preparation to eliminate the hydrogen peroxide. The weight of the hydrogen peroxide shall not exceed 0.05 percent of the weight of the milk and the weight of the catalase shall not exceed 20 parts per million of the weight of the milk treated.

(c) *Nomenclature.* The name of the food is ''cheddar cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order or predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[48 FR 2743, Jan. 21, 1983; 48 FR 11426, Mar. 18, 1983, as amended at 58 FR 2892, Jan. 6, 1993]

§ 133.114 Cheddar cheese for manufacturing.

Cheddar cheese for manufacturing conforms to the definition and standard of identity prescribed for cheddar cheese by §133.113, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (b)(3)(iv) of that section do not apply.

[48 FR 2743, Jan. 21, 1983]

§ 133.116 Low sodium cheddar cheese.

Low sodium cheddar cheese is the food prepared from the same ingredients and in the same manner prescribed in §133.113 for cheddar cheese and complies with all the provisions of §133.113, including the requirements for label statement of ingredients, except that:

(a) It contains not more than 96 milligrams of sodium per pound of finished food.

(b) The name of the food is ''low sodium cheddar cheese''. The letters in the words ''low sodium'' shall be of the same size and style of type as the letters in the words ''cheddar cheese'', wherever such words appear on the label.

(c) If a salt substitute is used, the label shall bear the statement ''_____ added as a salt substitute'', the blank being filled in with the common name or names of the ingredient or ingredients used as a salt substitute.

[48 FR 2743, Jan. 21, 1983, as amended at 85 FR 72907, Nov. 16, 2020]

§ 133.118 Colby cheese.

(a) Colby cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 40 percent of moisture, and its solids contain not less than 50 percent of milkfat, as determined by the methods prescribed in §133.5 (a), (b), and (d). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35 °F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity

not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. A part of the whey is drained off, and the curd is cooled by adding water, the stirring being continued so as to prevent the pieces of curd from matting. The curd is drained, salted, stirred, further drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of colby cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word ''milk'' means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water, in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Colby cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 133.5(c).

(3) During the cheesemaking process the milk may be treated with hydrogen peroxide/catalase as provided in § 133.113(a)(3).

(d)(1) Colby cheese in the form of slices or cuts may have added to it a clear aqueous solution prepared by condensing or precipitating wood smoke in water.

(2) Colby cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight calculated as sorbic acid.

(e)(1) If colby cheese has added to it a clear aqueous solution prepared by condensing or precipitating wood smoke in water as provided in paragraph (d)(1) of this section, the name of the food is immediately followed by the words ''with added smoke flavoring'' with all words in this phrase of the same type size, style, and color without intervening written, printed, or graphic matter.

(2) If colby cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d)(2) of this section, the label shall bear the statement ''_____ added to retard mold growth'' or ''_____ added as a preservative'', the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in paragraph (e)(2) of this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter except for the statement ''with added smoke flavoring,'' as set forth in paragraph (e)(1) of this section.

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10093, Mar. 19, 1984; 58 FR 2892, Jan. 6, 1993]

§ 133.119 Colby cheese for manufacturing.

Colby cheese for manufacturing conforms to the definition and standard of identity prescribed for colby cheese by § 133.118, except that the milk is not pasteurized, curing is not required, and the provisions of paragraph (d) of that section do not apply.

§ 133.121 Low sodium colby cheese.

Low sodium colby cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.118 for colby cheese and complies with all the provisions of § 133.118, including the requirements for label statement of ingredients, except that:

(a) Salt is not used. Any safe and suitable ingredient or combination of ingredients that contains no sodium and that is recognized as a salt substitute may be used.

(b) Sodium sorbate is not used.

(c) It contains not more than 96 milligrams of sodium per pound of finished food.

(d) The name of the food is ''low sodium colby cheese''. The letters in the words ''low sodium'' shall be of the same size and style of type as the letters in the words ''colby cheese'', wherever such words appear on the label.

(e) If a salt substitute as provided for in paragraph (a) of this section is used, the label shall bear the statement ''_____ added as a salt substitute'', the blank being filled in with the common name or names of the ingredient or ingredients used as a salt substitute.

[42 FR 14366, Mar. 15, 1977, as amended at 58 FR 2892, Jan. 6, 1993; 85 FR 72907, Nov. 16, 2020]

§ 133.123 Cold-pack and club cheese.

(a)(1) Cold-pack cheese, club cheese, is the food prepared by comminuting, without the aid of heat, one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, lowfat cottage cheese, cottage cheese dry curd, hard grating cheese, semisoft part-skim cheese, part-skim spiced cheese and skim milk cheese for manufacturing, into a homogeneous plastic mass. One or more of the optional ingredients designated in paragraph (c) of this section may be used.

(2) All cheeses used in a cold-pack cheese are made from pasteurized milk or are held for not less than 60 days at a temperature of not less than 35 °F before being comminuted.

(3)(i) The moisture content of a cold-pack cheese made from a single variety of cheese is not more than the maximum moisture content prescribed by the definition and standard of identity, if any there be, for the variety of cheese used. If there is no applicable definition and standard of identity, or if such standard contains no provision as to maximum moisture content, no water is used in the preparation of the cold-pack cheese.

(ii) The fat content of the solids of a cold-pack cheese made from a single variety of cheese is not less than the minimum prescribed by the definition and standard of identity, if any there be, for the variety of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of cold-pack swiss cheese is not less than 43 percent, and the fat content of the solids of cold-pack gruyere cheese is not less than 45 percent.

(4)(i) The moisture content of a cold-pack cheese made from two or more varieties of cheese is not more than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is the moisture content more than 42 percent, except that the moisture content of a cold-pack cheese made from two or more of the varieties cheddar cheese, washed curd cheese, colby cheese, and granular cheese is not more than 39 percent.

(ii) The fat content of the solids of a cold-pack cheese made from two or more varieties of cheese is not less than the arithmetical average of the minimum percent of fat prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of a cold-pack cheese made from swiss cheese and gruyere cheese is not less than 45 percent.

(5) Moisture and fat are determined by the methods prescribed in § 133.5(a), (b), and (d).

(6) The weight of each variety of cheese in a cold-pack cheese made from two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, or gorgonzola cheese is not less than 10 percent of the total weight of both, and the weight of limburger cheese is not less than 5 percent of the total weight

of both. The weight of each variety of cheese in a cold-pack cheese made from three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, or gorgonzola cheese is not less than 5 percent of the total weight of all, and the weight of limburger cheese is not less than 3 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as ''American cheese'' as prescribed in paragraph (d)(2) of this section. Such mixtures are considered as one variety of cheese for the purpose of this paragraph (a)(6).

(b) Cold-pack cheese may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the finished cold-pack cheese is not below 4.5. For the purposes of this section vinegar is considered to be acetic acid.

(2) Water.

(3) Salt.

(4) Harmless artificial coloring.

(5) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.

(6) Cold-pack cheese in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(d)(1) The name of a cold-pack cheese for which a definition and standard of identity is prescribed by this section is ''Cold-pack _____ cheese'', ''_____ cold-pack cheese'' or ''_____ club cheese'', the blanks being filled in with the name or names of the varieties of cheese used, in order of predominance by weight.

(2) If the cold-pack cheese is made of cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these, it may be designated ''Cold-pack American cheese''; or when cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these is combined with other varieties of cheese in the cheese ingredient any of such cheeses or such mixture may be designated as ''American cheese''.

(3) The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (f) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(e) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice that characterizes the product.

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, may be designated as ''American cheese''.

(1) Artificial coloring need not be declared.

(2) If the cheese ingredient contains cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, such

cheese or such mixture may be designated as ''American cheese''.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10093, Mar. 19, 1984; 58 FR 2892, Jan. 6, 1993]

§ 133.124 Cold-pack cheese food.

(a)(1) Cold-pack cheese food is the food prepared by comminuting and mixing, without the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section with one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (e) of this section may be used.

(2) All cheeses used in a cold-pack cheese food are made from pasteurized milk, or are held for not less than 60 days at a temperature of not less than 35 °F before being comminuted.

(3) The moisture content of a cold-pack cheese food is not more than 44 percent, and the fat content is not less than 23 percent.

(4) Moisture and fat are determined by the methods prescribed in § 133.5 (a), (b), and (d), except that in determining moisture the loss in weight which occurs in drying for 5 hours, under the conditions prescribed in such method, is taken as the weight of moisture.

(5) The weight of the cheese ingredient prescribed by paragraph (a)(1) of this section constitutes not less than 51 percent of the weight of the finished cold-pack cheese food.

(6) The weight of each variety of cheese in the cold-pack cheese food made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in the cold-pack cheese food made with three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as ''American cheese'' as prescribed in paragraph (h)(5) of this section. Such mixtures are considered as one variety of cheese for the purposes of this paragraph (a)(6).

(b) Cold-pack cheese food may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are: One or more cheeses of the same or two or more varieties, except that cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim-milk cheese for manufacturing are not used, and except that semisoft part-skim cheese, part-skim spiced cheese, and hard grating cheese may not be used, alone or in combination with each other, as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, skim milk cheese for manufacturing, and albumin from cheese whey. All optional dairy ingredients used in cold-pack cheese food are pasteurized or made from products that have been pasteurized.

(e) The other optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the finished cold-pack cheese food is not below 4.5.

(2) Water.

(3) Salt.

(4) Harmless artificial coloring.

(5) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of cheese of any age or variety.

(6) A sweetening agent consisting of one or any mixture of two or more of the following: Sugar, dextrose, corn

sugar, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, and hydrolyzed lactose, in a quantity necessary for seasoning.

(7) Cold-pack cheese food in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(8) In the preparation of cold-pack cheese food, guar gum or xanthan gum, or both, may be used, but the total quantity of such ingredient or combination is not to exceed 0.3 percent of the weight of the finished food. When one or both such optional ingredients is used, dioctyl sodium sulfosuccinate complying with the requirements of §172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredient or ingredients.

(f) The name of the food is ''cold-pack cheese food''. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of (other than in an ingredient statement any ingredient appears on the label as specified in paragraph (h) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(g) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice that characterizes the product.

(h) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, may be designated as ''American cheese''.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10093, Mar. 19, 1984; 58 FR 2892, Jan. 6, 1993]

§ 133.125 Cold-pack cheese food with fruits, vegetables, or meats.

(a) Cold-pack cheese food with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for cold pack cheese food by §133.124, except that:

(1) Its milk fat content is not less than 22 percent.

(2) It contains one or any mixture of two or more of the following: Any properly prepared fresh, cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by §133.5(b) and (d) is not applicable.

(b) The name of a cold-pack cheese food with fruits, vegetables or meats is ''Cold-pack cheese food with _____'', the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10093, Mar. 19, 1984; 58 FR 2892, Jan. 6, 1993]

§ 133.127 Cook cheese, koch kaese.

(a) *Description.* (1) Cook cheese, koch kaese, is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The maximum moisture content is 80 percent by weight, as determined by the method described in §133.5. The dairy ingredients used may be pasteurized.

(2) The phenol equivalent value of 0.25 gram of cook cheese is not more than 3 micrograms as determined by the method described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut, stirred, and heated with continued stirring, so as to separate the curd and whey. The whey is drained from the curd and the curd is cured for 2 or 3 days. It is then heated to a temperature of not less than 180 °F until the hot curd will drop from a ladle with a consistency like that of honey. The hot cheese is filled into packages and cooled. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Nonfat milk as defined in §133.3.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(ii) Culture of white mold.

(iii) Pasteurized cream.

(iv) Caraway seed.

(v) Salt.

(c) *Nomenclature.* The name of the food is ''cook cheese'' or, alternatively, ''koch kaese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130, except that enzymes of animal, plant, or microbial origin may be declared as ''enzymes''.

[54 FR 32053, Aug. 4, 1989, as amended at 55 FR 51409, Dec. 14, 1990; 58 FR 2892, Jan. 6, 1993]

§ 133.128 Cottage cheese.

(a) Cottage cheese is the soft uncured cheese prepared by mixing cottage cheese dry curd with a creaming mixture as provided in paragraph (b) of this section. The milkfat content is not less than 4 percent by weight of the finished food, within limits of good manufacturing practice. The finished food contains not more than 80 percent of moisture, as determined by the method prescribed in §133.129(a).

(b) The creaming mixture is prepared from safe and suitable ingredients including, but not limited to, milk or substances derived from milk. Any ingredients used that are not derived from milk shall serve a useful function other than building the total solids content of the finished food, and shall be used in a quantity not greater than is reasonably required to accomplish their intended effect. The creaming mixture shall be pasteurized; however, heat labile ingredients, such as bacterial starters, may be added following pasteurization.

(c) The name of the food consists of the following two phrases which shall appear together:

(1) The words ''cottage cheese'' which shall appear in type of the same size and style.

(2) The statement ''not less than __ percent milkfat'' or ''__ percent milkfat minimum'', the blank being filled in with the whole number that is closest to, but does not exceed, the actual fat content of the product. This statement of fat content shall appear in letters not less than one-half of the height of the letters in the phrase specified in paragraph (c)(1) of this section, but in no case less than one-eighth of an inch in height.

(d) When the optional process described in §133.129(b)(1) (ii) or (iii) is used to make the cottage cheese dry curd used in cottage cheese, the label shall bear the statement ''Directly set'' or ''Curd set by direct acidification''. Wherever the name of the food appears on the label so conspicuously as to be seen under customary conditions of purchase, the statement specified in this paragraph, showing the optional process used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections

of parts 101 and 130 of this chapter, except that milk-clotting enzymes may be declared by the word ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 58 FR 2892, Jan. 6, 1993]

§ 133.129 Dry curd cottage cheese.

(a) Cottage cheese dry curd is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished food contains less than 0.5 percent milkfat. It contains not more than 80 percent of moisture, as determined by the method prescribed in § 133.5(a).

(b)(1) One or more of the dairy ingredients specified in paragraph (b)(2) of this section is pasteurized; calcium chloride may be added in a quantity of not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the mix; thereafter one of the following methods is employed:

(i) Harmless lactic-acid-producing bacteria, with or without rennet and/or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, are added and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd may be washed with water and further drained; it may be pressed, chilled, worked, seasoned with salt; or

(ii) Food grade phosphoric acid, lactic acid, citric acid, or hydrochloric acid, with or without rennet and/or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, is added in such amount as to reach a pH of between 4.5 and 4.7; coagulation to a firm curd is achieved while heating to a maximum of 120 °F without agitation during a continuous process. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is washed with water, stirred, and further drained. It may be pressed, chilled, worked, seasoned with salt.

(iii) Food grade acids as provided in paragraph (b)(1)(ii) of this section, D-Glucono-delta-lactone with or without rennet, and/or other safe and suitable milk clotting enzyme that produces equivalent curd formation, are added in such amounts as to reach a final pH value in the range of 4.5–4.8, and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is then washed with water, and further drained. It may be pressed, chilled, worked, and seasoned with salt.

(2) The dairy ingredients referred to in paragraph (b)(1) of this section are sweet skim milk, concentrated skim milk, and nonfat dry milk. If concentrated skim milk or nonfat dry milk is used, water may be added in a quantity not in excess of that removed when the skim milk was concentrated or dried.

(3) For the purposes of this section the term ''skim milk'' means the milk of cows from which the milk fat has been separated, and ''concentrated skim milk'' means skim milk from which a portion of the water has been removed by evaporation.

(c) The name of the food consists of the following two phrases which shall appear together:

(1) The words ''cottage cheese dry curd'' or alternatively ''dry curd cottage cheese'' which shall all appear in type of the same size and style.

(2) The words ''less than ½% milkfat'' which shall all appear in letters not less than one-half of the height of the letters in the phrase specified in paragraph (c)(1) of this section, but in no case less than one-eighth of an inch in height.

(d) When either of the optional processes described in paragraph (b)(1) (ii) or (iii) of this section is used to make cottage cheese dry curd, the label shall bear the statement ''Directly set'' or ''Curd set by direct acidification''. Wherever the name of the food appears on the label so conspicuously as to be seen under customary conditions of purchase, the statement specified in this paragraph, showing the optional process used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections

of parts 101 and 130 of this chapter, except that milk-clotting enzymes may be declared by the word ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 47 FR 11826, Mar. 19, 1982; 49 FR 10093, Mar. 19, 1984; 58 FR 2892, Jan. 6, 1993]

§ 133.133 Cream cheese.

(a) *Description.* (1) Cream cheese is the soft, uncured cheese prepared by the procedure set forth in paragraph (a)(2) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 33 percent by weight of the finished food, and the maximum moisture content is 55 percent by weight, as determined by the methods described in §133.5. The dairy ingredients used are pasteurized.

(2) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be homogenized and is subjected to the action of lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to coagulate the dairy ingredients. The coagulated mass may be warmed and stirred and it is drained. The moisture content may be adjusted with one or more of the optional ingredients specified in paragraph (b)(3)(ii) of this section. The curd may be pressed, chilled, and worked and it may be heated until it becomes fluid. It may then be homogenized or otherwise mixed. One or more of the optional dairy ingredients specified in paragraph (b)(1) and the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Salt.

(ii) Cheese whey, concentrated cheese whey, dried cheese whey, or reconstituted cheese whey prepared by addition of water to concentrated cheese whey or dried cheese whey.

(iii) Stabilizers, in a total amount not to exceed 0.5 percent of the weight of the finished food, with or without the addition of dioctyl sodium sulfosuccinate in a maximum amount of 0.5 percent of the weight of the stabilizer(s) used.

(c) *Nomenclature.* The name of the food is ''cream cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial original may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32053, Aug. 4, 1989, as amended at 58 FR 2892, Jan. 6, 1993]

§ 133.134 Cream cheese with other foods.

(a) *Description.* Cream cheese with other foods is the class of foods prepared by mixing, with or without the aid of heat, cream cheese with one or a mixture of two or more types of foods (except other cheeses) listed in paragraph (b)(1) of this section, in an amount sufficient to differentiate the mixture from cream cheese. One or more of the other optional ingredients in paragraph (b)(2) of this section may be used. The maximum moisture content of the mixture is 60 percent by weight. The minimum milkfat is 33 percent by weight of the cream cheese and in no case less than 27 percent of the finished food. The moisture and fat contents will be determined by the methods described in §133.5, except that the method for determination of fat content is not applicable when the added food contains fat.

(b) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) *Foods.* Properly prepared fresh, cooked, canned, or dried fruits or vegetables; cooked or canned meats, relishes, pickles, or other suitable foods.

(2) *Other optional ingredients.* (i) Stabilizers, in a total amount not to exceed 0.8 percent, with or without the

addition of dioctyl sodium sulfosuccinate in a maximum amount of 0.5 percent of the weight of the stabilizer(s) used.

(ii) Coloring.

(c) *Nomenclature.* The name of the food is ''cream cheese with _____'' or, alternatively, ''cream cheese and _____'', the blank being filled in with the name of the foods used in order of predominance by weight.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32053, Aug. 4, 1989, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.136 Washed curd and soaked curd cheese.

(a) *Description.* (1) Washed curd, soaked curd cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 42 percent by weight, as determined by the methods described in § 133.5. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35 °F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of washed curd cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed, treated with hydrogen peroxide/catalase, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, cooled in water, and soaked therein until the whey is partly extracted and water is absorbed. The curd is drained, salted, stirred, and pressed into forms. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(v) Hydrogen peroxide, followed by a sufficient quantity of catalase preparation to eliminate the hydrogen peroxide. The weight of the hydrogen peroxide shall not exceed 0.05 percent of the weight of the dairy ingredients and the weight of the catalase shall not exeed 20 parts per million of the weight of dairy ingredients treated.

(c) *Nomenclature.* The name of the food is ''washed curd cheese'' or, alternatively, ''soaked curd cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32054, Aug. 4, 1989, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.137 Washed curd cheese for manufacturing.

Washed curd cheese for manufacturing conforms to the definition and standard of identity prescribed for washed curd cheese by § 133.136, except that the dairy ingredients are not pasteurized and curing is not required.

[54 FR 32054, Aug. 4, 1989]

§ 133.138 Edam cheese.

(a) *Description.* (1) Edam cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 40 percent by weight of the solids and the maximum moisture content is 45 percent by weight, as determined by the methods described in § 133.5. If the dairy ingredients used are not pasturized, the cheese is cured at a temperature of not less than than 35 °F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of edam cheese is not more than 3 micrograms, as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately three-eighths-inch long. The mass is stirred and heated to about 90 °F. and so handled by further stirring, heating, dilution with water or salt brine, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage the curd is pressed and turned. After drainage the curd is removed from the forms and is salted and cured. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedures.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(c) *Nomenclature.* The name of the food is ''edam cheese.''

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat,'' as appropriate.

[48 FR 2743, Jan. 21, 1983; 48 FR 11426, Mar. 18, 1983, as amended at 55 FR 6795, Feb. 27, 1990; 58 FR 2893, Jan. 6, 1993]

§ 133.140 Gammelost cheese.

(a) *Description.* (1) Gammelost cheese is the food prepared from nonfat milk, as defined in § 133.3, by the procedure set forth in paragraph (a)(2) of this section, or by any other procedure which

produces a finished cheese having the same physical and chemical properties. The maximum moisture content is 52 percent by weight, as determined by the methods described in § 133.5.

(2) The dairy ingredients are subjected to the action of a lactic acid-producing bacterial culture. The development of acidity is continued until the dairy ingredients coagulate to a semisolid mass. The mass is stirred and heated until a temperature of about 145 °F is reached, and is held at that temperature for at least 30 minutes. The whey is drained off and the curd removed and placed in forms and pressed. The shaped curd is placed in whey and heated for 3 or 4 hours, and may again be pressed. It is then stored under conditions suitable for curing.

(b) *Nomenclature.* The name of the food is ''gammelost cheese''.

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[54 FR 32054, Aug. 4, 1989, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.141 Gorgonzola cheese.

(a) *Description.* (1) Gorgonzola cheese is the food prepared by the procedure set forth in paragraph (a)(2) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It is characterized by the presence of bluish-green mold, *Penicillium roquefortii,* throughout the cheese. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 42 percent by weight, as determined by the methods described in § 133.5. The dairy ingredients used may be pasteurized. Gorgonzola cheese is at least 90 days old.

(2) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed into forms permitting further drainage. While being placed in forms, spores of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd and it is held at a temperature of approximately 50 °F at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage, the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, or corresponding products of goat origin, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Blue or green color in an amount to neutralize the natural yellow color of the curd.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(v) Benzoyl peroxide, or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the dairy ingredients being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If the dairy ingredients are bleached in

this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(vi) Vegetable fats or oil which may be hydrogenated, used as a coating for the rind.

(c) *Nomenclature.* The name of the food is ''gorgonzola cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate; ''milkfat from goat's milk and nonfat goat's milk'', etc.

[54 FR 32054, Aug. 4, 1989, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.142 Gouda cheese.

Gouda cheese conforms to the definition and standard of identity and complies with the requirements for label declaration of ingredients prescribed for edam cheese by § 133.138, except that the minimum milkfat content is 46 percent by weight of the solids, as determined by the methods described in § 133.5 and the maximum moisture content is 45 percent by weight.

[48 FR 2744, Jan. 21, 1983]

§ 133.144 Granular and stirred curd cheese.

(a) *Description.* (1) Granular cheese, stirred curd cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 39 percent by weight as determined by the methods described in § 133.5. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35 °F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of granular cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed, treated with hydrogen peroxide/catalase, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. A part of the whey is drained off. The curd is then alternately stirred and drained to prevent matting and to remove whey from curd. The curd is then salted, stirred, drained, and pressed into forms. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(v) Hydrogen peroxide, followed by a sufficient quantity of catalase preparation to eliminate the hydrogen peroxide. The weight of the hydrogen peroxide shall not exceed 0.05 percent of the weight of the dairy ingredients and

the weight of the catalase shall not exceed 20 parts per million of the weight of the dairy ingredients treated.

(c) *Nomenclature.* The name of the food is ''granular cheese'' or, alternatively, ''stirred curd cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32055, Aug. 4, 1989, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.145 Granular cheese for manufacturing.

Granular cheese for manufacturing conforms to the definition and standard of identity prescribed for granular cheese by § 133.144, except that the dairy ingredients are not pasteurized and curing is not required.

[54 FR 32056, Aug. 4, 1989]

§ 133.146 Grated cheeses.

(a) *Description.* Grated cheeses is the class of foods prepared by grinding, grating, shredding, or otherwise comminuting cheese of one variety or a mixture of two or more varieties. The cheese varieties that may be used are those for which there are definitions and standards of identity, except that cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim milk cheese for manufacturing may not be used. All cheese ingredients used are either made from pasteurized milk or held at a temperature of not less than 35 °F for at least 60 days. Moisture may be removed from the cheese ingredients in the manufacture of the finished food, but no moisture is added. One or more of the optional ingredients specified in paragraph (c) of this section may be used.

(b) *Composition.* (1) Each cheese ingredient used is present at a minimum level of 2 percent of the weight of the finished food.

(2) When one variety of cheese is used, the minimum milkfat content of the food is not more than 1 percent lower than the minimum prescribed by the standard of identity for that cheese.

(3) When two or more varieties of cheese are used, the minimum milkfat content is not more than 1 percent below the arithmetical average of the minimum fat content percentages prescribed by the standards of identity for the varieties of cheese used, and in no case is the milkfat content less than 31 percent.

(4) Milkfat and moisture contents are determined by the methods described in § 133.5.

(c) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Antimycotics.

(2) Anticaking agents.

(3) Spices.

(4) Flavorings other than those which, singly or in combination with other ingredients, simulate the flavor of cheese of any age or variety.

(d) *Nomenclature.* (1) The name of the food is ''grated cheese'' or ''grated cheeses'', as appropriate. The name of the food shall be accompanied by a declaration of the specific variety of cheese(s) used in the food and by a declaration indicating the presence of any added spice or flavoring.

(2) Any cheese varietal names used in the name of the food are those specified by applicable standards of identity, except that the designation ''American cheese'' may be used for cheddar, washed curd, colby, or granular cheese or for any mixture of these cheeses.

(3) The following terms may be used in place of the name of the food to describe specific types of grated cheese:

(i) If only one variety of cheese is used, the name of the food is ''grated _____ cheese'', the name of the cheese filling the blank.

(ii) If only parmesan and romano cheeses are used and each is present at a level of not less than 25 percent by weight of the finished food, the name of the food is ''grated _____ and _____ cheese'', the blanks being filled with

the names ''parmesan'' and ''romano'' in order of predominance by weight. The name ''reggiano'' may be used for ''parmesan''.

(iii) If a mixture of cheese varieties (not including parmesan or romano) is used and each variety is present at a level of not less than 25 percent of the weight of the finished food, the name of the food is ''grated _____ cheese'', the blank being filled in with the names of the varieties in order of predominance by weight.

(iv) If a mixture of cheese varieties in which one or more varieties (not including parmesan or romano) are each present at a level of not less than 25 percent by weight of the finished food, and one or more other varieties (which may include parmesan and romano cheese) are each present at a level of not less than 2 percent but in the aggregate not more than 10 percent of the weight of the finished food, the name of the food is ''grated _____ cheese with other grated cheese'' or ''grated _____ cheese with other grated cheeses'', as appropriate, the blank being filled in with the name or names of those cheese varieties present at levels of not less than 25 percent by weight of the finished food in order of predominance, in letters not more than twice as high as the letters in the phrase ''with other grated cheese(s)''.

(4) The following terms may be used in place of ''grated'' to describe alternative forms of cheese:

(i) ''Shredded'', if the particles of cheese are in the form of cylinders, shreds, or strings.

(ii) ''Chipped'' or ''chopped'', if the particles of cheese are in the form of chips.

(e) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', ''milkfat from goat's milk and nonfat goat's milk'', ''milkfat from sheep's milk and nonfat sheep's milk'', etc., as appropriate.

[54 FR 32056, Aug. 4, 1989; 54 FR 35756, Aug. 29, 1989, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.147 Grated American cheese food.

(a)(1) Grated American cheese food is the food prepared by mixing, with or without the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (b) of this section with one or more of the optional ingredients prescribed in paragraph (c) of this section, into a uniformly blended, partially dehydrated, powdered, or granular mixture.

(2) Grated American cheese food contains not less than 23 percent of milkfat, as determined by the method prescribed in § 133.5(b).

(b) The optional cheese ingredients referred to in paragraph (a) of this section are cheddar cheese, washed curd cheese, colby cheese, and granular cheese.

(c) The other optional ingredients referred to in paragraph (a) of this section are:

(1) Nonfat dry milk.

(2) Dried whey.

(3) An emulsifying agent consisting of one or any mixture of two or more of the emulsifying ingredients named in § 133.173(e)(1), in such quantity that the weight of the solids thereof is not more than 3 percent of the weight of the grated American cheese food.

(4) An acidifying agent consisting of one or more of the acid-reacting ingredients named in § 133.173(e)(2).

(5) Salt.

(6) Artificial coloring.

(d) The name of the food is ''Grated American cheese food''. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (e) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at

least the same size as the type used in such word or statement.

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated ''American cheese''.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10094, Mar. 19, 1984; 58 FR 2893, Jan. 6, 1993]

§ 133.148 Hard grating cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are hard grating cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 34 percent of moisture, and their solids contain not less than 32 percent of milkfat, as determined by the methods prescribed in §133.5 (a), (b), and (d). Hard grating cheeses are cured for not less than 6 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. The mass is cut into small particles, stirred, and heated. The curd is separated from the whey, drained, shaped into forms, pressed, salted, and cured. The rind may be colored or rubbed with vegetable oil or both. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of hard grating cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word ''milk'' means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(d) Safe and suitable antimycotic agent(s), the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(e) The name of each hard grating cheese for which a definition and standard of identity is prescribed by this section is ''Hard grating cheese'', preceded or followed by:

(1) The specific common or usual name of such hard grating cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name that is not false or misleading in any particular.

(3) When milk other than cow's milk is used, in whole or in part, the statement ''made from _____'', the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) When milk other than cow's milk is used, in whole or in part, the common or usual name of each such milk ingredient shall be declared in order of predominance by weight; and

(2) Enzymes of the animal, plant, or microbial origin may be declared as ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 48 FR 49013, Oct. 24, 1983; 49 FR 10094, Mar. 19, 1984; 58 FR 2893, Jan. 6, 1993]

§ 133.149 Gruyere cheese.

(a) *Description.* (1) Gruyere cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It contains small holes or eyes. It has a mild flavor, due in part to the growth of surface-curing agents. The minimum milkfat content is 45 percent by weight of the solids and the maximum moisture content is 39 percent by weight, as determined by the methods described in §133.5. The dairy ingredients used may be pasteurized. The cheese is at least 90 days old.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of gruyere cheese is not more than 3 micrograms as determined by the method described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of lactic acid-producing and propionic acid-producing bacterial cultures. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126 °F. Stirring is continued until the curd becomes firm. The curd is transferred to hoops or forms, and pressed until the desired shape and firmness are obtained. The cheese is surface-salted while held at a temperature of 48° to 54 °F for a few days. It is soaked for 1 day in a saturated salt solution. It is then held for 3 weeks in a salting cellar and wiped every 2 days with brine cloth to insure growth of biological curing agents on the rind. It is then removed to a heating room and held at progressively higher temperatures, finally reaching 65 °F with a relative humidity of 85 to 90 percent, for several weeks, during which time small holes, or so-called eyes, form. The cheese is then stored at a lower temperature for further curing. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(ii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iii) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* The name of the food is ''gruyere cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[48 FR 2744, Jan. 21, 1983; 48 FR 11426, Mar. 18, 1983, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.150 Hard cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are hard cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 39 percent of moisture, and their solids contain not less

than 50 percent of milkfat, as determined by the methods prescribed in §133.5 (a), (b), and (d). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35 °F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, with or without other harmless flavor-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into small particles, stirred, and heated. The curd is separated from the whey, drained, and shaped into forms, and may be pressed. The curd is salted at some stage of the manufacturing process. The shaped curd may be cured. The rind may be coated with paraffin or rubbed with vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of hard cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used. Harmless flavor-producing microorganisms may be added, and curing may be conducted under suitable conditions for the development of biological curing agents.

(c) For the purposes of this section:

(1) The word ''milk'' means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom, or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. A hard cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in §133.5(c).

(d) Safe and suitable antimycotic agent(s), the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(e) The name of each hard cheese for which a definition and standard of identity is prescribed by this section is ''Hard cheese'', preceded or followed by:

(1) The specific common or unusual name of such hard cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized, therefor, an arbitrary or fanciful name that is not false or misleading in any particular.

(3) When milk other than cow's milk is used, in whole or in part, the statement ''made from _____'', the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) When milk other than cow's milk is used, in whole or in part, the common or usual name of each such milk ingredient shall be declared in order of predominance by weight; and

(2) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 48 FR 49013, Oct. 24, 1983; 49 FR 10094, Mar. 19, 1984; 58 FR 2893, Jan. 6, 1993]

§ 133.152 Limburger cheese.

(a) *Description.* (1) Limburger cheese is the food prepared by one of the procedures set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 50 percent by weight, as determined by the methods described in §133.5. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35 °F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of limburger cheese is not more than 4 micrograms as determined by the method described in §133.5.

(3) One of the following procedures may be followed for producing limburger cheese:

(i) One or more of the dairy ingredients, unpasteurized, specified in paragraph (b)(1) of this section is warmed to about 92 °F and subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into cubes with sides approximately one-half inch long. After a few minutes the mass is stirred and heated, gradually raising the temperature to 96° to 98 °F. The curd is then allowed to settle, most of the whey is drained off, and the remaining curd and whey dipped into molds. During drainage the curd may be pressed. It is turned at regular intervals. After drainage the curd is cut into pieces of desired size and dry-salted at intervals for 24 to 48 hours. The cheese is then cured with frequent applications of a weak brine solution to the surface, until the proper growth of surface-curing organisms is obtained. It is then wrapped and held in storage for development of as much additional flavor as is desired. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(ii) One or more of the dairy ingredients specified in paragraph (b)(1) of this section is pasteurized, brought to a temperature of 89° to 90 °F. after pasteurization, and is subjected to the action of a lactic acid-producing bacterial culture. The procedure is then the same as in paragraph (a)(3)(i) of this section, except that heating is to 94 °F. After most of the whey is drained off, salt brine at a temperature of 66° to 70 °F is added, so that the pH of the curd is about 4.8. The mixed curd, whey, and brine is dipped into molds, and the remaining procedure specified in paragraph (a)(3)(i) of this section is followed.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(c) *Nomenclature.* The name of the food is ''limburger cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[48 FR 2744, Jan. 21, 1983; 48 FR 11426, Mar. 18, 1983, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.153 Monterey cheese and monterey jack cheese.

(a) *Description.* (1) Monterey cheese, monterey jack cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a

finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight of the solids, and the maximum moisture content is 44 percent by weight, as determined by the methods described in §133.5. The dairy ingredients used are pasteurized.

(2) The phenol equivalent of 0.25 gram of monterey cheese is not more than 3 micrograms, as determined by the method described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. Part of the whey is drained off, and water or salt brine may be added. The curd is drained and placed in a muslin or sheeting cloth, formed into a ball, and pressed; or the curd is placed in a cheese hoop and pressed. Later, the cloth bandage is removed, and the cheese may be covered with a suitable coating. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(ii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iii) Salt.

(iv) Antimycotic agents, the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(v) Vegetable oil, with or without rice flour sprinkled on the surface, used as a coating for the rind.

(c) *Nomenclature.* The name of the food is ''monterey cheese'' or alternatively, ''monterey jack cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes'', and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32056, Aug. 4, 1989, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.154 High-moisture jack cheese.

High-moisture jack cheese conforms to the definition and standard of identity and is subject to the requirement for label statement of ingredients prescribed for monterey cheese by §133.153, except that its moisture content is more than 44 percent but less than 50 percent.

[58 FR 2893, Jan. 6, 1993]

§ 133.155 Mozzarella cheese and scamorza cheese.

(a) *Description.* (1) Mozzarella cheese, scamorza cheese is the food prepared from dairy ingredients and other ingredients specified in this section by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It may be molded into various shapes. The minimum milkfat content is 45 percent by weight of the solids, and the moisture content is more than 52 percent but not more than 60 percent by weight as determined by the methods described in §133.5. The dairy ingredients are pasteurized.

(2) The phenol equivalent value of 0.25 gram of mozzarella cheese is not more than 3 micrograms as determined by the method described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of

this section is warmed to approximately 88 °F (31.1 °C) and subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut, and it may be stirred to facilitate separation of whey from the curd. The whey is drained, and the curd may be washed with cold water and the water drained off. The curd may be collected in bundles for further drainage and for ripening. The curd may be iced, it may be held under refrigeration, and it may be permitted to warm to room temperature and ripen further. The curd may be cut. It is immersed in hot water or heated with steam and is kneaded and stretched until smooth and free of lumps. It is then cut and molded. The molded curd is firmed by immersion in cold water and drained. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Cow's milk, nonfat milk, or cream, as defined in §133.3, or the corresponding products of water buffalo origin, except that cow's milk products are not combined with water buffalo products.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Vinegar.

(ii) Coloring to mask any natural yellow color in the curd.

(iii) Salt.

(iv) Antimycotics, the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the cheese during the kneading and stretching process and/or applied to the surface of the cheese.

(c) *Nomenclature.* The name of the food is ''mozzarella cheese'' or, alternatively, ''scamorza cheese''. When the food is made with water buffalo milk, the name of the food is accompanied by the phrase ''made with water buffalo milk''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', ''milkfat from water buffalo milk and nonfat buffalo milk'' or ''nonfat water buffalo milk and milkfat from water buffalo milk,'' as appropriate.

[53 FR 3743, Feb. 9, 1988, as amended at 58 FR 2893, Jan. 6, 1993]

§133.156 Low-moisture mozzarella and scamorza cheese.

(a) *Description.* (1) Low-moisture mozzarella cheese, low-moisture scamorza cheese is the food prepared from dairy ingredients and other ingredients specified in this section by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It may be molded into various shapes. The minimum milkfat content is 45 percent by weight of the solids and the moisture content is more than 45 percent but not more than 52 percent by weight as determined by the methods described in §133.5. The dairy ingredients are pasteurized.

(2) The phenol equivalent value of 0.25 gram of low-moisture mozzarella cheese is not more than 3 micrograms as determined by the method described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this action is added to set the dairy ingredients to a semisolid mass. The mass is cut, stirred, and allowed to stand. It may be reheated and again stirred. The whey is drained and the curd may be cut and piled to promote further separation of whey. It may be washed with cold water and the water drained off. The curd may be collected in bundles for further drainage and for ripening. The

curd may be iced, it may be held under refrigeration, and it may be permitted to warm to room temperature and ripen further. The curd may be cut. It is immersed in hot water or heated with steam and is kneaded and stretched until smooth and free of lumps. It is then cut and molded. In molding, the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is firmed by immersion in cold water and drained. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Cow's milk, nonfat milk, or cream, as defined in §133.3, or the corresponding products of water buffalo origin, except that cow's milk products are not combined with water buffalo products.

(2) *Clotting enzymes.* Rennet and/or clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Vinegar.

(ii) Coloring to mask any natural yellow color in the curd.

(iii) Salt.

(iv) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(v) Antimycotics, the cumulative levels of which shall not exceed current good manufacturing practices, may be added to the cheese during the kneading and stretching process and/or applied to the surface of the cheese.

(c) *Nomenclature.* The names of the food is ''low-moisture mozzarella cheese'' or, alternatively, ''low-moisture scamorza cheese''. When the food is made with water buffalo milk, the name of the food is accompanied by the phrase ''made with water buffalo milk''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', ''milkfat from water buffalo milk and nonfat water buffalo milk'' or ''nonfat water buffalo) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', ''milkfat from water buffalo milk and nonfat water buffalo milk'' or ''nonfat water buffalo milk and milkfat from water buffalo milk'', as appropriate.

[53 FR 3743, Feb. 9, 1988, as amended at 58 FR 2893, Jan. 6, 1993]

§ 133.157 Part-skim mozzarella and scamorza cheese.

Part-skim mozzarella cheese, part-skim scamorza cheese conforms to the definition and standard of identity as prescribed for mozzarella cheese by §133.155, except that its milk fat content, calculated on the solids basis, is less than 45 percent but not less than 30 percent.

§ 133.158 Low-moisture part-skim mozzarella and scamorza cheese.

Low-moisture part-skim mozzarella cheese and low-moisture part-skim scamorza cheese conform to the definition and standard of identity and comply with the requirements for label declaration of ingredients prescribed for low-moisture mozzarella cheese and low-moisture scamorza cheese by §133.156, except that their milkfat content, calculated on the solids basis, is less than 45 percent but not less than 30 percent.

[58 FR 2894, Jan. 6, 1993]

§ 133.160 Muenster and munster cheese.

(a) *Description.* (1) Muenster cheese, munster cheese, is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight

of the solids and the maximum moisture content is 46 percent by weight, as determined by the methods decribed in §133.5. The dairy ingredients used are pasteurized.

(2) The phenol equivalent of 0.25 gram of muenster cheese is not more than 3 micrograms, as determined by the methods described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a harmless lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. After coagulation the mass is divided into small portions, stirred, and heated, with or without dilution with water or salt brine, so as to promote and regulate the separation of whey and curd. The curd is transferred to forms permitting drainage of the whey. During drainage the curd may be pressed and turned. After drainage the curd is removed from the forms and is salted. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin used in curing or flavor development.

(iv) Antimycotic agents, the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(v) Vegetable oil, used as a coating for the rind.

(c) *Nomenclature.* The name of the food is ''muenster cheese'' or, alternatively, ''munster cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32057, Aug. 4, 1989; 54 FR 35756, Aug. 29, 1989, as amended at 58 FR 2894, Jan. 6, 1993]

§ 133.161 Muenster and munster cheese for manufacturing.

Muenster cheese for manufacturing conforms to the definition and standard of identity for muenster cheese prescribed by §133.160, except that the dairy ingredients are not pasteurized.

[54 FR 32057, Aug. 4, 1989]

§ 133.162 Neufchatel cheese.

(a) *Description.* (1) Neufchatel cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (a)(2) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The milkfat content is not less than 20 percent but less than 33 percent by weight of the finished food and the maximum moisture content is 65 percent by weight, as determined by the methods described in §133.5. The dairy ingredients used are pasteurized.

(2) One or more of the dairy ingredients specified in paragraph (b)(1) of this section is subjected to the action of a harmless lactic acid-producing bacterial culture, with or without one or more of the clotting enzymes specified in paragraph (b)(2) of this section. The mixture is held until the dairy ingredients coagulate. The coagulated mass may be warmed and stirred and it is drained. The moisture content may be adjusted with one of the optional ingredients in paragraph (b)(3)(ii) of this section. The curd may be pressed,

chilled, worked, and heated until it becomes fluid. It may then be homogenized or otherwise mixed. One or more of the dairy ingredients specified in paragraph (b)(1) of this section or the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Salt.

(ii) Cheese whey, concentrated cheese whey, dried cheese whey, or reconstituted cheese whey prepared by addition of water to concentrated cheese whey or dried cheese whey.

(iii) Stabilizers, in a total amount not to exceed 0.5 percent of the weight of the finished food, with or without the addition of dioctyl sodium sulfosuccinate in a maximum amount of 0.5 percent of the weight of the stabilizer(s) used.

(c) *Nomenclature.* The name of the food is ''neufchatel cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32057, Aug. 4, 1989, as amended at 58 FR 2894, Jan. 6, 1993]

§ 133.164 Nuworld cheese.

(a) *Description.* (1) Nuworld cheese is the food prepared by the procedure set forth in paragraph (a)(2) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It is characterized by the presence of creamy-white mold, a white mutant of *Penicillium roquefortii*, throughout the cheese. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 46 percent by weight, as determined by the methods described in §133.5. The dairy ingredients used may be pasteurized. Nuworld cheese is at least 60 days old.

(2) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed into forms permitting further drainage. While being placed in forms, spores of a white mutant of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd and it is held at a temperature of approximately 50 °F at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage, the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Blue or green color in an amount to neutralize the natural yellow color of the curd.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(c) *Nomenclature.* The name of the food is ''nuworld cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[54 FR 32058, Aug. 4, 1989, as amended at 58 FR 2894, Jan. 6, 1993]

§ 133.165 Parmesan and reggiano cheese.

(a) Parmesan cheese, reggiano cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by a granular texture and a hard and brittle rind. It grates readily. It contains not more than 32 percent of moisture, and its solids contain not less than 32 percent of milkfat, as determined by the methods prescribed in § 133.5 (a), (b), and (d). It is cured for not less than 10 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the milk, is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. The mass is cut into pieces no larger than wheat kernels, heated, and stirred until the temperature reaches between 115 °F and 125 °F. The curd is allowed to settle and is then removed from the kettle or vat, drained for a short time, placed in hoops, and pressed. The pressed curd is removed and salted in brine, or dry-salted. The cheese is cured in a cool, ventilated room. The rind of the cheese may be coated or colored. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of parmesan cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c)(1) For the purposes of this section, the word ''milk'' means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Safe and suitable antimycotic agent(s), the cumulative levels of which shall not exceed current good manufacturing practice may be added to the surface of the cheese.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 48 FR 49014, Oct. 24, 1983; 49 FR 10095, Mar. 19, 1984; 58 FR 2894, Jan. 6, 1993]

§ 133.167 Pasteurized blended cheese.

Pasteurized blended cheese conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese by § 133.169, except that:

(a) In mixtures of two or more cheeses, cream cheese or neufchatel cheese may be used.

(b) None of the ingredients prescribed or permitted for pasteurized process cheese by § 133.169 (c) and (d)(1) is used.

(c) In case of mixtures of two or more cheeses containing cream cheese or neufchatel cheese, the moisture content is not more than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity for the varieties of cheeses blended, for which such limits have been prescribed.

(d) The word ''process'' is replaced by the word ''blended'' in the name prescribed by § 133.169(e).

[42 FR 14366, Mar. 15, 1977, as amended at 58 FR 2894, Jan. 6, 1993]

§ 133.168 Pasteurized blended cheese with fruits, vegetables, or meats.

(a) Pasteurized blended cheese with fruits, vegetables, or meats, or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized blended cheese by § 133.167, except that:

(1) Its moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less, than the limits prescribed by § 133.167 for moisture and milk fat in the corresponding pasteurized blended cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 133.5(b) is not applicable.

(b) The name of a pasteurized blended cheese with fruits, vegetables, or meats is the name prescribed by § 133.167 for the applicable pasteurized blended cheese, followed by the term ''with _____'', the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1977; 58 FR 2894, Jan. 6, 1993]

§ 133.169 Pasteurized process cheese.

(a)(1) Pasteurized process cheese is the food prepared by comminuting and mixing, with the aid of heat, one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, lowfat cottage cheese, cottage cheese dry curd, cook cheese, hard grating cheese, semisoft part-skim cheese, part-skim spiced cheese, and skim milk cheese for manufacturing with an emulsifying agent prescribed by paragraph (c) of this section into a homogeneous plastic mass. One or more of the optional ingredients designated in paragraph (d) of this section may be used.

(2) During its preparation, pasteurized process cheese is heated for not less than 30 seconds at a temperature of not less than 150 °F. When tested for phosphatase by the method prescribed in § 133.5(c), the phenol equivalent of 0.25 gram of pasteurized process cheese is not more than 3 micrograms.

(3)(i) The moisture content of a pasteurized process cheese made from a single variety of cheese is not more than 1 percent greater than the maximum moisture content prescribed by the definition and standard of identity, if any there be, for the variety of cheese used; but in no case is more than 43 percent, except that the moisture content of pasteurized process washed curd cheese or pasteurized process colby cheese is not more than 40 percent; the moisture content of pasteurized process swiss cheese or pasteurized process gruyere cheese is not more than 44 percent; and the moisture content of pasteurized process limburger cheese is not more than 51 percent.

(ii) The fat content of the solids of a pasteurized process cheese made from a single variety of cheese is not less than the minimum prescribed by the definition and standard of identity, if any

there be, for the variety of cheese used, but in no case is less than 47 percent; except that the fat content of the solids of pasteurized process swiss cheese is not less than 43 percent, and the fat content of the solids of pasteurized process gruyere cheese is not less than 45 percent.

(4)(i) The moisture content of a pasteurized process cheese made from two or more varieties of cheese is not more than 1 percent greater than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used; but in no case is the moisture content more than 43 percent, except that the moisture content of a pasteurized process cheese made from two or more of the varieties cheddar cheese, washed curd cheese, colby cheese, and granular cheese is not more than 40 percent, and the moisture content of a mixture of swiss cheese and gruyere cheese is not more than 44 percent.

(ii) The fat content of the solids of a pasteurized process cheese made from two or more varieties of cheese is not less than the arithmetical average of the minimum fat contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of a pasteurized process gruyere cheese made from a mixture of swiss cheese and gruyere cheese is not less than 45 percent.

(5) Moisture and fat are determined by the methods prescribed in §133.5(a), (b), and (d).

(6) The weight of each variety of cheese in a pasteurized process cheese made from two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, or gorgonzola cheese is not less than 10 percent of the total weight of both, and the weight of limburger cheese is not less than 5 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese made from three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, or gorgonzola cheese is not less than 5 percent of the total weight of all, and the weight of limburger cheese is not less than 3 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese and granular cheese in mixtures which are designated as ''American cheese'' as prescribed in paragraph (e)(2)(ii) of this section. Such mixtures are considered as one variety of cheese for the purposes of this paragraph (a)(6).

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, muenster cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, muenster cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The emulsifying agent referred to in paragraph (a) of this section is one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium aluminum phosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of the pasteurized process cheese.

(d) The optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the pasteurized process cheese is not below 5.3.

(2) Cream, anhydrous milkfat, dehydrated cream, or any combination of two or more of these, in such quantity that the weight of the fat derived therefrom is less than 5 percent of the weight of the pasteurized process cheese.

(3) Water.

(4) Salt.

(5) Harmless artificial coloring.

(6) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.

(7) Pasteurized process cheese in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of not more than 0.2 percent by weight of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(8) Pasteurized process cheese in the form of slices or cuts in consumer-sized packages may contain lecithin as an optional anti-sticking agent in an amount not to exceed 0.03 percent by weight of the finished product.

(9) Safe and suitable enzyme modified cheese.

(e) The name of a pasteurized process cheese for which a definition and standard of identity is prescribed by this section is as follows:

(1) In case it is made from a single variety of cheese, its name is ''Pasteurized process _____ cheese'', the blank being filled in with the name of the variety of cheese used.

(2) In case it is made from two or more varieties of cheese, its name is ''Pasteurized process _____ and _____ cheese'', or ''Pasteurized process _____ blended with _____ cheese'', or ''Pasteurized process blend of _____ and _____ cheese'', the blanks being filled in with the names of the varieties of cheeses used, in order of predominance by weight; except that:

(i) In case it is made from gruyere cheese and swiss cheese, and the weight of gruyere cheese is not less than 25 percent of the weight of both, it may be designated ''Pasteurized process gruyere cheese''; and

(ii) In case it is made of cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these, it may be designated ''Pasteurized process American cheese''; or when cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these is combined with other varieties of cheese in the cheese ingredient, any of such cheeses or such mixture may be designated as ''American cheese''.

The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (g) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(f) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product.

(g) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as ''American cheese''.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 58 FR 2894, Jan. 6, 1993]

§ 133.170 Pasteurized process cheese with fruits, vegetables, or meats.

(a) Unless a definition and standard of identity specifically applicable is established by another section of this part, a pasteurized process cheese with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements

for label statement of ingredients, prescribed for pasteurized process cheese by §133.169, except that:

(1) Its moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less than the limits prescribed by §133.169 for moisture and fat in the corresponding pasteurized process cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by §133.5(b) is not applicable.

(b) The name of a pasteurized process cheese with fruits, vegetables, or meats is the name prescribed by §133.169 for the applicable pasteurized process cheese, followed by the term ''with _____'', the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 58 FR 2894, Jan. 6, 1993]

§133.171 Pasteurized process pimento cheese.

Pasteurized process pimento cheese is the food which conforms to the definition and standard of identity for pasteurized process cheese with fruits, vegetables, or meats, and is subject to the requirement for label statement of ingredients, except that:

(a) Its moisture content is not more than 41 percent, and the fat content of its solids is not less than 49 percent.

(b) The cheese ingredient is cheddar cheese, washed curd cheese, colby cheese, granular cheese or any mixture of two or more of these in any proportion.

(c) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, and granular cheese for manufacturing shall be considered as cheddar cheese, washed curd cheese, colby cheese, and granular cheese, respectively.

(d) The only fruit, vegetable, or meat ingredient is pimentos in such quantity that the weight of the solids thereof is not less than 0.2 percent of the weight of the finished pasteurized process pimento cheese.

(e) The optional ingredients designated in §133.169(b) and (d)(6) are not used.

[42 FR 14366, Mar. 15, 1977, as amended at 58 FR 2894, Jan. 6, 1993]

§133.173 Pasteurized process cheese food.

(a)(1) A pasteurized process cheese food is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, with one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (e) of this section may be used.

(2) During its preparation, a pasteurized process cheese food is heated for not less than 30 seconds, at a temperature of not less than 150 °F. When tested for phosphatase by the method prescribed in §133.5(c), the phenol equivalent of 0.25 gram of pasteurized process cheese food is not more than 3 micrograms.

(3) The moisture content of a pasteurized process cheese food is not more than 44 percent, and the fat content is not less than 23 percent.

(4) Moisture and fat are determined by the methods prescribed in §133.5(a) and (b), except that in determining moisture the loss in weight which occurs in drying for 5 hours, under the conditions prescribed in such method, is taken as the weight of the moisture.

(5) The weight of the cheese ingredient prescribed by paragraph (a)(1) of this section constitutes not less than 51 percent of the weight of the finished pasteurized process cheese food.

(6) The weight of each variety of cheese in a pasteurized process cheese food made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in a

pasteurized process cheese food made with three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as ''American cheese'' as prescribed in paragraph (h)(5) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, muenster cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, muenster cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese food may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim-milk cheese for manufacturing, and except that hard grating cheese, semisoft part skim cheese, and part-skim spiced cheese are not used alone or in combination with each other as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, albumin from cheese whey, and skim milk cheese for manufacturing.

(e) The other optional ingredients referred to in paragraph (a) of this section are:

(1) An emulsifying agent consisting of one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium aluminum phosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of the pasteurized process cheese food.

(2) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid in such quantity that the pH of the pasteurized process cheese food is not below 5.0.

(3) Water.

(4) Salt.

(5) Harmless artificial coloring.

(6) Spices or flavorings other than any which singly or in combination with other ingredients simulate the flavor of cheese of any age or variety.

(7) Pasteurized process cheese food in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of not more than 0.2 percent by weight of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(8) Pasteurized process cheese food in the form of slices or cuts in consumer-sized packages may contain lecithin as an optional anti-sticking agent in an amount not to exceed 0.03 percent by weight of the finished product.

(9) Safe and suitable enzyme modified cheese.

(f) The name of the food is ''Pasteurized process cheese food''. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in

paragraph (h) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(g) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice that characterizes the product.

(h) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as ''American cheese''.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 58 FR 2894, Jan. 6, 1993]

§ 133.174 Pasteurized process cheese food with fruits, vegetables, or meats.

(a) Pasteurized process cheese food with fruits, vegetables, or meats, or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese food by §133.173, except that:

(1) Its milk fat content is not less than 22 percent.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by §133.5(b) is not applicable.

(b) The name of a pasteurized process cheese food with fruits, vegetables, or meats is ''Pasteurized process cheese food with _____'', the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

(c) If the only vegetable ingredient is pimento, and no meat or fruit ingredient is used, the weight of the solids of such pimentos is not less than 0.2 percent of the weight of the finished food. The name of this food is ''Pimento pasteurized process cheese food'' or ''Pasteurized process pimento cheese food''.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 58 FR 2894, Jan. 6, 1993]

§ 133.175 Pasteurized cheese spread.

Pasteurized cheese spread is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese spread by §133.179, except that no emulsifying agent as prescribed by §133.179(e) is used.

[58 FR 2894, Jan. 6, 1993]

§ 133.176 Pasteurized cheese spread with fruits, vegetables, or meats.

(a) Pasteurized cheese spread with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized cheese spread by §133.175, except that:

(1) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(2) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by §133.5(b) is not applicable.

(b) The name of a pasteurized cheese spread with fruits, vegetables, or meats is ''Pasteurized cheese spread with _____'', the blank being filled in with the name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 58 FR 2894, Jan. 6, 1993]

§ 133.178 Pasteurized neufchatel cheese spread with other foods.

(a)(1) Pasteurized neufchatel cheese spread with other foods is the class of foods each of which is prepared by mixing, with the aid of heat, neufchatel cheese with one or a mixture of two or more properly prepared foods (except other cheeses), such as fresh, cooked, canned, or dried fruits or vegetables; cooked or canned meats; relishes, pickles or other foods suitable for blending with neufchatel cheese. It may contain one or any mixture of two or more of the optional ingredients named in paragraph (b) of this section. The amount of the added food or foods must be sufficient to so differentiate the blend that it does not simulate neufchatel cheese. It is spreadable at 70 °F.

(2) During its preparation the mixture is heated for not less than 30 seconds at a temperature of not less than 150 °F. When tested for phosphatase by the method prescribed in §133.5(c), the phenol equivalent of 0.25 gram of such food is not more than 3 micrograms.

(3)(i) No water other than that contained in the ingredients used is added to this food, but the moisture content in no case is more than 65 percent.

(ii) The milk fat is not less than 20 percent by weight of the finished food.

(b) The optional ingredients referred to in paragraph (a) of this section are:

(1)(i) One or any mixture of two or more of the following: Gum karaya, gum tragacanth, carob bean gum, gelatin, algin (sodium alginate), propylene glycol alginate, guar gum, sodium carboxymethylcellulose (cellulose gum), carrageenan, oat gum, or xanthan gum. The total quantity of any such substances, including that contained in the neufchatel cheese, is not more than 0.8 percent by weight of the finished food.

(ii) When one or more of the optional ingredients in paragraph (b)(1)(i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of §172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(2) Artificial coloring, unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(3) An acidifying agent consisting of one or a mixture of two or more of the following: A vinegar, acetic acid, lactic acid, citric acid, phosphoric acid.

(4) A sweetening agent consisting of one or a mixture of two or more of the following: Sugar, dextrose, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, hydrolyzed lactose.

(5) Cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, and albumin from cheese whey.

(c) The name of the food is ''pasteurized Neufchatel cheese spread with _____'' or ''pasteurized Neufchatel cheese spread and _____'', the blank being filled in with the common names of the foods added, in order of predominance by weight. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (d) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(d) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 58 FR 2894, Jan. 6, 1993]

§ 133.179 Pasteurized process cheese spread.

(a)(1) Pasteurized process cheese spread is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, with or without one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, with one or more of the emulsifying agents prescribed in paragraph (e) of this section, and with or

without one or more of the optional ingredients prescribed by paragraph (f) of this section, into a homogeneous plastic mass, which is spreadable at 70 °F.

(2) During its preparation, a pasteurized process cheese spread is heated for not less than 30 seconds at a temperature of not less than 150 °F. When tested for phosphatase by the method prescribed in §133.5(c), the phenol equivalent of 0.25 gram of pasteurized process cheese spread is not more than 3 micrograms.

(3) The moisture content of a pasteurized process cheese spread is more than 44 percent but not more than 60 percent, and the milk fat content is not less than 20 percent.

(4) Moisture and fat are determined by the methods prescribed in §133.5(a) and (b), except that in determining moisture the loss in weight which occurs in drying for 5 hours, under the conditions prescribed in such method, is taken as the weight of the moisture.

(5) The weight of the cheese ingredient referred to in paragraph (a)(1) of this section constitutes not less than 51 percent of the weight of the pasteurized process cheese spread.

(6) The weight of each variety of cheese in a pasteurized process cheese spread made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese spread made with three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, nuworld cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as ''American cheese'' as prescribed in paragraph (i)(5) of this section. Such mixtures are considered as one variety of cheese for the purposes of this paragraph (a)(6).

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, muenster cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, muenster cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese spread may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are one or more cheeses of the same or two or more varieties, except that skim-milk cheese for manufacturing may not be used, and except that cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, hard grating cheese, semisoft part-skim cheese, and part-skim spiced cheese are not used, alone or in combination with each other, as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are cream, milk, skim milk, buttermilk, cheese whey, any of the foregoing from which part of the water has been removed, anhydrous milkfat, dehydrated cream, albumin from cheese whey, and skim milk cheese for manufacturing.

(e) The emulsifying agents prescribed in paragraph (a) of this section are one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium aluminum phosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of the pasteurized process cheese spread.

(f) The other optional ingredients referred to in paragraph (a) of this section are:

(1)(i) One or any mixture of two or more of the following: Carob bean gum, gum karaya, gum tragacanth, guar gum, gelatin, sodium carboxymethylcellulose (cellulose gum), carrageenan, oat gum, algin (sodium alginate), propylene glycol alginate, or xanthan gum. The total weight of such substances is not more than 0.8 percent of the weight of the finished food.

(ii) When one or more of the optional ingredients in paragraph (f)(1)(i) of this section are used, dioctyl sodium sulfosuccinate complying with the requirements of §172.810 of this chapter may be used in a quantity not in excess of 0.5 percent by weight of such ingredients.

(2) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the pasteurized process cheese spread is not below 4.0.

(3) A sweetening agent consisting of one or any mixture of two or more of the following: Sugar, dextrose, corn sugar, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, and hydrolyzed lactose, in a quantity necessary for seasoning.

(4) Water.

(5) Salt.

(6) Harmless artificial coloring.

(7) Spices or flavorings other than any which singly or in combination with other ingredients simulates the flavor of a cheese of any age or variety.

(8) Pasteurized process cheese spread in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.2 percent by weight, calculated as sorbic acid or consisting of not more than 0.3 percent by weight of sodium propionate, calcium propionate, or a combination of sodium propionate and calcium propionate.

(9) Pasteurized process cheese spread in consumer-sized packages may contain lecithin as an optional anti-sticking agent in an amount not to exceed 0.03 percent by weight of the finished product.

(10) Safe and suitable enzyme modified cheese.

(11) Nisin preparation in an amount which results in not more than 250 parts per million nisin in the food.

(g) The name of the food is ''pasteurized process cheese spread''. The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. Wherever any word or statement emphasizing the name of any ingredient appears on the label (other than in an ingredient statement as specified in paragraph (i) of this section) so conspicuously as to be easily seen under customary conditions of purchase, the full name of the food shall immediately and conspicuously precede or follow such word or statement in type of at least the same size as the type used in such word or statement.

(h) The name of the food shall include a declaration of any flavoring, including smoke and substances prepared by condensing or precipitating wood smoke, that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice that characterizes the product.

(i) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as ''American cheese''.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 54 FR 6121, Feb. 8, 1989; 54 FR 22741, May 26, 1989; 58 FR 2895, Jan. 6, 1993]

§ 133.180 Pasteurized process cheese spread with fruits, vegetables, or meats.

(a) Pasteurized process cheese spread with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese spread by §133.179, except that:

(1) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked,

canned, or dried vegetable; any properly prepared cooked or canned meat.

(2) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by §133.5(b) is not applicable.

(b) The name of a pasteurized process cheese spread with fruits, vegetables, or meats is ''Pasteurized process cheese spread with _____'', the blank being filled in with the name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 58 FR 2895, Jan. 6, 1993]

§ 133.181 Provolone cheese.

(a) *Description.* (1) Provolone, a pasta filata or stretched curd-type cheese, is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other method which produces a finished cheese having the same physical and chemical properties. It has a stringy texture. The minimum milkfat content is 45 percent by weight of the solids, as determined by the methods described in §133.5 and the maximum moisture content is 45 percent by weight. If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35 °F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of provolone cheese is not more than 3 micrograms as determined by the method described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be bleached, warmed, and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut, stirred, and heated so as to promote and regulate the separation of whey from the curd. The whey is drained off, and the curd is matted and cut, immersed in hot water, and kneaded and stretched until it is smooth and free from lumps. Antimycotics may be added to the curd during the kneading and stretching process. Then it is cut and molded. During the molding the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is then firmed by immersion in cold water, salted in brine, and dried. It is given some additional curing. Provolone cheese may be smoked, and one or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Blue or green color in an amount to neutralize the natural yellow color of the curd.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Safe and suitable antimycotic agent(s), the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the cheese during the kneading and stretching process and/or applied to the surface of the cheese.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(c) *Nomenclature.* (1) The name of the food is ''provolone cheese''. The name of the food may include the common name of the shape of the cheese, such as ''salami provolone''.

(2) One of the following terms, in letters not less than one-half the height of the letters used in the name of the food, shall accompany the name of the food wherever it appears on the principal display panel or panels:

(i) ''Smoked'' if the food has been smoked.

(ii) ''Not smoked'' if the food has not been smoked.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[48 FR 2745, Jan. 21, 1983, as amended at 48 FR 49014, Oct. 24, 1983; 58 FR 2895, Jan. 6, 1993]

§ 133.182 Soft ripened cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are soft ripened cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. Their solids contain not less than 50 percent of milkfat, as determined by the methods prescribed in §133.5(a), (b), and (d). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35 °F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: Cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It is cured under conditions suitable for development of biological curing agents on the surface of the cheese, and the curing is conducted so that the cheese cures from the surface toward the center. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of soft ripened cheeses may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word ''milk'' means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water, in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction.

(d) The name of each soft ripened cheese for which a definition and standard of identity is prescribed by this section is ''Soft ripened cheese'', preceded or followed by:

(1) The specific common or usual name of such soft ripened cheese, if any

such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement ''made from _____'', the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10095, Mar. 19, 1984; 58 FR 2895, Jan. 6, 1993]

§ 133.183 Romano cheese.

(a) Romano cheese is the food prepared from cow's milk or sheep's milk or goat's milk or mixtures of two or all of these and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It grates readily, and has a granular texture and a hard and brittle rind. It contains not more than 34 percent of moisture, and its solids contain not less than 38 percent of milkfat, as determined by the methods prescribed in § 133.5(a), (b), and (d). It is cured for not less than 5 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to be a semisolid mass. The mass is cut into particles no larger than corn kernels, stirred, and heated to a temperature of about 120 °F. The curd is allowed to settle to the bottom of the kettle or vat, and is then removed and drained for a short time, packed in forms or hoops, and pressed. The pressed curd is salted by immersing in brine for about 24 hours and is then removed from the brine and the surface allowed to dry. It is then alternately rubbed with salt and washed at intervals. It may be perforated with needles. It is finally drycured. During curing it is turned and scraped. The surface may be rubbed with vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of romano cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c)(1) For the purposes of this section, the word ''milk'' means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk bleached, and the weight of the potassium alum, calcium, sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, sufficient vitamin A is added to the curd to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(d) Safe and suitable antimycotic agent(s), the cumulative levels of which shall not exceed current good manufacturing practice, may be added to the surface of the cheese.

(e) When romano cheese is made solely from cow's milk, the name of such cheese is ''Romano cheese made from cow's milk'', and may be preceded by the word ''Vaccino'' (or ''Vacchino''); when made solely from sheep's milk, the name is ''Romano cheese made from sheep's milk'', and may be preceded by the word ''Pecorino''; when made solely from goat's milk, the name is ''Romano cheese made from goat's milk'', and may be preceded by the word ''Caprino''; and when a mixture of two or all of the milks specified in this section is used, the name of the cheese is ''Romano cheese made from _____'', the blank being filled in with the names of the milks used, in order of predominance by weight.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) When milk other than cow's milk is used, in whole or in part, the common or usual name of each such milk ingredient shall be declared in order of predominance by weight; and

(2) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''.

[42 FR 14366, Mar. 15, 1977, as amended at 48 FR 49014, Oct. 24, 1983; 49 FR 10095, Mar. 19, 1984; 58 FR 2895, Jan. 6, 1993]

§ 133.184 Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk.

(a) *Description.* (1) Roquefort cheese, sheep's milk blue-mold cheese, blue-mold cheese from sheep's milk, is the food prepared by the procedure set forth in paragraph (a)(2) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It is characterized by the presence of bluish-green mold, *Penicillium roquefortii*, throughout the cheese. The minimum milkfat content is 50 percent by weight of the solids and the maximum moisture content is 45 percent by weight, as determined by the methods described in § 133.5. The dairy ingredients used may be pasteurized. Roquefort cheese is at least 60 days old.

(2) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed into forms permitting further drainage. While being placed in forms, spores of the mold *Penicillium roquefortii* are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd and it is held at a temperature of approximately 50 °F at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage, the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Operational ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Forms of milk, nonfat milk, or cream, as defined in § 133.3, of sheep origin, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(c) *Nomenclature.* The name of the food is ''roquefort cheese'', or alternatively, ''sheep's milk blue-mold cheese'' or ''blue-mold cheese from sheep's milk.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat from sheep's milk and nonfat sheep's milk'' or ''nonfat sheep's milk and milkfat from sheep's milk'', as appropriate.

[54 FR 32058, Aug. 4, 1989, as amended at 58 FR 2895, Jan. 6, 1993]

§ 133.185 Samsoe cheese.

(a) *Description.* (1) Samsoe cheese is the food prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. It has a small amount of eye formation of approximately uniform size of about five-sixteenths inch (8 millimeters). The minimum milkfat content is 45 percent by weight of the solids and the maximum moisture content is 41 percent by weight, as determined by the methods described in § 133.5. The dairy ingredients used may be pasteurized. Samsoe cheese is cured at not less than 35 °F for at least 60 days.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of samsoe cheese is not more than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately three-eighths inch (1 centimeter). The mass is stirred and heated to about 102 °F, and so handled by further stirring, heating, dilution with water, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage, the curd is pressed. After drainage, the curd is removed from the forms and is further salted by immersing in a concentrated salt solution for about 3 days. The curd is then cured at a temperature of from 60° to 70 °F for 3 to 5 weeks to obtain the desired eye formation. Further curing is conducted at a lower temperature. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* The name of the food is ''samsoe cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[48 FR 2745, Jan. 21, 1983; 48 FR 11426, Mar. 18, 1983, as amended at 58 FR 2895, Jan. 6, 1993]

§ 133.186 Sap sago cheese.

(a) *Description.* (1) Sap sago cheese is the food prepared by the procedure set forth in paragraph (a)(2) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The cheese is pale green in color and has the shape of a truncated cone. The

maximum moisture content is 38 percent by weight, as determined by the method described in §133.5. Sap sago cheese is not less than 5 months old.

(2) One or more of the dairy ingredients specified in paragraph (b)(1) of this section is allowed to become sour, and is heated to boiling temperature, with stirring. Sufficient sour whey is added to precipitate the casein. The curd is removed, spread out in boxes, and pressed, and while under pressure is allowed to drain and ferment. It is ripened for not less than 5 weeks. The ripened curd is dried and ground; salt and dried clover of the species *Melilotus coerulea* are added. The mixture is shaped into truncated cones and ripened. The optional ingredient in paragraph (b)(2) of this section may be added during this procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Nonfat milk, as defined in §133.3.

(2) *Other optional ingredients.* Buttermilk.

(c) *Nonmenclature.* The name of the food is ''sap sago cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[54 FR 32058, Aug. 4, 1989, as amended at 58 FR 2895, Jan. 6, 1993]

§ 133.187 Semisoft cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are semisoft cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain more than 39 percent, but not more than 50 percent, of moisture, and their solids contain not less than 50 percent of milkfat, as determined by the methods prescribed in §133.5 (a), (b), and (d). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35 °F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft cheese may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word ''milk'' means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom, or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143 °F for a period of not less than 30 minutes, or

for a time and at a temperature equivalent thereto in phosphatase destruction. A semisoft cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 5 micrograms when tested by the method prescribed in §133.5(c).

(d) Semisoft cheeses in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) The name of each semisoft cheese for which a definition and standard of identity is prescribed by this section is ''Semisoft cheese'', preceded or followed by:

(1) The specific common or usual name of such semisoft cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(f)(1) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement ''made from _____'', the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(2) If semisoft cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement ''_____ added to retard mold growth'' or ''_____ added as a preservative'', the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10096, Mar. 19, 1984; 58 FR 2895, Jan. 6, 1993]

§ 133.188 Semisoft part-skim cheeses.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are semisoft part-skim cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from partly skimmed milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 50 percent of moisture, and their solids contain not less than 45 percent, but less than 50 percent, of milkfat, as determined by the methods set forth in §133.5 (a), (b), and (d). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35 °F, for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: Cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and it may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner

to promote the growth of biological curing agents. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft part-skim cheese may be added in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word ''milk'' means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. A semisoft part-skim cheese shall be deemed not to have been made from pasteurized milk if 0.25 gram shows a phenol equivalent of more than 5 micrograms when tested by the method prescribed in § 133.5(c).

(d) Semisoft part-skim cheeses in the form of slices or cuts in consumer-sized packages may contain an optional mold-inhibiting ingredient consisting of sorbic acid, potassium sorbate, sodium sorbate, or any combination of two or more of these, in an amount not to exceed 0.3 percent by weight, calculated as sorbic acid.

(e) The name of each semisoft part-skim cheese for which a definition and standard of identity is prescribed by this section is ''Semisoft part-skim cheese,'' preceded or followed by:

(1) The specific common or usual name of such semisoft cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(f)(1) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement ''made from _____'', the blank being filled in with the name or names of the milk used, in order of predominance by weight.

(2) If semi-soft part-skim cheese in sliced or cut form contains an optional mold-inhibiting ingredient as specified in paragraph (d) of this section, the label shall bear the statement ''_____ added to retard mold growth'' or ''_____ added as a preservative'', the blank being filled in with the common name or names of the mold-inhibiting ingredient or ingredients used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by this section, showing the optional ingredient used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(g) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14366, Mar. 19, 1977, as amended at 49 FR 10096, Mar. 19, 1984; 58 FR 2895, Jan. 6, 1993]

§ 133.189 Skim milk cheese for manufacturing.

(a) Skim milk cheese for manufacturing is the food prepared from skim milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 50 percent of moisture, as determined by the method prescribed in § 133.5 (a). It is coated with blue-colored paraffin or other tightly adhering coating, colored blue.

(b) Skim milk or the optional dairy ingredients specified in paragraph (c)

of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, or both, with or without purified calcium chloride in a quantity not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the skim milk, is added to set the skim milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. Proteins from the whey may be incorporated. The mass is cut into slabs which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by pouring or sprinkling water over them, with free and continuous drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is salted, stirred, further drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of skim milk cheese for manufacturing may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) The optional dairy ingredients referred to in paragraph (b) of this section are: Skim milk or concentrated skim milk or nonfat dry milk or a mixture of any two or more of these, with water in a quantity not in excess of that sufficient to reconstitute any concentrated skim milk or nonfat dry milk used.

(d) For the purposes of this section, ''skim milk'' means cow's milk from which the milk fat has been separated.

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14366, Mar. 15, 1977, as amended at 49 FR 10096, Mar. 19, 1984; 58 FR 2895, Jan. 6, 1993]

§ 133.190 Spiced cheeses.

(a) *Description.* (1) Spiced cheeses are cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. The food is prepared by the procedure set forth in paragraph (a)(3) of this section or by any other procedure which produces a finished cheese having the same physical and chemical properties. The minimum milkfat content is 50 percent by weight of the solids, as determined by the method described in §133.5. The food contains spices, in a minimum amount of 0.015 ounce per pound of cheese, and may contain spice oils. If the dairy ingredients are not pasteurized, the cheese is cured at a temperature of not less than 35 °F for at least 60 days.

(2) The phenol equivalent of 0.25 gram of spiced cheese is not more than 3 micrograms, as determined by the method described in §133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be warmed and is subjected to the action of a harmless lactic acid-producing bacterial culture. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is divided into smaller portions and so handled by stirring, heating, and diluting with water or salt brine as to promote and regulate the separation of whey and curd. The whey is drained off. The curd is removed and may be further drained. The curd is then shaped into forms, and may be pressed. At some time during the procedure, spices are added so as to be evenly distributed throughout the finished cheese. One or more of the other optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in §133.3, or

corresponding products of goat or sheep origin, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the dairy ingredients, used as a coagulation aid.

(iii) Salt.

(iv) Spice oils which do not, alone or in combination with other ingredients, simulate the flavor of cheese of any age or variety.

(v) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(vi) Antimycotic agents, applied to the surface of slices or cuts in consumer-sized packages.

(c) *Nomenclature.* The name of the food is ''spiced cheese''. The following terms shall accompany the name of the food, as appropriate:

(1) The specific common or usual name of the spiced cheese, if any such name has become generally recognized; or

(2) An arbitrary or fanciful name that is not false or misleading in any particular.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', or ''milkfat from goat's milk and nonfat goat's milk'', etc., as appropriate.

[54 FR 32059, Aug. 4, 1989, as amended at 58 FR 2895, Jan. 6, 1993]

§ 133.191 Part-skim spiced cheeses.

Part-skim spiced cheeses conform to the definition and standard of identity, and are subject to the requirements for label statement of ingredients prescribed for spiced cheeses by § 133.190, except that their solids contain less than 50 percent, but not less than 20 percent, of milkfat.

[58 FR 2895, Jan. 6, 1993]

§ 133.193 Spiced, flavored standardized cheeses.

(a) Except as otherwise provided for herein and in applicable sections in this part, a spiced or flavored standardized cheese conforms to the applicable definitions, standard of identity and requirements for label statement of ingredients prescribed for that specific natural cheese variety promulgated pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act. In addition a spiced and/or flavored standardized cheese shall contain one or more safe and suitable spices and/or flavorings, in such proportions as are reasonably required to accomplish their intended effect: *Provided*, That, no combination of ingredients shall be used to simulate the flavor of cheese of any age or variety.

(b) The name of a spiced or flavored standardized cheese shall include in addition to the varietal name of the natural cheese, a declaration of any flavor and/or spice that characterizes the food, in the manner prescribed in § 101.22 of this chapter.

[42 FR 14366, Mar. 15, 1977, as amended at 58 FR 2895, Jan. 6, 1993]

§ 133.195 Swiss and emmentaler cheese.

(a) *Description.* (1) Swiss cheese, emmentaler cheese, is the food prepared by the procedure set forth in paragraph (a)(3) of this section, or by any other procedure which produces a finished cheese having the same physical and chemical properties. It has holes or eyes developed throughout the cheese. The minimum milkfat content is 43 percent by weight of the solids and the maximum moisture content is 41 percent by weight, as determined by the methods described in § 133.5. The dairy ingredients used may be pasteurized. Swiss cheese is at least 60 days old.

(2) If pasteurized dairy ingredients are used, the phenol equivalent value of 0.25 gram of swiss cheese is not more

than 3 micrograms as determined by the method described in § 133.5.

(3) One or more of the dairy ingredients specified in paragraph (b)(1) of this section may be bleached, warmed, or treated with hydrogen peroxide/catalase, and is subjected to the action of lactic acid-producing and propionic acid-producing bacterial cultures. One or more of the clotting enzymes specified in paragraph (b)(2) of this section is added to set the dairy ingredients to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126 °F. Stirring is continued until the curd becomes firm. The acidity of the whey at this point, calculated as lactic acid, does not exceed 0.13 percent. The curd is transferred to hoops or forms and pressed until the desired shape and firmness are obtained. The cheese is then salted by immersing it in a saturated salt solution for about 3 days. It is then held at a temperature of about 50° to 60 °F. for a period of 5 to 10 days, after which it is held at a temperature of about 75 °F. until it is approximately 30 days old, or until the so-called eyes form. Salt, or a solution of salt in water, is added to the surface of the cheese at some time during the curing process. The cheese is then stored at a lower temperature for further curing. One or more of the optional ingredients specified in paragraph (b)(3) of this section may be added during the procedure.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) *Dairy ingredients.* Milk, nonfat milk, or cream, as defined in § 133.3, used alone or in combination.

(2) *Clotting enzymes.* Rennet and/or other clotting enzymes of animal, plant, or microbial origin.

(3) *Other optional ingredients.* (i) Coloring.

(ii) Calcium chloride in an amount not more than 0.02 percent (calculated as anhydrous calcium chloride) by weight of the dairy ingredients, used as a coagulation aid.

(iii) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(iv) Antimycotic agents, the cumulative levels of which shall not exceed good manufacturing practice, may be added to the surface of the cheese.

(v) Benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate used to bleach the dairy ingredients. The weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(vi) Hydrogen peroxide, followed by a sufficient quantity of catalase preparation to eliminate the hydrogen peroxide. The weight of the hydrogen peroxide shall not exceed 0.05 percent of the weight of the milk and the weight of the catalase shall not exceed 20 parts per million of the weight of the milk treated.

(c) *Nomenclature.* The name of the food is ''swiss cheese'', or alternatively, ''emmentaler cheese''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) Enzymes of animal, plant, or microbial origin may be declared as ''enzymes''; and

(2) The dairy ingredients may be declared, in descending order of predominance, by the use of the terms ''milkfat and nonfat milk'' or ''nonfat milk and milkfat'', as appropriate.

[48 FR 2746, Jan. 21, 1983; 48 FR 11426, Mar. 18, 1983, as amended at 55 FR 6795, Feb. 27, 1990; 58 FR 2895, Jan. 6, 1993]

§ 133.196 Swiss cheese for manufacturing.

Swiss cheese for manufacturing conforms to the definition and standard of identity prescribed for swiss cheese by § 133.195, except that the holes, or eyes, have not developed throughout the entire cheese.

[55 FR 6795, Feb. 27, 1990]

PART 135—FROZEN DESSERTS

Subpart A—General Provisions

Subpart B—Requirements for Specific Standardized Frozen Desserts

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

Subpart A—General Provisions

§ 135.3 Definitions.

For the purposes of this part, a pasteurized mix is one in which every particle of the mix has been heated in properly operated equipment to one of the temperatures specified in the table in this section and held continuously at or above that temperature for the specified time (or other time/temperature relationship which has been demonstrated to be equivalent thereto in microbial destruction):

Temperature	Time
155 °F	30 min.
175 °F	25 sec.

[42 FR 19132, Apr. 12, 1977]

Subpart B—Requirements for Specific Standardized Frozen Desserts

§ 135.110 Ice cream and frozen custard.

(a) *Description.* (1) Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, one or more of the optional hydrolyzed milk proteins as provided for in paragraph (d) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. Ice cream is sweetened with safe and suitable sweeteners and may be characterized by the addition of flavoring ingredients.

(2) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Ice cream contains not less than 10 percent milkfat, nor less than 10 percent nonfat milk solids, except that when it contains milkfat at 1 percent increments above the 10 percent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

Percent milkfat	Minimum percent nonfat milk solids
10	10
11	9
12	8
13	7
14	6

Except that when one or more bulky flavors are used, the weights of milkfat and total milk solids are not less than 10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of the bulky flavors from the weight of the finished food; but in no case is the weight of milkfat or total milk solids less than 8 percent and 16 percent, respectively, of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard shall contain 1.4 percent egg yolk solids by weight of the finished food: *Provided, however,* That when bulky flavors are added the egg yolk solids content of frozen custard may be reduced in proportion to the amount by weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12 percent. A product containing egg yolk solids in excess of 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (e)(1) of this section.

(3) When calculating the minimum amount of milkfat and nonfat milk solids required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream; dried cream; plastic cream (sometimes known as concentrated milkfat); butter; butter oil; milk; concentrated milk; evaporated milk; sweetened condensed milk; superheated condensed milk; dried milk; skim milk; concentrated skim milk; evaporated skim milk; condensed skim milk; superheated condensed skim milk; sweetened condensed skim milk; sweetened condensed part-skim milk; nonfat dry milk; sweet cream buttermilk; condensed sweet cream buttermilk; dried sweet cream buttermilk; skim milk, that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure; skim milk in concentrated or dried form that has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate; and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term ''milk'' as used in this section means cow's milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. The modified skim milk, when adjusted with water to a total solids content of 9 percent, is substantially free of lactic acid as determined by titration with 0.1*N* NaOH, and it has a Ph value in the range of 8.0 to 8.3.

(c) *Optional caseinates.* The optional caseinates referred to in paragraph (a) of this section that may be added to ice cream mix containing not less than 20 percent total milk solids are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.

(d) *Optional hydrolyzed milk proteins.* One or more of the optional hydrolyzed milk proteins referred to in paragraph (a) of this section may be added as stabilizers at a level not to exceed 3 percent by weight of ice cream mix containing not less that 20 percent total milk solids, provided that any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. Further, when hydrolyzed milk proteins are used in the food, the declaration of these ingredients on the food label shall comply with the requirements of §102.22 of this chapter.

(e) *Methods of analysis.* The fat content shall be determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), sections 16.287 and 16.059, under ''Fat, Roese-Gottlieb Method—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(f) *Nomenclature.* (1) The name of the food is ''ice cream''; except that when

the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is ''frozen custard'' or ''french ice cream'' or ''french custard ice cream''.

(2)(i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., ''vanilla'', in letters not less than one-half the height of the letters used in the words ''ice cream''.

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words ''ice cream'', followed by the word ''flavored'', in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., ''Vanilla flavored'', or ''Peach flavored'', or ''Vanilla flavored and Strawberry flavored''.

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words ''ice cream'', preceded by ''artificial'' or ''artificially flavored'', in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., ''artificial Vanilla'', or ''artifically flavored Strawberry'' or ''artificially flavored Vanilla and artificially flavored Strawberry''.

(3)(i) If the food is subject to the requirements of paragraph (f)(2)(ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words ''artificial flavor added'' or ''artificial _____ flavor added'', the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: *Provided, however*, That where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: *And provided further*, That if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., ''Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added''.

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., ''strawberry and artificial strawberry flavor''.

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used

is greater than 1 ounce per unit of vanilla constituent, as that term is defined in §169.3(c) of this chapter.

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e)(5) (ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be ''artificially flavored banana-almond ice cream''. However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be ''banana-almond flavored ice cream''.

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., ''Neapolitan'' ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.

(7) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term ''ice cream'' but in any case no smaller than one-sixteenth of an inch. If the food purports to be or is represented for special dietary use, it shall bear labeling in accordance with the requirements of part 105 of this chapter.

(g) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that the sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms ''milkfat and nonfat milk'' when one or any combination of two or more of the ingredients listed in §101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used or, alternatively, as permitted in §101.4 of this chapter. Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by §101.22(c) or (k) of this chapter. Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

[43 FR 4598, Feb. 3, 1978, as amended at 45 FR 63838, Sept. 26, 1980; 46 FR 44433, Sept. 4, 1981; 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2896, Jan. 6, 1993; 59 FR 47079, Sept. 14, 1994; 63 FR 14035, Mar. 24, 1998; 63 FR 14818, Mar. 27, 1998]

§135.115 Goat's milk ice cream.

(a) *Description.* Goat's milk ice cream is the food prepared in the same manner prescribed in §135.110 for ice cream, and complies with all the provisions of §135.110, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this section; caseinates and hydrolyzed milk proteins may not be used; and paragraphs (f)(1) and (g) of §135.110 shall not apply.

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are goat's skim milk, goat's milk, and goat's cream. These optional dairy ingredients may be used in liquid, concentrated, and/or dry form.

(c) *Nomenclature.* (1) The name of the food is ''goat's milk ice cream'' or, alternatively, ''ice cream made with goat's milk'', except that when the egg yolk solids content of the food is in excess of that specified for ice cream in paragraph (a) of §135.110, the name of

the food is ''goat's milk frozen custard'' or, alternatively, ''frozen custard made with goat's milk'', or ''goat's milk french ice cream'', or, alternatively, ''french ice cream made with goat's milk'', or ''goat's milk french custard ice cream'', or, alternatively, ''french custard ice cream made with goat's milk''.

(2) Until September 14, 1998, when safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term ''goat's milk ice cream'' but in any case no smaller than one-sixteenth of an inch. If the food purports to be or is represented for special dietary use, it shall bear labeling in accordance with the requirements of part 105 of this chapter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[47 FR 41526, Sept. 21, 1982, as amended at 58 FR 2896, Jan. 6, 1993; 59 FR 47080, Sept. 14, 1994]

§ 135.130 Mellorine.

(a) *Description.* (1) Mellorine is a food produced by freezing, while stirring, a pasteurized mix consisting of safe and suitable ingredients including, but not limited to, milk-derived nonfat solids and animal or vegetable fat, or both, only part of which may be milkfat. Mellorine is sweetened with nutritive carbohydrate sweetener and is characterized by the addition of flavoring ingredients.

(2) Mellorine contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Mellorine contains not less than 6 percent fat and 2.7 percent protein having a protein efficiency ratio (PER) not less than that of whole milk protein (108 percent of casein) by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. In no case shall the fat content of the finished food be less than 4.8 percent or the protein content be less than 2.2 percent. The protein to meet the minimum protein requirements shall be provided by milk solids, not fat and/or other milk-derived ingredients.

(3) When calculating the minimum amount of milkfat and protein required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) *Fortification.* Vitamin A is present in a quantity which will ensure that 40 international units (IU) are available for each gram of fat in mellorine, within limits of good manufacturing practice.

(c) *Methods of analysis.* Fat and protein content, and the PER shall be determined by following the methods contained in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Fat content shall be determined by the method: ''Fat, Roese-Gottlieb Method—Official Final Action,'' section 16.287.

(2) Protein content shall be determined by one of the following methods: ''Nitrogen—Official Final Action,'' Kjeldahl Method, section 16.285, or Dye Binding Method, section 16.286.

(3) PER shall be determined by the method: ''Biological Evaluation of Protein Quality—Official Final Action,'' sections 43.212–43.216.

(d) *Nomenclature.* The name of the food is ''mellorine''. The name of the food on the label shall be accompanied by a declaration indicating the presence of characterizing flavoring in the same manner as is specified in §135.110(c).

(e) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of the terms ''milkfat and nonfat milk'' when one or any combination of two or more of the ingredients listed in §101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used, or alternatively as permitted in §101.4 of this chapter.

[42 FR 19137, Apr. 12, 1977, as amended at 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2896, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§135.140 Sherbet.

(a) *Description.* (1) Sherbet is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. Sherbet is sweetened with nutritive carbohydrate sweeteners and is characterized by the addition of one or more of the characterizing fruit ingredients specified in paragraph (d) of this section or one or more of the nonfruit-characterizing ingredients specified in paragraph (e) of this section.

(2) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 percent nor more than 2 percent, the nonfat milk-derived solids content not less than 1 percent, and the total milk or milk-derived solids content is not less than 2 percent nor more than 5 percent by weight of the finished food. Sherbet that is characterized by a fruit ingredient shall have a titratable acidity, calculated as lactic acid, of not less than 0.35 percent.

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream (sometimes known as concentrated milkfat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent calculated as lactic acid. The term ''milk'' as used in this section means cow's milk.

(c) *Optional caseinates.* The optional caseinates referred to in paragraph (a) of this section which may be added to sherbet mix are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali, such caseinates are not considered to be milk solids.

(d) *Optional fruit-characterizing ingredients.* The optional fruit-characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other

optional ingredients. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated. In the case of concentrated fruit or fruit juices, from which part of the water is removed, substances contributing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would have been obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 percent in the case of citrus sherbets, 6 percent in the case of berry sherbets, and 10 percent in the case of sherbets prepared with other fruits. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.

(e) *Optional nonfruit characterizing ingredients.* The optimal nonfruit characterizing ingredients referred to in paragraph (a) of this section include but are not limited to the following:

(1) Ground spice or infusion of coffee or tea.

(2) Chocolate or cocoa, including sirup.

(3) Confectionery.

(4) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the sherbet.

(5) Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).

(f) *Nomenclature.* (1) The name of each sherbet is as follows:

(i) The name of each fruit sherbet is ''_____ sherbet'', the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

(ii) The name of each nonfruit sherbet is ''_____ sherbet'', the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, ''peppermint'', except that if the characterizing flavor used is vanilla, the name of the food is ''_____ sherbet'', the blank being filled in as specified by § 135.110(e)(2) and (5)(i).

(2) When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they shall be named on the label as follows:

(i) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation shall be ''artificially flavored''.

(ii) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be ''artificial and natural flavoring added''.

(iii) The label shall designate artificial coloring by the statement ''artificially colored'', ''artificial coloring added'', ''with added artificial coloring'', or ''_____, an artificial color added'', the blank being filled in with the name of the artificial coloring used.

(g) *Characterizing flavor(s).* Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statment required by paragraph (f)(2)(i) and (ii) of this section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word ''sherbet'' may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon,

and not less than 12-point on packages containing 1 gallon or over.

(h) *Display of statements required by paragraph* (f)(2). Except as specified in paragraph (g) of this section, the statements required by paragraph (f)(2) of this section shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(i) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[43 FR 4599, Feb. 3, 1978, as amended at 46 FR 44434, Sept. 4, 1981; 58 FR 2896, Jan. 6, 1993]

§ 135.160 Water ices.

(a) *Description.* Water ices are the foods each of which is prepared from the same ingredients and in the same manner prescribed in §135.140 for sherbets, except that the mix need not be pasteurized, and complies with all the provisions of §135.140 (including the requirements for label statement of ingredients), except that no milk or milk-derived ingredient and no egg ingredient, other than egg white, is used.

(b) *Nomenclature.* The name of the food is ''_____ ice'', the blank being filled in, in the same manner as specified in §135.140(f)(1) (i) and (ii), as appropriate.

[42 FR 19132, Apr. 12, 1977, as amended 58 FR 2876, Jan. 6, 1993]

PART 136—BAKERY PRODUCTS

Subpart A—General Provisions

Sec.

Subpart B—Requirements for Specific Standardized Bakery Products

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

Subpart A—General Provisions

§ 136.3 Definitions.

For purposes of this part, the following definitions apply:

(a) The word *bread* when used in the name of the food means the unit weighs one-half pound or more after cooling.

(b) The words *rolls* and *buns* when used in the name of the food mean the unit weighs less than one-half pound after cooling.

Subpart B—Requirements for Specific Standardized Bakery Products

§ 136.110 Bread, rolls, and buns.

(a) Bread, white bread, and rolls, white rolls, or buns, and white buns are the foods produced by baking mixed yeast-leavened dough prepared from one or more of the farinaceous ingredients listed in paragraph (c)(1) of this section and one or more of the moistening ingredients listed in paragraphs (c) (2), (6), (7), and (8) of this section and one or more of the leavening agents provided for by paragraph (c)(3) of this section. The food may contain additional ingredients as provided for by paragraph (c) of this section. Each of the finished foods contains not less than 62 percent total solids as determined by the method prescribed in paragraph (d) of this section.

(b) All ingredients from which the food is fabricated shall be safe and suitable.

(c) The following optional ingredients are provided for:

(1) Flour, bromated flour, phosphated flour, or a combination of two or more of these. The potassium bromate in any bromated flour used and the monocalcium phosphate in any phosphated flour used are deemed to be additional optional ingredients in the bread, rolls, or buns. All ingredients in any flour, bromated flour, or phosphated flour used are deemed to be optional ingredients of the bread, rolls, or buns prepared therefrom.

(2) Water.

(3) Yeast—any type which produces the necessary leavening effect.

(4) Salt.

(5) Shortening, in which or in conjunction with which may be used one or any combination of two or more of the following:

(i) Lecithin, hydroxylated lecithin complying with the provisions of part 172 of this chapter, either of which may include related phosphatides derived from the corn oil or soybean oil from which such ingredients were obtained.

(ii) Mono- and diglycerides of fat-forming fatty acids, diacetyl tartaric acid esters of mono- and diglycerides of fat-forming fatty acids, propylene glycol mono- and diesters of fat-forming fatty acids, and other ingredients that perform a similar function.

(6) Milk and/or other dairy products in such quantity and composition as not to meet the requirements for milk and/or other dairy products prescribed for milk bread by §136.130. Whenever nonfat milk solids in any form are used, carrageenan or salts of carrageenan complying with the provisions of part 172 of this chapter may be used in a quantity not in excess of 0.8 percent by weight of such nonfat milk solids.

(7) Egg products.

(8) Nutritive carbohydrate sweeteners.

(9) Enzyme active preparations.

(10) Lactic-acid-producing bacteria.

(11) Nonwheat flours, nonwheat meals, nonwheat grits, wheat and nonwheat starches, any of which may be wholly or in part dextrinized, dextrinized wheat flour, or any combination of 2 or more of these, if the total quantity is not more than 3 parts for each 100 parts by weight of flour used.

(12) Ground dehulled soybeans which may be heat-treated, and from which oil may be removed, but which retain enzymatic activity, if the quantity is not more than 0.5 part for each 100 parts by weight of flour used.

(13) Yeast nutrients and calcium salts, if the total quantity of such ingredients, with the exception of monocalcium phosphate and calcium propionate, is not more than 0.25 part for each 100 parts by weight of flour used. The quantity of monocalcium phosphate, including any quantity in the flour used, is not more than 0.75 part for each 100 parts by weight of flour used. Any calcium propionate used as a preservative in bread, rolls, or buns is not subject to the limitation prescribed in this paragraph.

(14)(i) Potassium bromate, calcium bromate, potassium iodate, calcium iodate, calcium peroxide, or any combination of 2 or more of these if the total quantity, including the potassium bromate in any bromated flour used, is not more than 0.0075 part for each 100 parts by weight of flour used.

(ii) Azodicarbonamide, if the total quantity, including any quantity in the flour used, is not more than 0.0045 part for each 100 parts by weight of flour used.

(15) Dough strengtheners and other dough conditioners not listed or referred to in this paragraph, if the total quantities of such ingredients or combination is not more than 0.5 part for each 100 parts by weight of flour used.

(16) Spices, spice oil, and spice extract.

(17) Coloring may not be added as such or as part of another ingredient except as permitted by paragraph (c)(16) of this section and except that coloring which may be present in butter or margarine if the intensity of the butter or margarine color does not exceed ''medium high'' (MH) when viewed under diffused light (7400 Kelvin) against the Munsell Butter Color Comparator. The MH designation corresponds to the Munsell renotation of 3.8Y7.9/7.6.

(18) Other ingredients that do not change the basic identity or adversely affect the physical and nutritional characteristics of the food.

(d) Total solids are determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 14.091(a), which is incorporated by reference, except that if the baked unit weighs 454 grams (1 pound) or more, one entire unit is used for the determination; if the baked unit weighs less than 454 grams, enough units to weigh 454 grams or more are used. Copies of the material incorporated by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and

Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(e)(1) The name of the food is ''bread'', ''white bread'', ''rolls'', ''white rolls'', ''buns'', ''white buns'', as applicable. When the food contains not less than 2.56 percent by weight of whole egg solids, the name of the food may be ''egg bread'', ''egg rolls'', or ''egg buns'', as applicable, accompanied by the statement ''Contains ____ medium-sized egg(s) per pound'' in the manner prescribed by §102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but not greater than the amount actually present. For the purpose of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any nonegg solids which may be present in standardized and other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids.

(2) When the label bears any representation, other than in the ingredient listing, of the presence of egg in the food, e.g., the word egg or any phonetic equivalent spelling of the word egg, or a picture of an egg, the food shall contain not less than 2.56 percent of whole egg solids.

(f) *Label declaration*. Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14400, Mar. 15, 1977, as amended at 43 FR 47177, Oct. 13, 1978; 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 49 FR 13692, Apr. 6, 1984; 54 FR 24894, June 12, 1989; 58 FR 2877, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 136.115 Enriched bread, rolls, and buns.

(a) Each of the foods enriched bread, enriched rolls, and enriched buns conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for bread, rolls or buns by §136.110, except that:

(1) Each such food contains in each pound 1.8 milligrams of thiamin, 1.1 milligrams of riboflavin, 15 milligrams of niacin, 0.43 milligrams of folic acid, and 12.5 milligrams of iron.

(2) Each such food may contain added calcium in such quantity that the total calcium content is 600 milligrams per pound. If insufficient calcium is added to meet the 600-milligram level per pound of the finished food, no claim may be made on the label for calcium as a nutrient except as a part of nutrition labeling.

(3) The requirements of paragraphs (a) (1) and (2) of this section will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to ensure that the required levels of the vitamins and minerals are maintained throughout the expected shelf life of the food under customary conditions of distribution and storage. The quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Vitamin	Reference form		
	Name	Empirical formula	Molecular weight
Thiamine ...	Thiamine chloride hydrochloride.	$C_{12}H_{17}ClN_4OS{\cdot}HCl$	337.28
Riboflavin ..	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Niacin	$C_6H_5NO_2$	123.11

(4) Each such food may also contain wheat germ or partly defatted wheat germ, but the total quantity thereof, including any wheat germ or partly defatted wheat germ in any enriched flour used, shall not be more than 5 percent of the flour ingredient.

(5) Enriched flour may be used, in whole or in part, instead of flour. As used in this section, the term ''enriched flour'' includes enriched bromated flour.

(6) The limitation prescribed by §136.110(c)(6) on the quantity and composition of milk and/or other dairy products does not apply.

(7) The vitamins and minerals added to the food for enrichment purposes

may be supplied by any safe and suitable substances. Niacin equivalents as derived from tryptophan content shall not be used in determining total niacin content.

(b) The name of the food is ''enriched bread'', ''enriched rolls'', or ''enriched buns'', as applicable. When the food contains not less than 2.56 percent by weight of whole egg solids, the name of the food may be ''enriched egg bread'', ''enriched egg rolls'', or ''enriched egg buns'', as applicable, accompanied by the statement ''Contains __ medium-sized egg(s) per pound'' in the manner prescribed by §102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but not greater than the amount actually present. For the purpose of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any non-egg solids which may be present in standardized and other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids. When the food complies with the requirements for milk and/or other dairy products content in §136.130 for milk bread, the name of the food may be ''enriched milk bread'', ''enriched milk rolls'', or ''enriched milk buns'', as applicable. When the food complies with the requirements for both enriched egg bread and enriched milk bread in this section, the name of the food may be ''enriched milk and egg bread'', ''enriched milk and egg rolls'', or ''enriched milk and egg buns'', as applicable accompanied by the statement ''Contains __ medium-sized egg(s) per pound'' in the manner prescribed by §102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but no greater than the amount actually present. For purposes of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any non-egg solids which may be present in standardized or other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids.

[42 FR 14400, Mar. 15, 1977, as amended at 43 FR 38578, Aug. 29, 1978; 46 FR 43413, Aug. 28, 1981; 61 FR 8796, Mar. 5, 1996; 61 FR 14245, Apr. 1, 1996]

§ 136.130 Milk bread, rolls, and buns.

(a) Each of the foods milk bread, milk rolls, and milk buns conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for bread, rolls or buns by §136.110 except that:

(1) The only moistening ingredient permitted in the preparation of the dough is milk or, as an alternative, a combination of dairy products in such a proportion that the weight of the nonfat milk solids is not more than 2.3 times and not less than 1.2 times the weight of the milkfat therein, with or without water, in a quantity that provides not less than 8.2 parts milk solids for each 100 parts by weight of flour.

(2) No buttermilk, buttermilk product, cheese whey, cheese whey product, or milk protein is used.

(b) The name of the food is ''milk bread'', ''milk rolls'', ''milk buns'', as applicable.

§ 136.160 Raisin bread, rolls, and buns.

(a) Each of the foods raisin bread, raisin rolls, and raisin buns conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for bread, rolls or buns by §136.110, except that:

(1) Not less than 50 parts by weight of seeded or seedless raisins are used for each 100 parts by weight of flour used.

(2) Water extract of raisins may be used, but not to replace raisins.

(3) The baked units may bear icing or frosting.

(4) The limitation prescribed by §136.110(c)(6) on the quantity and composition of milk and/or other dairy products does not apply.

(5) The total solids are determined by the method prescribed in §136.110(d), except that section 14.091(b) of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference, will apply. Copies

may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) The name of the food is ''raisin bread'', ''raisin rolls'', ''raisin buns'', as applicable. When the food contains not less than 2.56 percent by weight of whole egg solids, the name of the food may be ''raisin and egg bread'', ''raisin and egg rolls'', or ''raisin and egg buns'', as applicable, accompanied by the statement ''Contains __ medium-sized egg(s) per pound'' in the manner prescribed by §102.5(c)(3) of this chapter, the blank to be filled in with the number which represents the whole egg content of the food expressed to the nearest one-fifth egg but not greater than the amount actually present. For purposes of this regulation, whole egg solids are the edible contents of eggs calculated on a moisture-free basis and exclusive of any nonegg solids which may be present in standardized and other commercial egg products. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids.

[42 FR 14400, Mar. 15, 1977, as amended at 47 FR 11826, Mar. 19, 1982; 49 FR 10096, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

§ 136.180 Whole wheat bread, rolls, and buns.

(a) Each of the foods whole wheat bread, graham bread, entire wheat bread, whole wheat rolls, graham rolls, entire wheat rolls, whole wheat buns, graham buns, and entire wheat buns conforms to the definition and standard of identity and is subject to the label statement of ingredients prescribed for bread, rolls and buns by §136.110, except that:

(1) The dough is made from the optional ingredient whole wheat flour, bromated whole wheat flour, or a combination of these. No flour, bromated flour, or phosphated flour is used. The potassium bromate in any bromated whole wheat flour used is deemed to be an additional optional ingredient in the whole wheat bread, whole wheat rolls, or whole wheat buns.

(2) The limitation prescribed by §136.110(c)(6) on the quantity and composition of milk and/or other dairy products does not apply.

(b) The name of the food is ''whole wheat bread'', ''graham bread'', ''entire wheat bread'', ''whole wheat rolls'', ''graham rolls'', ''entire wheat rolls'', ''whole wheat buns'', ''graham buns'', ''entire wheat buns'', as applicable.

PART 137—CEREAL FLOURS AND RELATED PRODUCTS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Cereal Flours and Related Products

Sec.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14402, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 137 appear at 63 FR 14035, Mar. 24, 1998.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Cereal Flours and Related Products

§ 137.105 Flour.

(a) Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.75 percent. Harmless preparations of α-amylase obtained from *Aspergillus oryzae*, alone or in a safe and suitable carrier, may be used. When tested for granulation as prescribed in paragraph (c)(4) of this section, not less than 98 percent of the flour passes through a cloth having openings not larger than those of woven wire cloth designated ''212 μm (No. 70)'' complying with the specifications for such cloth set forth in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The flour is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than the sum of 1/20 of the percent of protein therein, calculated to a moisture-free basis, plus 0.35. Its moisture content is not more than 15 percent. It may contain ascorbic acid in a quantity not to exceed 200 parts per million as a dough conditioner. Unless such addition conceals damage or inferiority or makes the flour appear to be better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching or, in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect:

(1) Oxides of nitrogen.

(2) Chlorine.

(3) Nitrosyl chloride.

(4) Chlorine dioxide.

(5) One part by weight of benzoyl peroxide mixed with not more than six parts by weight of one or any mixture of two or more of the following: potassium alum, calcium sulfate, magnesium carbonate, sodium aluminum sulfate, dicalcium phosphate, tricalcium phosphate, starch, calcium carbonate.

(6) Acetone peroxides complying with the provisions of § 172.802 of this chapter.

(7) Azodicarbonamide (complying with the requirements of § 172.806 of this chapter, including the quantitative limit of not more than 45 parts per million).

(b)(1) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2) When ascorbic acid is added, the label shall bear the statement ''Ascorbic acid added as a dough conditioner''. When the optional ingredient α-amylase obtained from *Aspergillus oryzae*'' is used, it may alternatively be declared in the list of ingredients as ''Fungal *alpha*-amylase,'' ''Fungal α-amylase'', ''Enzyme'', or ''Enzyme added for improved baking''. When any optional bleaching ingredient is used, the label shall bear the word ''Bleached''. Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word ''Bleached'' shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trademark or brand, other written, printed, or graphic matter, which is also a part of such trademark or brand, may so intervene if the word

''Bleached'' is in such juxtaposition with such trademark or brand as to be conspicuoulsy related to such name.

(c) For the purposes of this section:

(1) Ash is determined by the method prescribed in the AOAC, 13th Ed. (1980), section 14.006, ''Direct Method—Official Final Action,'' under the heading ''Ash (5),'' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a) of this section. Ash is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of ash, and multiplying the quotient by 100.

(2) Protein is 5.7 times the nitrogen as determined by the method prescribed in section 2.057, ''Improved Kjeldahl Methods for Nitrate-Free Samples (20)—Official Final Action,'' AOAC, 13th Ed. (1980), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a) of this section. Protein is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of protein, and multiplying the quotient by 100.

(3) Moisture is determined by the method prescribed in the AOAC, 13th Ed. (1980), sections 14.002 and 14.003, ''Vacuum Oven Method (2)—Official Final Action,'' under the heading ''Total Solids Moisture, Indirect Method,'' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a) of this section.

(4) Granulation is determined as follows: Use No. 70 sieve complying with the specifications for ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)'' prescribed in paragraph (a) of this section. Attach bottom pan to sieve in Ro-Tap sifter (or an equivalent sifter). Place half of a rubber ball or other sieving aid in the sieve. Pour 100 grams of the sample in the sieve and turn on the sifter with knocker. Sift exactly 5 minutes. Weigh the residue on the No. 70 sieve and convert to percentage.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11827, Mar. 19, 1982; 47 FR 24693, June 8, 1982; 47 FR 43363, Oct. 1, 1982; 49 FR 10097, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2877, Jan. 6, 1993]

§ 137.155 Bromated flour.

Bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for flour by § 137.105, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished bromated flour, and is added only to flours whose baking qualities are improved by such addition.

[57 FR 2877, Jan. 6, 1993]

§ 137.160 Enriched bromated flour.

Enriched bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for enriched flour by § 137.165, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished enriched bromated flour, and is added only to enriched flours whose baking qualities are improved by such addition.

[58 FR 2877, Jan. 6, 1993]

§ 137.165 Enriched flour.

Enriched flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for flour by § 137.105, except that:

(a) It contains in each pound 2.9 milligrams of thiamin, 1.8 milligrams of riboflavin, 24 milligrams of niacin, 0.7 milligrams of folic acid, and 20 milligrams of iron.

(b) It may contain added calcium in such quantity that the total calcium content is 960 milligrams per pound. Enriched flour may be acidified with monocalcium phosphate within the limits prescribed by § 137.175 for phosphated flour, but, if insufficient additional calcium is present to meet the 960 milligram level, no claim may

be made on the label for calcium as a nutrient;

(c) The requirement of paragraphs (a) and (b) of this section will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to insure that the required levels of the vitamins and minerals are maintained throughout the expected shelf life of the food under customary conditions of distribution and storage. The quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Vitamin	Reference form		
	Name	Empirical formula	Molecular weight
Thiamine ...	Thiamine chloride hydrochloride.	$C_{12}H_{17}ClN_4OS{\cdot}HCl$	337.28
Riboflavin ..	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Niacin	$C_6H_5NO_2$	123.11

(d) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

(e) In determining whether the ash content complies with the requirements of this section, ash resulting from any added iron or salts of iron or calcium or wheat germ is excluded in calculating ash content.

(f) All ingredients from which the food is fabricated shall be safe and suitable. The vitamins and minerals added to the food for enrichment purposes may be supplied by any safe and suitable substance. Niacin equivalents as derived from tryptophan content shall not be used in determining total niacin content.

[42 FR 14402, Mar. 15, 1977, as amended at 43 FR 38578, Aug. 29, 1978; 46 FR 43414, Aug. 28, 1981; 58 FR 2877, Jan. 6, 1993; 61 FR 8796, Mar. 5, 1996]

§ 137.170 Instantized flours.

(a) Instantized flours, instant blending flours, and quick-mixing flours, are the foods each of which conforms to the definition and standard of identity and is subject to the requirement for label statement of ingredients prescribed for the corresponding kind of flour by §§ 137.105, 137.155, 137.160, 137.165, 137.175, 137.180, and 137.185, except that each such flour has been made by one of the optional procedures set forth in paragraph (b) of this section, and is thereby made readily pourable. Such flours will all pass through a No. 20 mesh U.S. standard sieve (840-micron opening), and not more than 20 percent will pass through a 200 mesh U.S standard sieve (74-micron opening).

(b) The optional procedures referred to in paragraph (a) of this section are:

(1) A selective grinding and bolting procedure or other milling procedure, whereby controlled techniques are used to obtain a food too fine to meet the granulation specification prescribed in § 137.300(a) for farina.

(2) An agglomerating procedure, whereby flour that originally meets the granulation specification prescribed in § 137.105(a) has been modified by further processing, so that a number of the individual flour particles have been combined into agglomerates conforming to the granulation specifications set out in paragraph (a) of this section.

(c) The name of each product covered by this section is the name prescribed by the definition and standard of identity for the corresponding kind of flour as referred to in paragraph (a) of this section, preceded immediately and conspicuously by the words ''Instantized'', ''Instant blending'', or ''Quick-mixing''.

[42 FR 14402, Mar. 15, 1977, as amended at 58 FR 2877, Jan. 6, 1993]

§ 137.175 Phosphated flour.

Phosphated flour, phosphated white flour, and phosphated wheat flour, conform to the definition and standard of identity, and are subject to the requirements for label declaration of ingredients, prescribed for flour by § 137.105, except that:

(a) Monocalcium phosphate is added in a quantity not less than 0.25 percent and not more than 0.75 percent of the weight of the finished phosphated flour; and

(b) In determining whether the ash content complies with the requirements of this section allowance is

made for the added monocalcium phosphate.

[42 FR 14402, Mar. 15, 1977, as amended at 58 FR 2877, Jan. 6, 1993]

§ 137.180 Self-rising flour.

(a) Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and one or more of the acid-reacting substances monocalcium phosphate, sodium acid pyrophosphate, and sodium aluminum phosphate. It is seasoned with salt. When it is tested by the method prescribed in paragraph (c) of this section not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used. Subject to the conditions and restrictions prescribed by §137.105(a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient used therein (see §137.105(a)) is also an optional ingredient of the self-rising flour.

(b) *Label declaration.* Each of the ingredients used in the food, shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(c) The method referred to in paragraph (a) of this section is the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), section 8.002, ''Reagent (Displacement soln.),'' and section 8.003, ''Chittick apparatus,'' under the heading ''Total Carbon Dioxide (1)—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*The following procedure is substituted for the procedure specified in the AOAC, under section 8.004, ''Determination'':

(1) Weigh 17 grams of the official sample into flask A, add 15–20 glass beads (4–6 mm. diameter), and connect this flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1–2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1 + 5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of mL of gas evolved by the factor given in section 52.007, ''Correction factors for gasometric determination of carbon dioxide,'' AOAC, 13th Ed. (1980), which is incorporated by reference (the availability of this incorporation by reference is given in paragraph (c) of this section), for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

(2) Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by

the same method in the same apparatus.

(3) Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U.S.P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

(4) Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

(5) Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11827, Mar. 19, 1982; 49 FR 10097, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2877, Jan. 6, 1993]

§ 137.185 Enriched self-rising flour.

Enriched self-rising flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for self-rising flour by § 137.180, except that:

(a) It contains in each pound 2.9 milligrams of thiamin, 1.8 milligrams of riboflavin, 24 milligrams of niacin, 0.7 milligrams of folic acid, and 20 milligrams of iron.

(b) It contains added calcium in such quantity that the total calcium content is 960 milligrams per pound. If a calcium compound is added for technical purposes to give self-rising characteristics to the flour, the amount of calcium per pound of flour may exceed 960 milligrams provided that the excess is no greater than necessary to accomplish the intended effect. However, if such calcium is insufficient to meet the 960-milligram level, no claim may be made on the label for calcium as a nutrient.

(c) The requirements of paragraphs (a) and (b) of this section will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to insure that the required levels of the vitamins and minerals are maintained throughout the expected shelf life of the food under customary conditions of distribution and storage. The quantitative content of the following vitamins shall be calculated in terms of the following chemically identifiable reference forms:

Vitamin	Referemce form		
	Name	Empirical formula	Molecular weight
Thiamine ...	Thiamine chloride hydrochloride.	$C_{12}H_{17}ClN_4OS{\cdot}HCl$	337.28
Riboflavin ..	Riboflavin	$C_{17}H_{20}N_4O_6$	376.37
Niacin	Niacin	$C_6H_5NO_2$	123.11

(d) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

(e) When calcium is added as dicalcium phosphate, such dicalcium phosphate is also considered to be an acid-reacting substance;

(f) When calcium is added as carbonate, the method set forth in § 137.180(c) does not apply as a test for carbon dioxide evolved; but in such case the quantity of carbon dioxide evolved under ordinary conditions of use of the enriched self-rising flour is not less than 0.5 percent of the weight thereof;

(g) All ingredients from which the food is fabricated shall be safe and suitable. The vitamins and minerals added to the food for enrichment purposes may be supplied by any safe and suitable substances. Niacin equivalents as derived from tryptophan content shall not be used in determining total niacin content.

[42 FR 14402, Mar. 15, 1977, as amended at 43 FR 38578, Aug. 29, 1978; 46 FR 43414, Aug. 28, 1981; 58 FR 2877, Jan. 6, 1993; 61 FR 8796, Mar. 5, 1996]

§ 137.190 Cracked wheat.

Cracked wheat is the food prepared by so cracking or cutting into angular fragments cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 137.200(c)(2), not less than 90 percent passes through a No. 8 sieve and not more than 20 percent passes through a No. 20 sieve. The proportions

of the natural constituents of such wheat, other than moisture, remain unaltered. Cracked wheat contains not more than 15 percent of the moisture as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 7.002 under ''Preparation of Sample—Official Final Action,'' and section 7.003 under ''Moisture—Official Final Action. I. Drying in Vacuo at 95–100° (2),'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11827, Mar. 19, 1982; 49 FR 10097, Mar. 19, 1984; 54 FR 24894, June 12, 1989]

§ 137.195 Crushed wheat.

Crushed wheat, coarse ground wheat, is the food prepared by so crushing cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 137.200(c)(2), 40 percent or more passes through a No. 8 sieve and less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 7.002 under ''Preparation of Sample—Official Final Action,'' and section 7.003 under ''Moisture—Official Final Action. I. Drying in Vacuo at 95–100° (2),'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11827, Mar. 19, 1982; 49 FR 10097, Mar. 19, 1984; 54 FR 24894, June 12, 1989]

§ 137.200 Whole wheat flour.

(a) Whole wheat flour, graham flour, entire wheat flour is the food prepared by so grinding cleaned wheat, other than durum wheat and red durum wheat, that when tested by the method prescribed in paragraph (c)(2) of this section, not less than 90 percent passes through a 2.36 mm (No. 8) sieve and not less than 50 percent passes through a 850 μm (No. 20) sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.75 percent. It may contain harmless preparations of α-amylase obtained from *Aspergillus oryzae*, alone or in a safe and suitable carrier. The moisture content of whole wheat flour is not more than 15 percent. It may contain ascorbic acid in a quantity not to exceed 200 parts per million as a dough conditioner. Unless such addition conceals damage or inferiority or makes the whole wheat flour appear to be better or of greater value than it is, the optional bleaching ingredient azodicarbonamide (complying with the requirements of § 172.806 of this chapter, including the quantitative limit of not more than 45 parts per million) or chlorine dioxide, or chlorine, or a mixture of nitrosyl chloride and chlorine, may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

(b)(1) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2) When ascorbic acid is added, the label shall bear the statement ''Ascorbic acid added as a dough conditioner''. When the optional ingredient ''α''-amylase obtained from *Aspergillus oryzae*'' is used, it may alternatively be declared in the list of ingredients as

''Fungal *alpha*-amylase,'' ''Fungal α-amylase'', ''Enzyme'', or ''Enzyme added for improved baking''. When any optional bleaching ingredient is used, the label shall bear the word ''Bleached''. Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word ''Bleached'' shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trademark or brand, other written, printed or graphic matter, which is also a part of such trademark or brand, may so intervene if the word ''Bleached'' is in such juxtaposition with such trademark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:

(1) Moisture is determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), section 14.002. ''Vacuum Oven Method—Official Final Action,'' and section 14.003, ''Determination,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full-height frames, complying with the specifications set forth in the AOAC, Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 gm. of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11827, Mar. 19, 1982; 47 FR 24693, June 8, 1982; 47 FR 43364, Oct. 1, 1982; 49 FR 10097, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2877, Jan. 6, 1993]

§ 137.205 Bromated whole wheat flour.

Bromated whole wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for whole wheat flour by § 137.200, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.

[58 FR 2877, Jan. 6, 1993]

§ 137.211 White corn flour.

(a) White corn flour is the food prepared by so grinding and bolting cleaned white corn that when tested by the method prescribed in paragraph (b)(2) of this section, not less than 98 percent passes through a No. 50 sieve and not less than 50 percent passes through No. 70 woven-wire cloth. Its moisture content is not more than 15 percent. In its preparation, part of the ground corn may be removed, but in any such case, the content (on a moisture-free basis) of neither the crude fiber nor fat in the finished white corn flour exceeds the content (on a moisture-free basis) of such substance in the cleaned corn from which it was ground.

(b)(1) For the purpose of this section, moisture, fat, and crude fiber are determined by methods therefore referred to in § 137.250(b)(1).

(2) The method referred to in paragraph (a) of this section is as follows: Weigh 5 grams of sample into a tared truncated metal cone (top diameter 5 centimeters, bottom diameter 2 centimeters, height 4 centimeters), fitted at

bottom with 70-mesh wire cloth complying with the specifications for No. 70 wire cloth in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.Attach cone to a suction flask. Wash with 150 ml. of petroleum ether applied in a small stream without suction, while gently stirring the sample with a small glass rod. Apply suction for 2 minutes after washing is completed, then shake the cone for 2 minutes with a vigorous horizontal motion, striking the side against the hand, and then weigh. The decrease in weight of sample, calculated as percent by weight of sample shall be considered the percent passing through No. 70 wire cloth. Transfer the residue from cone to a No. 50 sieve having a standard 20.3 centimeter (8-inch) diameter full-height frame, complying with the specifications for wire cloth and sieve frame in ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series).'' Shake for 2 minutes with a vigorous horizontal motion, striking the side against the hand; remove and weigh the residue; calculate the weight of residue as percent by weight of sample, and subtract from 100 percent to obtain the percent of sample passing through the No. 50 sieve.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11827, Mar. 19, 1982; 49 FR 10098, Mar. 19, 1984; 54 FR 24894, June 12, 1989]

§ 137.215 Yellow corn flour.

Yellow corn flour conforms to the definition and standard of identity prescribed by § 137.211 for white corn flour except that cleaned yellow corn is used instead of clean white corn.

§ 137.220 Durum flour.

(a) Durum flour is the food prepared by grinding and bolting cleaned durum wheat. When tested for granulation as prescribed in § 137.105(c)(4), not less than 98 percent of such flour passes through the No. 70 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 1.5 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section, ash, moisture, and granulation are determined by the methods prescribed in § 137.105(c).

§ 137.225 Whole durum flour.

Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for whole wheat flour by § 137.200, except that cleaned durum wheat, instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.

[58 FR 2877, Jan. 6, 1993]

§ 137.250 White corn meal.

(a) White corn meal is the food prepared by so grinding cleaned white corn that when tested by the method prescribed in paragraph (b)(2) of this section not less than 95 percent passes through a No. 12 sieve, not less than 45 percent through a No. 25 sieve, but not more than 35 percent through a No. 72 grits gauze. Its moisture content is not more than 15 percent. In its preparation coarse particles of the ground corn may be separated and discarded, or reground and recombined with all or part of the material from which they were separated, but in any such case the crude fiber content of the finished corn meal is not less than 1.2 percent and not more than that of the cleaned corn from which it was ground, and its fat content does not differ more than 0.3 percent from that of such corn. The contents of crude fiber and fat in all the foregoing provisions relating thereto are on a moisture-free basis.

(b)(1) For the purposes of this section, moisture, fat, and crude fiber content will be determined by the following methods of analysis from ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference (copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*):

(i) Moisture content—sections 14.062 and 14.063 (Official Final Action).

(ii) Fat content—sections 14.062 and 14.067 (Official Final Action).

(iii) Crude fiber content—sections 14.062 and 14.065 (Official Final Action).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 12 and No. 25 sieves, having standard 20.3 centimeter (8-inch) diameter full-height frames, complying with the specifications for wire cloth and sieve frames in ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)'' prescribed in §137.105(a), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* A sieve with frame of the same dimensions as the Nos. 12 and 25 and fitted with 72 XXX grits gauze is used as the third sieve. It is referred to hereafter as the No. 72 sieve. The 72 XXX grits gauze has openings equivalent in size with those of No. 70 woven-wire cloth, complying with specifications for such cloth contained in such ''Standard Specifications for Sieves.'' Attach bottom pan to No. 72 sieve. Fit the No. 25 sieve into the No. 72 sieve and the No. 12 sieve into the No. 25 sieve. Pour 100 grams of sample into the No. 12 sieve, attach cover and hold the assembly in a slightly inclined position and shake the assembly of sieves by striking the sides against one hand with an upward stroke, at the rate of about 150 times per minute. Turn the assembly of sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh separately the material remaining on each sieve and in the pan, and calculate each weight as percent of sample. Sometimes when meals are tested, fine particles clog the sieve openings. If any sieve is clogged by fine material smaller than its openings, empty the contents onto a piece of paper. Remove the entrapped material on the bottom of the sieve by a hair brush and add to the sieve below. In like manner, clean the adhering material from inside the sieve and add to the material on the paper. Return mixture on the paper to the sieve, reassemble the sieves, and shake in the same manner as before for 1 minute. Repeat cleaning procedure if necessary until a 5-gram or less loss in weight occurs in any sieve during a 1-minute shaking. The percent of sample passing through No. 12 sieve shall be determined by subtracting from 100 percent, the percent of material remaining on the No. 12 sieve. The percent passing through a No. 25 sieve shall be determined by adding the percents remaining on the No. 72 sieve and the percent in pan. The percent in the pan shall be considered as the percent passing through a No. 72 XXX grits gauze.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11828, Mar. 19, 1982; 49 FR 10098, Mar. 19, 1984; 54 FR 24894, June 12, 1989]

§ 137.255 Bolted white corn meal.

(a) Bolted white corn meal is the food prepared by so grinding and sifting cleaned white corn that:

(1) Its crude fiber content is less than 1.2 percent but its fat content is not less than 2.25 percent; and

(2) When tested by the method prescribed in §137.250(b)(2), except that a No. 20 standard sieve is used instead of the No. 12 sieve, not less than 95 percent passes through a No. 20 sieve, not less than 45 percent through a No. 25 sieve, but not more than 25 percent

through No. 72 XXX grits gauze. Its moisture content is not more than 15 percent. In its preparation particles of ground corn which contain germ may be separated, reground, and recombined with all or part of the material from which it was separated, but in any such case the fat content of the finished bolted white corn meal does not exceed by more than 0.3 percent the fat content of the cleaned corn from which it was ground. The contents of crude fiber and fat in all the foregoing provisions relating thereto are on a moisture-free basis.

(b) For the purposes of this section, moisture, fat and crude fiber are determined by the methods therefor referred to in §137.250(b)(1).

§ 137.260 Enriched corn meals.

(a) Enriched corn meals are the foods, each of which conforms to the definition and standard of identity prescribed for a kind of corn meal by §§137.250, 137.255, 137.265, 137.270, 137.275, 137.280, 137.285, and 137.290, except that:

(1) It contains in each pound not less than 2.0 milligrams (mg) and not more than 3.0 mg of thiamin, not less than 1.2 mg and not more than 1.8 mg of riboflavin, not less than 16 mg and not more than 24 mg of niacin or niacinamide, not less than 0.7 mg and not more than 1.0 mg of folic acid, and not less than 13 mg and not more than 26 mg of iron (Fe);

(2) It may contain in each pound not less than 250 U.S.P. units and not more than 1,000 U.S.P. units of vitamin D; and

(3) It may contain in each pound not less than 500 milligrams and not more than 750 milligrams of calcium (Ca); *Provided, however,* That enriched self-rising corn meals shall contain in each pound not more than 1,750 milligrams of calcium (Ca). Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in this paragraph (a)(3) and in paragraphs (a) (1) and (2) of this section may be added in a harmless carrier which does not impair the enriched corn meal; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the kind of corn meal used. Dried yeast in quantities not exceeding 1.5 percent by weight of the finished food may be used.

(b) The name of each kind of enriched corn meal is the word ''Enriched'' followed by the name of the kind of corn meal used which is prescribed in the definition and standard of identity therefor.

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14402, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993; 61 FR 8796, Mar. 5, 1996]

§ 137.265 Degerminated white corn meal.

(a) Degerminated white corn meal, degermed white corn meal, is the food prepared by grinding cleaned white corn and removing bran and germ so that:

(1) On a moisture-free basis, its crude fiber content is less than 1.2 percent and its fat content is less than 2.25 percent; and

(2) When tested by the method prescribed in §137.250(b)(2), except that a No. 20 standard sieve is used instead of a No. 12 sieve, not less than 95 percent passes through a No. 20 sieve, not less than 45 percent through a No. 25 sieve, but not more than 25 percent through No. 72 XXX grits gauze. Its moisture content is not more than 15 percent.

(b) For the purposes of this section, moisture, fat and crude fiber are determined by methods therefor referred to in §137.250(b)(1).

§ 137.270 Self-rising white corn meal.

(a) Self-rising white corn meal is an intimate mixture of white corn meal, sodium bicarbonate, and one or both of the acid-reacting substances monocalcium phosphate and sodium aluminum phosphate. It is seasoned with salt. When it is tested by the method prescribed in paragraph (b) of this section, not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of white corn meal used.

(b) The method referred to in paragraph (a) of this section is the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), section 8.002, ''Reagent (Displacement soln.),'' and section 8.003, ''Chittick apparatus,'' under the heading ''Total Carbon Dioxide (1)—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The following procedure is substituted for the procedure specified in the AOAC, under section 8.004, ''Determination'':

(1) Weigh 17 grams of the official sample into flask *A*, add 15–20 glass beads (4–6 mm. diameter), and connect this flask with the apparatus (fig. 25). Open stopcock *C* and by means of the leveling bulk *E* bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1–2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette *F* 45 cc. of sulfuric acid (1 + 5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for 3 minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of mL of gas evolved by the factor given in the AOAC, 13th Ed. (1980), section 52.007 under Reference Tables for the temperature and pressure observed, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

(2) Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

(3) Prepare the synthetic sample with 16.2 grams of corn meal, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U.S.P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

(4) Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

(5) Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11828, Mar. 19, 1982; 49 FR 10098, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2878, Jan. 6, 1993]

§ 137.275 Yellow corn meal.

Yellow corn meal conforms to the definition and standard of identity prescribed by § 137.250 for white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 137.280 Bolted yellow corn meal.

Bolted yellow corn meal conforms to the definition and standard of identity prescribed by § 137.255 for bolted white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 137.285 Degerminated yellow corn meal.

Degerminated yellow corn meal, degermed yellow corn meal, conforms to the definition and standard of identity prescribed by § 137.265 for degerminated white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 137.290 Self-rising yellow corn meal.

Self-rising yellow corn meal conforms to the definition and standard of identity prescribed by § 137.270 for self-rising white corn meal except that yellow corn meal is used instead of white corn meal.

§ 137.300 Farina.

(a) Farina is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat, to such fineness that, when tested by the method prescribed in paragraph (b)(2) of this section, it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.6 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section:

(1) Ash and moisture are determined by the methods therefor referred to in § 137.105(c).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 20 and No. 100 sieves, having standard 20.3 centimeter (8-inch) full-height frames, complying with the specifications for such cloth set forth in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh the material which fails to pass through the No. 20 sieve and the material which passes through the No. 100 sieve.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11828, Mar. 19, 1982; 49 FR 10098, Mar. 19, 1984; 54 FR 24894, June 12, 1989]

§ 137.305 Enriched farina.

(a) Enriched farina conforms to the definition and standard of identity prescribed for farina by § 137.300, except that:

(1) It contains in each pound not less than 2.0 milligrams (mg) and not more than 2.5 mg of thiamin, not less than 1.2 mg and not more than 1.5 mg of riboflavin, not less than 16.0 mg and not more than 20.0 mg of niacin or niacinamide, not less than 0.7 mg and not more than 0.87 mg of folic acid, and not less than 13.0 mg of iron (Fe).

(2) Vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U.S.P. units of the optional ingredient vitamin D.

(3) Calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 500 milligrams of the optional ingredient calcium (Ca).

(4) It may contain not more than 8 percent by weight of the optional ingredient wheat germ or partly defatted wheat germ.

(5)(i) It may contain not less than 0.5 percent and not more than 1 percent by weight of the optional ingredient disodium phosphate; or

(ii) It may be treated with one of the proteinase enzymes papain or pepsin to reduce substantially the time required for cooking. In such treatment papain or pepsin, in an amount not to exceed 0.1 percent by weight, is added to the farina, which is moistened, warmed, and subsequently heated sufficiently to inactivate the enzyme and to dry the product to comply with the limit for moisture prescribed by § 137.300(a).

(6) In determining whether the ash content complies with the requirements of this section allowance is made for ash resulting from any added iron or salts of iron or calcium, or from any added disodium phosphate, or from any added wheat germ or partly defatted wheat germ.

Iron and calcium may be added only in forms which are harmless and assimilable. Dried irradiated yeast may be used as a source of vitamin D. The substances referred to in paragraphs (a) (1) and (2) of this section may be added in a harmless carrier which does not impair the enriched farina; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the farina.

(b)(1) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2)(i) When the optional ingredient disodium phosphate is used, the label shall bear the statement ''Disodium phosphate added for quick cooking''.

(ii) When the proteinase enzyme treatment is used, the label shall bear the statement ''Enzyme treated for quicker cooking''.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed by paragraph (b)(2) of this section shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter; except that where the name of the food is a part of a trademark or brand, then other written, printed, or graphic matter that is also a part of the trademark or brand may so intervene, if such statement is in such juxtaposition with the trademark or brand as to be conspicuously related to the name of the food.

[42 FR 14402, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993; 61 FR 8796, Mar. 5, 1996]

§ 137.320 Semolina.

(a) Semolina is the food prepared by grinding and bolting cleaned durum wheat to such fineness that, when tested by the method prescribed in § 137.300(b)(2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.92 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section, ash and moisture are determined by the methods therefor referred to in § 137.105(c).

§ 137.350 Enriched rice.

(a) The foods for which definitions and standards of identity are prescribed by this section are forms of milled rice (except rice coated with talc and glucose and known as coated rice), to which nutrients have been added so that each pound of the rice contains:

(1) Not less than 2.0 milligrams (mg) and not more than 4.0 mg of thiamin, not less than 1.2 mg and not more than 2.4 mg of riboflavin, not less than 16 mg and not more than 32 mg of niacin or niacinamide, not less than 0.7 mg and not more than 1.4 mg of folic acid, and not less than 13 mg and not more than 26 mg of iron (Fe).

(2) Each pound may contain not less than 250 U.S.P. units and not more than 1,000 U.S.P. units of vitamin D.

(3) Each pound may contain not less than 500 milligrams and not more than 1,000 milligrams of calcium (Ca). Calcium carbonate derived from the use of this substance in milling rice, when present in quantities that furnish less than 500 milligrams of calcium (Ca) per pound, is considered a normal ingredient of the milled rice used and not an optional ingredient of the enriched rice unless such enriched rice is labeled to

show it contains the optional ingredient calcium. Iron and calcium may be added only in forms that are harmless and assimilable. The vitamins referred to in paragraphs (a) (1) and (2) of this section may be combined with harmless substances to render them insoluble in water, if the water-insoluble products are assimilable.

(4) In the case of enriched parboiled rice, butylated hydroxytoluene may be added as an optional ingredient in an amount not to exceed 0.0033 percent by weight of the finished food.

(b) The substances referred to in paragraphs (a) (1), (2), and (3) of this section may be added in a harmless carrier. Such carrier is used only in the quantity necessary to effect an intimate and uniform mixture of such substances with the rice.

(c) Unless the label of the food bears the statement ''To retain vitamins do not rinse before or drain after cooking'' immediately preceding or following the name of the food and in letters not less than one-fourth the point size of type used for printing the name of the food (but in no case less than 8-point type) and the label bears no cooking directions calling for washing or draining or unless the food is precooked and it is packaged in consumer packages which are conspicuously and prominently labeled with directions for preparation which, if followed, will avoid washing away or draining off enriching ingredients, the substances named in paragraphs (a) (1), (2), and (3) of this section shall be present in such quantity or in such form that when the enriched rice is washed as prescribed in paragraph (e) of this section, the washed rice contains not less than 85 percent of the minimum quantities of the substances named in paragraph (a)(1) of this section, as required for enriched rice; and in case any optional ingredients named in paragraphs (a) (2) and (3) of this section are used, the washed rice also contains not less than 85 percent of the minimum quantity specified for the substance or substances used.

(d) The name specified for each food for which a definition and standard of identity is prescribed by this section is the common name of the kind of milled rice to which the enriching substances are added, preceded by the word ''enriched'' as, for example, ''Enriched rice'' or ''Enriched parboiled rice''.

(e) The method referred to in paragraph (c) of this section is as follows: Mix the contents of one or more containers and transfer ½ pound thereof to a 4-liter flask containing 2 liters of distilled water at room temperature (but not below 20 °C). Stopper the flask and swirl it moderately for ½ minute so that the rice is in motion and in uniform suspension. Allow the rice to settle for ½ minute, then pour off 1,600 milliliters of the water, together with any floating and suspended matter, and discard. To the contents of the flask, add 1,600 milliliters of distilled water and 20 milliliters of 10 *N* hydrochloric acid. Agitate vigorously and wash down the sides of the flask with 150 milliliters of 0.1 *N* hydrochloric acid. In order to avoid excess foaming during the extraction, heat the mixture slowly to about 100 °C, agitate if necessary, and maintain at this temperature until air is expelled. Again wash down the sides of the flask with 150 milliliters of 0.1 *N* hydrochloric acid. Heat the mixture in an autoclave at 120 °C to 123 °C for 30 minutes, remove and cool to room temperature. Dilute the mixture with distilled water so that the total volume is 2,500 milliliters. Swirl the flask, and while the solids are in uniform suspension pour off about 250 milliliters of the mixture for later determination of iron (and calcium, if this is to be determined). With filter paper that has been shown not to adsorb thiamine, riboflavin, or niacin, filter enough of the remaining mixture for determination of thiamine, riboflavin, and niacin. (In the case of a mixture difficult to filter, centrifuging or filtering through fritted glass, or both, using a suitable analytical filter-aid, may be substituted for, or may precede, filtering through paper.) Dilute an aliquot of filtrate with 0.1 *N* hydrochloric acid, so that each milliliter contains about 0.2 microgram of thiamine, and determine thiamine by the ''Rapid Fluorometric Method—Official Final Action,'' in section 43.034 of ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), which is incorporated by reference. Copies may

be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.With a suitable aliquot determine riboflavin by the method prescribed in section 43.041(a) by the ''Fluorometric Method—Official Final Action,'' AOAC, 13th Ed. (1980), beginning with the third sentence of the second paragraph, ''Adjust, with vigorous agitation * * *.'' Determine niacin in a 200-milliliter aliquot of the filtrate by the ''Colorimetric Method—Official Final Action,'' in section 43.045, AOAC, 13th Ed. (1980), beginning with the sixth sentence of the first paragraph, ''Adjust to pH 4.5 with * * *.'' Evaporate to dryness a 100-milliliter aliquot of the nonfiltered material withdrawn while agitating, and determine iron using the method ''Iron—Official Final Action,'' in sections 14.011, 14.012, and 14.013, AOAC, 13th Ed. (1980), and, if required, determine calcium as directed in section 14.014 under the heading ''Calcium—Official Final Action,'' AOAC, 13th Ed. (1980).

(f) When the optional ingredient specified in paragraph (a)(4) of this section is added, the statement ''Butylated hydroxytoluene added as a preservative'' shall be placed on the label prominently and with such conspicuousness (as compared with other words, statements, designs, or devices in the label) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase.

(g) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

NOTE: The Order of the Commissioner of Food and Drugs appearing at 23 FR 1170, Feb. 25, 1958, amending paragraphs (a)(1) and (c) provides in part as follows: The regulations in § 137.350 (formerly § 15.525) are stayed insofar as they require each pound of the food to contain not less than 1.2 milligrams and not more than 2.4 milligrams of riboflavin. This stay shall continue until final action is taken disposing of the objections, after public hearing thereon.

[42 FR 14402, Mar. 15, 1977, as amended at 47 FR 11828, Mar. 19, 1982; 49 FR 10098, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2878, Jan. 6, 1993; 61 FR 8796, Mar. 5, 1996]

PART 139—MACARONI AND NOODLE PRODUCTS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Macaroni and Noodle Products

Sec.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14409, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Macaroni and Noodle Products

§ 139.110 Macaroni products.

(a) Macaroni products are the class of food each of which is prepared by drying formed units of dough made from semolina, durum flour, farina, flour, or any combination of two or more of these, with water and with or without one or more of the optional ingredients specified in paragraphs (a) (1) to (6), inclusive, of this section.

(1) Egg white, frozen egg white, dried egg white, or any two or all of these, in such quantity that the solids thereof are not less than 0.5 percent and not

more than 2.0 percent of the weight of the finished food.

(2) Disodium phosphate, in a quantity not less than 0.5 percent and not more than 1.0 percent of the weight of the finished food.

(3) Onions, celery, garlic, bay leaf, or any two or more of these, in a quantity which seasons the food.

(4) Salt, in a quantity which seasons the food.

(5) Gum gluten, in such quantity that the protein content of the finished food is not more than 13 percent by weight. The finished macaroni product contains not less than 87 percent of total solids as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), in section 14.133, under the heading ''Vacuum Oven Method—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(6) Concentrated glyceryl monostearate (containing not less than 90 percent monoester), in a quantity not exceeding 2 percent by weight of the finished food.

(b) Macaroni is the macaroni product the units of which are tube-shaped and more than 0.11 inch but not more than 0.27 inch in diameter.

(c) Spaghetti is the macaroni product the units of which are tube-shaped or cord-shaped (not tubular) and more than 0.06 inch but not more than 0.11 inch in diameter.

(d) Vermicelli is the macaroni product the units of which are cord-shaped (not tubular) and not more than 0.06 inch in diameter.

(e) The name of each food for which a definition and standard of identity is prescribed by this section is ''Macaroni product''; or alternatively, the name is ''Macaroni'', ''Spaghetti'', or ''Vermicelli'', as the case may be, when the units of the food are of the shapes and sizes specified in paragraph (b), (c), or (d), respectively, of this section.

(f)(1) When disodium phosphate is used the label shall bear the statement ''Disodium phosphate added for quick cooking''.

(2) When any ingredient specified in paragraph (a)(3) of this section is used the label shall bear the statement ''Seasoned with _____'', the blank being filled in with the common name of the ingredient; or in the case of bay leaves the statement ''Spiced'', ''Spice added'', or ''Spiced with bay leaves''.

(3) When the ingredient specified in paragraph (a)(6) of this section is used, the label shall bear the statement ''Glyceryl monostearate added'' or the statement ''With added glyceryl monostearate''.

(4) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow, or in part precede and in part follow, such name, without intervening written, printed, or graphic matter.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14409, Mar. 15, 1977, as amended at 47 FR 11828, Mar. 19, 1982; 49 FR 10099, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2878, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 139.115 Enriched macaroni products.

(a) *Description.* Enriched macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f), and (g), except that:

(1) Each such food contains in each pound not less than 4.0 milligrams (mg) and not more than 5.0 mg of thiamin, not less than 1.7 mg and not more than 2.2 mg of riboflavin, not less than 27 mg and not more than 34 mg of niacin or niacinamide, not less than 0.9 mg and not more than 1.2 mg of folic acid, and

not less than 13 mg and not more than 16.5 mg of iron (Fe);

(2) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 250 U.S.P. units and not more than 1000 U.S.P. units of vitamin D.

(3) Each such food may also contain as an optional ingredient added calcium in such quantity that each pound of the finished food contains not less than 500 mg. and not more than 625 mg. of calcium (Ca);

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ but the amount thereof does not exceed 5 percent of the weight of the finished food;

(5) Each such food may be supplied, wholly or in part, with the prescribed quantity of any substance referred to in paragraphs (a) (1), (2), and (3) of this section through the use of dried yeast, dried torula yeast, partly defatted wheat germ, enriched farina, or enriched flour, or through the direct additions of any of the substances prescribed in paragraphs (a) (1), (2), and (3) of this section.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) (1) and (2) of this section may be added in a harmless carrier which does not impair the enriched macaroni product, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished enriched macaroni product.

(b) Enriched macaroni is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 139.110(b).

(c) Enriched spaghetti is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 139.110(c).

(d) Enriched vermicelli is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is ''Enriched Macaroni product''; or alternatively, the name is ''Enriched macaroni'', ''Enriched spaghetti'', or ''Enriched vermicelli'', as the case may be, when the units of the food comply with the requirements of paragraphs (b), (c), or (d) respectively of this section.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993; 61 FR 8797, Mar. 5, 1996]

§ 139.117 Enriched macaroni products with fortified protein.

(a)(1) Each of the foods for which a standard of identity is prescribed by this section is produced by drying formed units of dough made with one or more of the milled wheat ingredients designated in §§ 139.110(a) and 139.138(a), and other ingredients to enable the finished food to meet the protein requirements set out in paragraph (a)(2)(i) of this section. Edible protein sources, including food grade flours or meals made from nonwheat cereals or from oilseeds, may be used. Vitamin and mineral enrichment nutrients are added to bring the food into conformity with the requirements of paragraph (b) of this section. Safe and suitable ingredients, as provided for in paragraph (c) of this section, may be added. The proportion of the milled wheat ingredient is larger than the proportion of any other ingredient used.

(2) Each such finished food, when tested by the methods described in the cited sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference (copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*), meets the following specifications:

(i) The protein content (N × 6.25) is not less than 20 percent by weight (on a 13 percent moisture basis) as determined by the method in section 14.142. The protein quality is not less than 95 percent that of casein as determined on

the cooked food by the method in sections 43.212 through 43.216 of the official methods.

(ii) The total solids content is not less than 87 percent by weight as determined by the method in section 14.133 of the official methods.

(b)(1) Each food covered by this section contains in each pound 5 milligrams of thiamin, 2.2 milligrams of riboflavin, 34 milligrams of niacin or niacinamide, and 16.5 milligrams of iron.

(2) Each pound of such food may also contain 625 milligrams of calcium.

(3) Iron and calcium may be added only in forms which are harmless and assimilable. The enrichment nutrients may be added in a harmless carrier used only in a quantity necessary to effect a uniform distribution of the nutrients in the finished food. The requirements of paragraphs (b) (1) and (2) of this section shall be deemed to have been met if reasonable overages, within the limits of good manufacturing practice, are present to assure that the prescribed levels of the vitamins and mineral(s) are maintained throughout the expected shelf life of the food under customary conditions of distribution.

(c) The safe and suitable ingredients referred to in paragraph (a) of this section are ingredients that serve a useful purpose, e.g., to fortify the protein or facilitate production of the food, but they do not include color additives, artificial flavorings, artificial sweeteners, chemical preservatives, or starches. Ingredients deemed suitable for use by this paragraph are added in amounts that are not in excess of those reasonably required to achieve their intended purposes. Ingredients are deemed to be safe if they are not food additives within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act, or in case they are food additives, if they are used in conformity with regulations established pursuant to section 409 of the act.

(d)(1) The name of any food covered by this section is ''Enriched Wheat _____ Macaroni Product—with Fortified Protein'', the blank being filled in with appropriate word(s) such as ''Soy'' to show the source of any flours or meals used that were made from nonwheat cereals or from oilseeds. In lieu of the words ''Macaroni Product'' the word ''Macaroni'', ''Spaghetti'', or ''Vermicelli'', as appropriate, may be used if the units conform in shape and size to the requirements of § 139.110 (b), (c), or (d).

(2) When any ingredient, not designated in the part of the name prescribed in paragraph (d)(1) of this section, is added in such proportion as to contribute 10 percent or more of the quantity of protein contained in the finished food, the name shall include the statement ''Made with _____'', the blank being filled in with the name of each such ingredient, e.g., ''Made with nonfat milk''.

(3) When, in conformity with paragraph (d) (1) or (2) of this section, two or more ingredients are listed in the name, their designations shall be arranged in descending order of predominance by weight.

(4) In the case of a food made to comply with another section of this part, but which also meets the compositional requirements of this section, it may alternatively bear the name set out in that other section.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14409, Mar. 15, 1977, as amended at 47 FR 11829, Mar. 19, 1982; 49 FR 10099, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2878, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

EFFECTIVE DATE NOTE: Section 139.117 was stayed in its entirety at 43 FR 11695, Mar. 21, 1978.

§ 139.120 Milk macaroni products.

(a) Milk macaroni products are the class of food, each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

(1) Milk is used as the sole moistening ingredient in preparing the dough; or in lieu of milk one or more of the milk ingredients specified in paragraph (f) of this section is used, with or without water, in such quantity that the weight of milk solids therein is not less than 3.8 percent of the weight of

the finished milk macaroni product; and

(2) None of the optional ingredients permitted by §139.110(a) (1) and (2) is used. When the optional ingredient gum gluten (§139.110(a)(5)) is added, the quantity is such that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour, or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Milk macaroni is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by §139.110(b).

(c) Milk spaghetti is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by §139.110(c).

(d) Milk vermicelli is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by §139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is ''Milk Macaroni Product''; or alternatively, the name is ''Milk macaroni'', ''Milk spaghetti'', or ''Milk vermicelli'', as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d), respectively, of this section.

(f) The milk ingredients referred to in paragraph (a)(1) of this section are concentrated milk, evaporated milk, dried milk, and a mixture of butter with skim milk, concentrated skim milk, evaporated skim milk, nonfat dry milk (dried skim milk), or any two or more of these, in such proportion that the weight of nonfat milk solids in such mixture is not more than 2.275 times the weight of milk fat therein.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993]

§ 139.121 Nonfat milk macaroni products.

(a) Each of the macaroni products made with nonfat milk for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by §139.110(a), (f)(2), (f)(3), (f)(4), and (g), except that:

(1)(i) In preparing the dough, nonfat dry milk or concentrated skim milk, or a mixture of these, is used in an amount such that the finished macaroni product made with nonfat milk contains by weight not less than 12 percent and not more than 25 percent of milk solids-not-fat. Carrageenan or salts of carrageenan conforming to the requirements of §§172.620 and 172.626 of this chapter may be used in a quantity not in excess of 0.833 percent by weight of the milk solids-not-fat used.

(ii) When the ingredient carrageenan or the salts of carrageenan specified in paragraph (a)(1)(i) of this section is used, the label shall bear the statement, ''Carrageenan added'' or ''Salts of carrageenan added'' or the statement ''With added carrageenan'' or ''With added salts of carrageenan'', in the manner further prescribed by §139.110(f)(4).

(2) None of the optional ingredients permitted by §139.110(a) (1), (2), and (5) are used.

(b) The name of each food for which a definition and standard of identity is prescribed by this section is ''Macaroni products made with nonfat milk'' or, alternatively, the name is ''Macaroni made with nonfat milk'', ''Spaghetti made with nonfat milk'' or ''Vermicelli made with nonfat milk'', as the case may be when the units of the food conform to the specifications of shape and size prescribed by §139.110 (b), (c), or (d), respectively.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993]

§ 139.122 Enriched nonfat milk macaroni products.

(a) Each of the enriched macaroni products made with nonfat milk for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by §139.110(a), (f)(2), (f)(3), (f)(4), and (g), except that:

(1)(i) In preparing the dough, nonfat dry milk or concentrated skim milk, or a mixture of these, is used in an

amount such that the finished enriched macaroni product made with nonfat milk contains by weight not less than 12 percent and not more than 25 percent of milk solids-not-fat. Carrageenan or the salts of carrageenan conforming to the requirements of §172.620 and §172.626 of this chapter may be used in a quantity not in excess of 0.833 percent by weight of the milk solids-not-fat used.

(ii) When the ingredient carrageenan or the salts of carrageenan specified in paragraph (a)(1)(i) of this section is used, the label shall bear the statement, ''Carrageenan added'' or ''Salts of carrageenan added'' or the statement ''With added carrageenan'' or ''With added salts of carrageenan'', in the manner further prescribed by §139.110(f)(4).

(2) None of the optional ingredients permitted by §139.110(a) (1), (2), and (5) are used.

(3) Each such food contains in each pound not less than 4.0 milligrams (mg) and not more than 5.0 mg of thiamin, not less than 1.7 mg and not more than 2.2 mg of riboflavin, not less than 27 mg and not more than 34 mg of niacin or niacinamide, not less than 0.9 mg and not more than 1.2 mg of folic acid, and not less than 13 mg and not more than 16.5 mg of iron (Fe). These substances may be added through direct addition or wholly or in part through the use of dried yeast, dried torula yeast, partly defatted wheat germ (as provided for in paragraph (a)(4) of this section), enriched farina, or enriched flour. They may be added in a harmless carrier, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished food. Iron may be added only in a form that is harmless and assimilable.

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ, but the amount thereof does not exceed 5 percent by weight of the finished food.

(b) The name of each food for which a definition and standard of identity is prescribed by this section is ''Enriched macaroni product made with nonfat milk'' or, alternatively, the name is ''Enriched macaroni made with nonfat milk'', ''Enriched spaghetti made with nonfat milk'', or ''Enriched vermicelli made with nonfat milk,'' as the case may be when the units of the food conform to the specifications of shape and size prescribed by §139.110 (b), (c), or (d), respectively.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993]

§139.125 Vegetable macaroni products.

(a) Vegetable macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by §139.110(a), (f)(2), (f)(3), and (g), except that:

(1) Tomato (of any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity that the solids thereof are not less than 3 percent by weight of the finished vegetable macaroni product (the vegetable used may be fresh, canned, dried, or in the form of puree or paste); and

(2) None of the optional ingredients permitted by §139.110(a) (1) and (2) is used. When the optional ingredient gum gluten (§139.110(a)(5)) is added, the quantity is such that the protein derived therefrom, together with the protein derived from the semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Vegetable macaroni is the vegetable macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by §139.110(b).

(c) Vegetable spaghetti is the vegetable macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by §139.110(c).

(d) Vegetable vermicelli is the vegetable macaroni product, the units of which conform to the specifications of shape and size prescribed for vermicelli by §139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is ''_____ macaroni product'', the blank being filled in with the name whereby the

vegetable used is designated in paragraph (a) of this section; or alternatively, the name is ''_____ macaroni'', ''_____ spaghetti'', or ''_____ vermicelli'', as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d) of this section, respectively, the blank in each instance being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993]

§ 139.135 Enriched vegetable macaroni products.

(a) Each of the macaroni products for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f), and (g), and in addition is enriched to meet the requirements prescribed for enriched macaroni products by § 139.115 and contains a vegetable ingredient in compliance with the requirements prescribed for vegetable macaroni products by § 139.125.

(b) The name of each food for which a definition and standard of identity is prescribed by this section is ''Enriched _____ macaroni product'', or, alternatively, the name is ''Enriched _____ macaroni'', ''Enriched _____ spaghetti'', or ''Enriched _____ vermicelli'', when the units comply with the shape and size requirements prescribed for macaroni, spaghetti, or vermicelli in § 139.110 (b), (c), or (d). The blank in each instance is filled in with the name of the vegetable used, as specified in § 139.125(a). For example, the name of an enriched macaroni product containing the prescribed amount of spinach and made in units not conforming in shape and size to the requirements for macaroni, spaghetti, or vermicelli is ''Enriched spinach macaroni product''.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993]

§ 139.138 Whole wheat macaroni products.

(a) Whole wheat macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

(1) Whole wheat flour or whole durum wheat flour or both are used as the sole wheat ingredient; and

(2) None of the optional ingredients permitted by § 139.110(a) (1), (2), and (5) is used.

(b) Whole wheat macaroni is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 139.110(b).

(c) Whole wheat spaghetti is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 139.110(c).

(d) Whole wheat vermicelli is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is ''Whole wheat macaroni product''; or alternatively, the name is ''Whole wheat macaroni'', ''Whole wheat spaghetti'', or ''Whole wheat vermicelli'', as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d), respectively, of this section.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993]

§ 139.140 Wheat and soy macaroni products.

(a) Wheat and soy macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

(1) Soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is

made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom); and

(2) None of the optional ingredients permitted by §139.110(a) (1) and (2) is used. When the optional ingredient gum gluten (§139.110(a)(5)) is added, the quantity is such that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Wheat and soy macaroni is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by §139.110(b).

(c) Wheat and soy spaghetti is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by §139.110(c).

(d) Wheat and soy vermicelli is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by §139.110(d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is ''Wheat and soy macaroni product'', ''Wheat and soybean macaroni product'', ''_____ and soy macaroni product'', or ''_____ and soybean macaroni product'', the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in §139.110(a); or alternatively, the name is ''Wheat and soy macaroni'', ''Wheat and soybean macaroni'', ''_____ and soy macaroni'', or ''_____ and soybean macaroni'' when the units of the food comply with the requirements of paragraph (b) of this section; or ''Wheat and soy spaghetti'', ''Wheat and soybean spaghetti'', ''_____ and soy spaghetti'', or ''_____ and soybean spaghetti'' when such units comply with the requirements of paragraph (c) of this section; or ''Wheat and soy vermicelli'', ''Wheat and soybean vermicelli'', ''_____ and soy vermicelli'', or ''_____ and soybean vermicelli'' when such units comply with the requirements of paragraph (d) of this section, the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in §139.110(a).

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2878, Jan. 6, 1993]

§139.150 Noodle products.

(a) Noodle products are the class of food each of which is prepared by drying formed units of dough made from semolina, durum flour, farina, flour, or any combination of two or more of these, with liquid eggs, frozen eggs, dried eggs, egg yolks, frozen yolks, dried yolks, or any combination of two or more of these, with or without water and with or without one or more of the optional ingredients specified in paragraphs (a) (1) to (4) of this section inclusive:

(1) Onions, celery, garlic, bay leaf, or any two or more of these, in a quantity which seasons the food.

(2) Salt, in a quantity which seasons the food.

(3) Gum gluten, in such quantity that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(4) Concentrated glyceryl monostearate (containing not less than 90 percent monoester) in a quantity not exceeding 3 percent by weight of the finished food.

The finished noodle product contains not less than 87 percent of total solids as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), in section 14.133, under the heading ''Vacuum Oven Method—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The total solids of noodle products contains not less than 5.5 percent by weight of the solids of egg, or egg yolk.

(b) Noodles, egg noodles, is the noodle product the units of which are ribbon-shaped.

(c) Egg macaroni is the noodle product the units of which are tube-shaped and more than 0.11 inch but not more than 0.27 inch in diameter.

(d) Egg spaghetti is the noodle product the units of which are tube-shaped or cord-shaped (not tubular) and more than 0.06 inch but not more than 0.11 inch in diameter.

(e) Egg vermicelli is the noodle product the units of which are cord-shaped (not tubular) and not more than 0.06 inch in diameter.

(f) The name of each food for which a definition and standard of identity is prescribed by this section is ''Noodle product'' or ''Egg noodle product''; or alternatively, the name is ''Noodles'' or ''Egg noodles'', ''Egg macaroni'', ''Egg spaghetti'', or ''Egg vermicelli'', as the case may be, when the units of the food are of the shapes and sizes specified in paragraph (b), (c), (d), or (e), respectively, of this section.

(g)(1) When any ingredient specified in paragraph (a)(1) of this section is used, the label of the noodle product shall bear the statement ''Seasoned with _____'', the blank being filled in with the common name of the ingredient; or in the case of bay leaves, the statement ''Spiced'', ''Spice added'', or ''Spiced with bay leaves''.

(2) When the ingredient specified in paragraph (a)(4) of this section is used, the label shall bear the statement ''Glyceryl monostearate added'' or the statement ''With added glyceryl monostearate''.

(h) Wherever the name of the food appears on such label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the ingredients used shall immediately and conspicuously precede or follow, or in part precede and in part follow, such name without intervening written, printed, or other graphic matter.

(i) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14409, Mar. 15, 1977, as amended at 47 FR 11829, Mar. 19, 1982; 49 FR 10099, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2879, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 139.155 Enriched noodle products.

(a) Enriched noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for noodle products by § 139.150 (a), (g), and (i), except that:

(1) Each such food contains in each pound not less than 4 milligrams (mg) and not more than 5 mg of thiamin, not less than 1.7 mg and not more than 2.2 mg of riboflavin, not less than 27 mg and not more than 34 mg of niacin or niacinamide, not less than 0.9 mg and not more than 1.2 mg of folic acid, and not less than 13 mg and not more than 16.5 mg of iron (Fe);

(2) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 250 U.S.P. units and not more than 1000 U.S.P. units of vitamin D;

(3) Each such food may also contain as an optional ingredient added calcium in such quantity that each pound of the finished food contains not less than 500 mg. and not more than 625 mg. of calcium (Ca);

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ, but the amount thereof does not exceed 5 percent of the weight of the finished food;

(5) Each such food may be supplied, wholly or in part, with the prescribed quantity of any substance referred to in paragraphs (a) (1), (2), and (3) of this section through the use of dried yeast, dried torula yeast, partly defatted wheat germ, enriched farina, or enriched flour, or through the direct additions of any of the substances prescribed in paragraphs (a) (1), (2), and (3) of this section.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) (1) and (2) of this section may be added in a harmless carrier which does not impair the enriched

noodle product, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished enriched noodle product.

(b) Enriched noodles, enriched egg noodles are the enriched noodle products the units of which conform to the specifications of shape and size prescribed for noodles in §139.150(b).

(c) Enriched egg macaroni is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni in §139.150(c).

(d) Enriched egg spaghetti is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti in §139.150(d).

(e) Enriched egg vermicelli is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli in §139.150(e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is ''Enriched noodle product'' or ''Enriched egg noodle product''; or alternatively, the name is ''Enriched noodles'', or ''Enriched egg noodles'', ''Enriched egg macaroni'', ''Enriched egg spaghetti'', or ''Enriched egg vermicelli'', as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), (d), or (e) respectively of this section.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2879, Jan. 6, 1993]

§ 139.160 Vegetable noodle products.

(a) Vegetable noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for noodle products by §139.150(a), (g), and (i), except that tomato (of any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity that the solids thereof are not less than 3 percent by weight of the finished vegetable noodle product (the vegetable used may be fresh, canned, dried, or in the form of puree or paste).

(b) Vegetable noodles, vegetable egg noodles, is the vegetable noodle product the units of which are ribbon-shaped.

(c) Vegetable egg macaroni is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni by §139.150(c).

(d) Vegetable egg spaghetti is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti by §139.150(d).

(e) Vegetable egg vermicelli is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli by §139.150(e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is ''_____ noodle product'' or ''_____ egg noodle product'', the blank being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section; or alternatively, the name is ''_____ noodles'' or ''_____ egg noodles'', ''_____ egg macaroni'', ''_____ egg spaghetti'', or ''_____ egg vermicelli'', as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), (d), or (e) of this section, respectively, the blank in each instance being filled in with the name whereby the vegetable is designated in paragraph (a) of this section.

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2879, Jan. 6, 1993]

§ 139.165 Enriched vegetable noodle products.

(a) Each of the noodle products for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity and is subject to the requirements for label declaration of ingredients prescribed for noodle products by §139.150 (a), (g), (h), and (i), and in addition is enriched to meet the requirements prescribed for enriched noodle products by §139.155 and, except as hereinafter provided, contains a vegetable ingredient in compliance with the requirements prescribed for vegetable noodle products by §139.160. Because they are apt to impart an egg-yolk color, carrots are not used in enriched vegetable noodle products.

(b) The name of each food for which a definition and standard of identity is prescribed by this section is ''Enriched _____ noodle product'', ''Enriched _____ egg noodle product'', or, alternatively, the name is ''Enriched _____ noodles'', or ''Enriched _____ egg noodles'', ''Enriched _____ egg macaroni'', ''Enriched _____ egg spaghetti'', or ''Enriched _____ egg vermicelli'', when the units comply with the size and shape requirements for noodles, macaroni, spaghetti, or vermicelli in §139.150 (b), (c), (d), or (e). The blank in each instance is filled in with the name of the vegetable used, as specified in §139.160(a).

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2879, Jan. 6, 1993]

§139.180 Wheat and soy noodle products.

(a) Wheat and soy noodle products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for noodle products by §139.150(a), (g), and (i), except that soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom).

(b) Wheat and soy noodles, wheat and soy egg noodles, is the wheat and soy noodle product the units of which are ribbon-shaped.

(c) Wheat and soy egg macaroni is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni by §139.150(c).

(d) Wheat and soy egg spaghetti is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti by §139.150(d).

(e) Wheat and soy egg vermicelli is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli by §139.150(e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is ''Wheat and soy noodle product'', ''Wheat and soy egg noodle product'', ''Wheat and soybean noodle product'', ''Wheat and soybean egg noodle product'', ''_____ and soy noodle product'', ''_____ and soy egg noodle product'', ''_____ and soybean noodle product'', or ''_____ and soybean egg noodle product'', the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in §139.150(a); or alternatively, the name is ''Wheat and soy noodles'', ''Wheat and soy egg noodles'', ''Wheat and soybean noodles'', ''Wheat and soybean egg noodles'', ''_____ and soy noodles'', ''_____ and soy egg noodles'', ''_____ and soybean noodles'', or ''_____ and soybean egg noodles'' when the units of the food comply with the requirements of paragraph (b) of this section; or ''Wheat and soy egg macaroni'', ''Wheat and soybean egg macaroni'', ''_____ and soy egg macaroni'', or ''_____ and soybean egg macaroni'' when such units comply with the requirements of paragraph (c) of this section; or ''Wheat and soy egg spaghetti'', ''Wheat and soybean egg spaghetti'', ''_____ and soy egg spaghetti'', or ''_____ and soybean egg spaghetti'' when such units comply with the requirements of paragraph (d) of this section; or ''Wheat and soy egg vermicelli'', ''Wheat and soybean egg vermicelli'', ''_____ and soy egg vermicelli'', or ''_____ and soybean egg vermicelli'', when such units comply with the requirements of paragraph (e) of this section, the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in §139.150(a).

[42 FR 14409, Mar. 15, 1977, as amended at 58 FR 2879, Jan. 6, 1993]

PART 145—CANNED FRUITS

Subpart A—General Provisions

Subpart B—Requirements for Specific Standardized Canned Fruits

(iv) *Sample unit.* A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(v) *Defective.* Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(vi) *Acceptance number* (*c*). The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(vii) *Acceptable quality level* (*AQL*). The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(2) *Sampling plans:*

Lot size (primary containers)	Size in container	
	n[1]	*c*[2]
NET WEIGHT EQUAL TO OR LESS THAN 1 KG (2.2 LB)		
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
NET WEIGHT GREATER THAN 1 KG (2.2 LB) BUT NOT MORE THAN 4.5 KG (10 LB)		
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
NET WEIGHT GREATER THAN 4.5 KG (10 LB)		
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

[1] *n* = number of primary containers in sample.
[2] *c* = acceptance number.

[42 FR 14414, Mar. 15, 1977, as amended at 47 FR 11829, Mar. 19, 1982; 49 FR 10099, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

Subpart B—Requirements for Specific Standardized Canned Fruits

§ 145.110 Canned applesauce.

(a) *Identity*—(1) *Definition.* Canned applesauce is the food prepared from comminuted or chopped apples (*Malus domestica* Borkhausen), which may or may not be peeled and cored, and which may have added thereto one or more of the optional ingredients specified in paragraph (a)(2) of this section. The apple ingredient is heated and, in accordance with good manufacturing practices, bruised apple particles, peel, seed, core material, carpel tissue, and other coarse, hard, or extraneous materials are removed. The food is sealed in containers. It is so processed by heat, either before or after sealing, as to prevent spoilage. The soluble solids content, measured by refractometer and expressed as percent sucrose (degrees Brix) with correction for temperature to the equivalent at 20 °C (68 °F), is not less than 9 percent (exclusive of the solids of any added optional nutritive carbohydrate sweeteners) as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 22.024, ''Soluble Solids by Refractometer in Fresh and Canned Fruits, Jams, Marmalades, and Preserves—Official First Action,'' which is incorporated by reference, but without correction for invert sugar or other substances. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(2) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(i) Water.

(ii) Apple juice.

(iii) Salt.

(iv) Any organic acid added for the purpose of acidification. (Organic acids

generally recognized as having a preservative effect are not permitted in applesauce except as provided for in paragraph (a)(2)(viii) of this section.)

(v) Nutritive carbohydrate sweeteners.

(vi) Spices.

(vii) Natural and artificial flavoring.

(viii) Either of the following:

(*a*) Erythorbic acid or ascorbic acid as an antioxidant preservative in an amount not to exceed 150 parts per million; or

(*b*) Ascorbic acid (vitamin C) in a quantity such that the total vitamin C in each 113 g (4 ounces) by weight of the finished food amounts to 60 mg. This requirement will be deemed to have been met if a reasonable overage of the vitamin, within limits of good manufacturing practice, is present to insure that the required level is maintained throughout the expected shelf life of the food under customary conditions of distribution.

(ix) Color additives in such quantity as to distinctly characterize the food unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(3) *Nomenclature.* The name of the food is ''applesauce''. The name of the food shall include a declaration indicating the presence of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product. If a nutritive sweetener as provided for in paragraph (a)(2)(v) of this section is added and the soluble solids content of the finished food is not less than 16.5 percent as determined by the method referred to in paragraph (a)(1) of this section, the name may include the word ''sweetened''. If no such sweetener is added, the name may include the word ''unsweetened''.

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. However, when ascorbic acid (vitamin C) is added as provided for in paragraph (a)(2)(viii)(*b*) of this section, after the application of heat to the apples, preservative labeling requirements do not apply.

(b) [Reserved]

(c) *Fill of container.* (1) The standard of fill of container for canned applesauce is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of containers prescribed in § 130.12(b) of this chapter; except that in the case of glass containers having a total capacity of 192 ml (6½ fluid ounces) or less, the fill is not less than 85 percent.

(2) Sampling and acceptance procedure: A lot will be deemed to fall below the standard of fill when the number of ''defectives'' exceeds the acceptance number ''c'' in the sampling plans prescribed in paragraph (c)(2)(ii) of this section.

(i) Definitions of terms to be used in the sampling plans in paragraph (c)(2)(ii) of this section are as follows:

(*a*) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(*b*) *Lot size.* The number of primary containers or units in the lot.

(*c*) *Sample size ''n.''* The total number of sample units drawn for examination from a lot as indicated in paragraph (c)(2)(ii) of this section.

(*d*) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for examination or testing as a single unit.

(*e*) *Defective.* A container that falls below the requirement for minimum fill prescribed in paragraph (c)(1) of this section is considered a ''defective.''

(*f*) *Acceptable number ''c.''* The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(*g*) *Acceptable quality level* (*AQL*). The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(ii) Sampling and acceptance:

ACCEPTABLE QUALITY LEVEL (AQL) 6.5

Lot size (primary containers)	Size of container	
	n[1]	c[2]
NET WEIGHT EQUAL TO OR LESS THAN 1 KG (2.2 LB)		
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
NET WEIGHT GREATER THAN 1 KG (2.2 LB) BUT NOT MORE THAN 4.5 KG (10 LB)		
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
NET WEIGHT GREATER THAN 4.5 KG (10 LB)		
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

[1] n = number of primary containers in sample.
[2] c = acceptance number.

(3) If canned applesauce falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14414, Mar. 15, 1977, as amended at 47 FR 11829, Mar. 19, 1982; 49 FR 10099, Mar. 19, 1984; 54 FR 24894, June 12, 1989; 58 FR 2879, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 145.115 Canned apricots.

(a) *Identity*—(1) *Ingredients.* Canned apricots is the food prepared from mature apricots of one of the optional styles specified in paragraph (a)(2) of this section, which may be packed as solid pack or in one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Apricot pits, except in the cases of unpeeled whole apricots and peeled whole apricots, in a quantity not more than 1 apricot pit to each 227 grams (8 ounces) of finished canned apricots.

(v) Apricot kernels, except in the cases of unpeeled whole apricots and peeled whole apricots, and except when optional ingredient under paragraph (a)(4) of this section is used.

(vi) Ascorbic acid in an amount no greater than necessary to preserve color.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Optional styles of the apricot ingredient.* The optional styles of the apricot ingredient referred to in paragraph (a) of this section are peeled or unpeeled:

(i) Whole.

(ii) Halves.

(iii) Quarters.

(iv) Slices.

(v) Pieces or irregular pieces.

Each such ingredient, except in the cases of unpeeled whole apricots and peeled whole apricots, is pitted.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in §145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in §145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in §145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in §145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is 10 percent or more but less than 16

percent, the medium shall be designated as ''slightly sweetened water''; or ''extra light sirup''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(*b*) When the density of the solution is 16 percent or more but less than 21 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(*c*) When the density of the solution is 21 percent or more but less than 25 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(*d*) When the density of the solution is 25 percent or more but not more than 40 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(4) *Labeling requirements.* (i) The name of the food is ''apricots''. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice Added'', or in lieu of the word ''Spice'', the common name of the spice, ''Seasoned with Vinegar'' or ''Seasoned with Apricot Kernels''. When two or more of the optional ingredients specified in paragraphs (a)(1) (ii) through (iv), inclusive, of this section are used, such words may be combined as for example, ''Seasoned with Cider Vinegar, Cloves, Cinnamon Oil and Apricot Kernels''.

(ii) The style of the apricot ingredient as provided in paragraph (a)(2) of this section and the name of the packing medium as used in paragraphs (a)(3)(i) and (ii) of this section, preceded by ''In'' or ''Packed in'' or the words ''solid pack'', where applicable, shall be included as part of the name or in close proximity to the name of the food, except that pieces or irregular pieces shall be designated ''Pieces'', ''Irregular pieces'', or ''Mixed pieces of irregular sizes and shapes''. The style of the apricot ingredient shall be preceded or followed by ''Unpeeled'' or ''Peeled'', as the case may be. ''Halves'' may be alternatively designated ''Halved'', ''Quarters'' as ''Quartered'' and ''Slices'' as ''Sliced''. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be ''_____ sirup of brown sugar and honey'' the blank to be filled in with the word ''light'', ''heavy'', or ''extra heavy'' as the case may be. When the liquid portion of the packing media provided for in paragraphs (a)(3) (i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit''.

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section, and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(*b*) of this section, such names and the words ''from concentrate,'' as specified in paragraph (a)(4)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(iv) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned apricots is as follows:

(i) All units tested in accordance with the method prescribed in paragraph (b)(2) of this section are pierced by a weight of not more than 300 grams.

(ii) In the cases of whole apricots, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein.

(iii) Not more than 20 percent of the units in the container are blemished with scab, hail injury, discoloration, or other abnormalities.

(iv) In the cases of whole apricots, halves, and quarters, all units are untrimmed, or are so trimmed as to preserve normal shape.

(v) Except in the case of mixed pieces of irregular sizes and shapes, not more than 5 percent of the units in a container of 20 or more units, and not more than 1 unit in a container of less than 20 units, are crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(2) Canned apricots shall be tested by the following method to determine whether or not they meet the requirements of paragraph (b)(1)(i) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 1⅛ inches inside diameter, with vertical sides; or rectangular in shape, ¾ inch by 1 inch inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of ¾ inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod 3/16 inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(3) If the quality of canned apricots falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement ''Below standard in quality _____'', the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (b)(1) of this section which such canned apricots fail to meet, as follows:

(i) ''Not tender'';
(ii) ''Mixed sizes'';
(iii) ''Blemished'';
(iv) ''Unevenly trimmed'';
(v) ''Partly crushed or broken''.

Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name ''apricots'' and any words and statements required or authorized to appear with such name by §145.115(a)(2).

(c) *Fill of container.* (1) The standard of fill of container for canned apricots is the maximum quantity of the optional apricot ingredient that can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(2) If canned apricots fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2879, Jan. 6, 1993]

§ 145.116 Artificially sweetened canned apricots.

(a) Artificially sweetened canned apricots is the food which conforms to the definition and standard of identity prescribed for canned apricots by §145.115(a), except that in lieu of a packing medium specified in §145.115(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is ''artificially sweetened _____'', the blank being filled in with the name prescribed by §145.115(a) for canned apricots having the same optional apricot ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned apricots by §145.115(a). If the packing medium is thickened with pectin, the label shall bear the statement ''thickened with pectin''. When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2879, Jan. 6, 1993]

§ 145.120 Canned berries.

(a) *Identity*—(1) *Ingredients.* Canned berries is the food prepared from any suitable variety of one of the optional berry ingredients specified in paragraph (a)(2) of this section, which may be packed in one of the optional packing media specified in paragraph (a)(3) of this section, and may contain one or any combination of two or more of the safe and suitable optional ingredients specified in paragraph (a)(4) of this section. Such food is sealed in a container and before or after sealing is so processed by heat to prevent spoilage.

(2) *Varietal types.* The optional berry ingredients referred to in paragraph (a)(1) of this section are prepared from stemmed fruit of the following optional varietal types of berry ingredient; namely:

(i) Raspberry varieties conforming to the characteristics of *Rubus idaeus* L. or *Rubus occidentalis* L.

(ii) Blackberries.

(iii) Blueberries.

(iv) Boysenberries.

(v) Dewberries.

(vi) Gooseberries.

(vii) Huckleberries.

(viii) Loganberries.

(ix) Strawberry varieties conforming to the characteristics of *Fragaria.*

(x) Youngberries.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section as defined in §145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweeteners may be added. Sweeteners listed in §145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in §145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the four density ranges of the resulting packing media hereinafter specified for each berry ingredient, expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure described in §145.3(m), shall be designated by the appropriate name for each of the respective density ranges for each berry ingredient as:

(*a*) ''Slightly sweetened water''; or ''extra light sirup''; ''slightly sweetened fruit juice(s) and water''; or

''slightly sweetened fruit juice(s)'', as the case may be.

(*b*) ''Light sirup'', when the liquid used is water, ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(*c*) ''Heavy sirup'', when the liquid used is water; or ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(*d*) ''Extra heavy sirup'', when the liquid used is water; or ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

The density ranges referred to herein are:

Optional berry ingredient	Density ranges							
	(*a*)		(*b*)		(*c*)		(*d*)	
	Minimum	Maximum less than	Minimum	Maximum less than	Minimum	Maximum less than	Minimum	Maximum not more than
Blackberries	.....	14	14	19	19	24	24	35
Blueberries	.....	15	15	20	20	25	25	35
Boysenberries	.....	14	14	19	19	24	24	35
Dewberries	.....	14	14	19	19	24	24	35
Gooseberries	.....	14	14	20	20	25	25	35
Huckleberries	.....	15	15	20	20	25	25	35
Loganberries	.....	14	14	19	19	24	24	35
Raspberries	11	15	15	20	20	27	27	35
Strawberries	10	14	14	19	19	27	27	35
Youngberries	.....	14	14	19	19	24	24	35

(*a*) ''Slightly sweetened water.'' (*b*) ''Light sirup.'' (*c*) ''Heavy sirup.'' (*d*) ''Extra heavy sirup.''

(4) *Optional ingredients.* The optional ingredients referred to in paragraph (a)(1) of this section are:

(i) Natural and artificial flavors.

(ii) Calcium salts as firming agents provided that the calcium added is no more than 0.035 percent, calculated as calcium, of the weight of the finished canned berries.

(iii) Organic acids.

(5) *Labeling requirements.* (i) The name of the food is the appropriate name of the berry ingredient specified in paragraph (a)(2) of this section.

(ii) The name of the packing medium, as used in paragraph (a)(3)(i) of this section preceded by ''In'' or ''Packed in.'' as provided in paragraph (a)(3) of this section and, in the case of raspberries other than red raspberries provided for in paragraph (a)(2) of this section, the name of such packing medium and the color of such raspberry shall be included as part of the name or in close proximity to the name of the food. When the liquid portion of the packing media provided for in paragraphs (a)(3)(i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the cases of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'';

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (a)(3) of this section; and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(5)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(5)(ii)(*b*) of this section, such names and the words ''from concentrate'', as specified in paragraph (a)(5)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(iv) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

[46 FR 2339, Jan. 9, 1981; 47 FR 6426, Feb. 12, 1982, as amended at 48 FR 2748, Jan. 21, 1983; 58 FR 2879, Jan. 6, 1993]

§ 145.125 Canned cherries.

(a) *Identity*—(1) *Ingredients.* Canned cherries is the food prepared from one of the optional fresh or previously canned cherry ingredients specified in paragraph (a)(2) of this section, which may be packed in one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids. Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Varietal types and styles.* The optional cherry ingredients referred to in paragraph (a)(1) of this section are prepared from mature pitted or unpitted cherries of the red tart or alternatively, red sour, light sweet or dark sweet varietal group.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in § 145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) In the case of sweet cherries:

(*i*) When the density of the solution is less than 16 percent, the medium shall be designated as ''slightly sweetened water''; or ''extra light sirup''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(*ii*) When the density of the solution is 16 percent or more but less than 20 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(*iii*) When the density of the solution is 20 percent or more but less than 25 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(*iv*) When the density of the solution is 25 percent or more but not more than 35 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(*b*) In the case of red tart cherries:

(*i*) When the density of the solution is less than 18 percent, the medium shall be designated as ''slightly sweetened water''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(*ii*) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(*iii*) When the density of the solution is 22 percent or more but less than 28 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(*iv*) When the density of the solution is 28 percent or more but not more than 45 percent, the medium shall be designated as ''extra heavy sirup'';

''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(4) *Labeling requirements.* (i) The name of the food is ''cherries''. The optional varietal type as set forth in paragraph (a)(2) of this section, preceded or followed by the word ''pitted'' when this is the fact, shall be a part of the name. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or in lieu of the word ''Spice'', the common name of the spice, or ''Seasoned with lemon juice''. When two or more of the optional ingredients specified in paragraph (a)(1)(ii) and (iii) of this section are used, such words may be combined as for example, ''Seasoned with cider vinegar, cloves, and cinnamon oil''.

(ii) The color type and style of the cherry ingredient as provided in paragraph (a)(2) of this section and the name of the packing medium specified in paragraphs (a)(3) (i) and (ii) of this section, preceded by ''In'' or ''Packed in'' or the words ''solid pack'', where applicable, shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be ''_____ sirup of brown sugar and honey'' the blank to be filled in with the word ''light'', ''heavy'', or ''extra heavy'' as the case may be. When the liquid portion of the packing media provided for in paragraphs (a)(3) (i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'';

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section; and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(*b*) of this section, such names and the words ''from concentrate'', as specified in paragraph (a)(4)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(iv) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned cherries is as follows:

(i) In the case of pitted cherries, not more than 1 pit is present in each 20 ounces of canned cherries, as determined by the method prescribed in paragraph (b)(2)(i) of this section.

(ii) In the case of unpitted cherries, the weight of each cherry in the container is not less than 1/10 ounce.

(iii) In the case of unpitted cherries, the weight of the largest cherry in the container is not more than twice the weight of the smallest cherry therein.

(iv) In the case of unpitted cherries, the total weight of pits is not more than 12 percent of the weight of drained cherries, as determined by the method prescribed in paragraph (b)(2)(ii) of this section.

(v) Not more than 15 percent by count of the cherries in the container are blemished with scab, hail injury, discoloration, scar tissue or other abnormality. A cherry showing skin discoloration (other than scald) having an aggregate area exceeding that of a circle 9/32 inch in diameter is considered to be blemished. A cherry showing discoloration of any area but extending into

the fruit tissue is also considered to be blemished.

(2)(i) Pitted canned cherries shall be tested by the following method to determine whether or not they comply with the requirements of paragraph (b)(1)(i) of this section: Take at random such number of containers as to have a total quantity of contents of at least 24 pounds. Open the containers and weigh the contents. Count the pits and pieces of pit shell in such total quantity. Count a piece of pit shell equal to or smaller than one-half pit shell as one-half pit, and a piece of pit shell larger than one-half pit shell as one pit; but when two or more pieces of pit shell are within or attached to a single cherry, count such pieces as one-half pit if their combined size is equivalent to that of one-half pit shell or less, and as one pit if their combined size is equivalent to that of more than one-half pit shell. From the total number of pits so counted and the combined weight of the contents of all the containers, calculate the number of pits present in each 20 ounces of canned cherries.

(ii) Unpitted canned cherries shall be tested by the following method to determine whether or not they comply with the requirements of paragraph (b)(1)(iv) of this section: Tilt the opened container so as to distribute the contents over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, or 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is No. 8 woven-wire cloth that complies with the specifications for such cloth set forth in the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD, 20877–2504, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. Without shifting the cherries, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and drained cherries. The weight so found, less the weight of the sieve, shall be considered to be the weight of drained cherries. Pit the cherries and wash the pits free from adhering flesh. Drain and weigh the pits by the method prescribed above. Divide the weight of pits so found by the weight of drained cherries, and multiply by 100.

(3) If the quality of canned cherries falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement ''Below Standard in Quality _____'', the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (b)(1) of this section which such canned cherries fail to meet, as follows:

(i) ''Partially pitted'';
(ii) ''Small'';
(iii) ''Mixed sizes'';
(iv) ''Thin-fleshed'';
(v) ''Blemished''.

Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name ''Cherries'' and any words and statements required or authorized to appear with such name by § 145.125(a)(2).

(c) *Fill of container.* (1) The standard of fill of container for canned cherries is the maximum quantity of the optional cherry ingredient that can be sealed in the container and processed by heat to prevent spoilage, without crushing such ingredient.

(2) If canned cherries fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in

§ 130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14414, Mar. 15, 1977, as amended at 47 FR 11829, Mar. 19, 1982; 49 FR 10099, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2879, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 145.126 Artificially sweetened canned cherries.

(a) Artificially sweetened canned cherries is the food which conforms to the definition and standard of identity prescribed for canned cherries by § 145.125(a), except that in lieu of a packing medium specified in § 145.125(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is ''artificially sweetened _____'', the blank being filled in with the name prescribed by § 145.125(a) for canned cherries having the same optional cherry ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned cherries by § 145.125(a). If the packing medium is thickened with pectin, the label shall bear the statement ''thickened with pectin''. When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2879, Jan. 6, 1993]

§ 145.130 Canned figs.

(a) *Ingredients.* Canned figs is the food prepared from one of the optional fig ingredients specified in paragraph (b) of this section and one of the optional packing media specified in paragraph (c) of this section, to which lemon juice, concentrated lemon juice or organic acid(s) is added, when necessary to reduce the pH of the finished product to pH 4.9 or below. Such food may also contain one, or any combination of two or more of the following safe and suitable optional ingredients:

(1) Natural and artificial flavoring.

(2) Spice.

(3) Vinegar.

(4) Unpeeled segments of citrus fruits.

(5) Salt.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(b) *Varietal types.* The optional fig ingredients referred to in paragraph (a) of this section are prepared from mature figs of the light or dark varieties. Figs (or whole figs), split figs (or broken figs), or any combination thereof are optional fig ingredients. A ''whole fig'' is one which is whole, but may be slightly cracked, provided it retains its natural conformation without exposing the interior. A ''split'' or ''broken'' fig is one that is open to such an extent that the seed cavity is exposed. The shape of the fruit may be distorted, and the fruit may or may not be broken apart into entirely separate pieces.

(c) *Packing media.* (1) The optional packing media referred to in paragraph (a) of this section, as defined in § 145.3 are:

(i) Water.

(ii) Fruit juice(s) and water.

(iii) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(2) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(i) When the density of the solution is 11 percent or more but less than 16

percent, the medium shall be designated as ''slightly sweetened water''; or ''extra light syrup''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(ii) When the density of the solution is 16 percent or more but less than 21 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(iii) When the density of the solution is 21 percent or more but less than 26 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(iv) When the density of the solution is 26 percent or more but not more than 35 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(d) *Labeling requirements.* (1) The name of the food is ''figs''. The words ''broken'' or ''split'' shall be a part of the name when the optional fig ingredient is a broken or split fig. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or in lieu of the word ''Spice'', the common name of the spice, ''Seasoned with vinegar'' or ''Seasoned with unpeeled segments of citrus fruits''. When two or more of the optional ingredients specified in paragraphs (a) (2) through (5), inclusive, of this section are used, such words may be combined as for example, ''Seasoned with cider vinegar, cloves, cinnamon oil and unpeeled segments of citrus fruits.''

(2) The name of the packing medium as used in paragraph (c)(1) of this section, preceded by ''In'' or ''Packed in'', as provided in paragraph (c) of this section, shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food other than sweetness, as for example, a mixture of brown sugar and honey, the statement ''_____ sirup of brown sugar and honey'' the blank to be filled in with the word ''light'', ''heavy'', or ''extra heavy'', as the case may be, shall be included as part of the name or in close proximity to the name of the food. When the liquid portion of the packing media provided for in paragraphs (c) (1) and (2) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(i) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'';

(ii) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (d)(3) of this section; and

(iii) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (d)(3) of this section.

(3) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (d)(2)(ii) of this section, such names and the words ''from contrate'', as specified in paragraph (d)(2)(iii) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2879, Jan. 6, 1993]

§ 145.131 Artificially sweetened canned figs.

(a) Artificially sweetened canned figs is the food which conforms to the definition and standard of identity prescribed for canned figs by §145.130, except that in lieu of a packing medium

specified in §145.130(c), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is ''artificially sweetened _____'', the blank being filled in with the name prescribed by §145.130 for canned figs having the same optional fig ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned figs by §145.130. If the packing medium is thickened with pectin, the label shall bear the statement ''thickened with pectin''. When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

§ 145.134 Canned preserved figs.

(a) Canned preserved figs is the food prepared from one of the optional fig ingredients specified in paragraph (b) of this section and the packing medium specified in paragraph (c) of this section, to which citric acid or lemon juice or concentrated lemon juice is added, if necessary, in such quantity as to reduce the pH of the finished product to 4.9 or below. The figs are precooked in the packing medium, sealed in a container, and so processed by heat, either before or after sealing, as to prevent spoilage.

(b) The optional fig ingredients referred to in paragraph (a) of this section are whole mature figs of the light or dark varieties that may be either peeled or unpeeled.

(c)(1) The packing medium referred to in paragraph (a) of this section is prepared from water and one of the following optional sweetening ingredients:

(i) Sugar.

(ii) Invert sugar sirup.

(iii) Any mixture of optional sweetening ingredients designated in paragraphs (c)(1) (i) and (ii) of this section.

(iv) Any of the optional sweetening ingredients designated in paragraphs (c)(1) (i), (ii), and (iii) of this section with dextrose: *Provided,* That the weight of the solids of dextrose does not exceed one-third of the total weight of the solids of the combined sweetening ingredients.

(v) Any of the optional sweetening ingredients designated in paragraphs (c)(1) (i), (ii), and (iii) of this section with corn sirup or with dried corn sirup or with glucose sirup or with dried glucose sirup, or with any two or more of these: *Provided,* That the weight of the solids of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup or the sum of the weights of the solids of corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup, in case two or more of these are used, does not exceed one-fourth of the total weight of the solids of the combined sweetening ingredients.

(vi) Any mixture of the optional ingredients designated in paragraphs (c)(1) (iv) and (v) of this section.

(2) The density of the packing medium described in paragraph (c)(1) of this section, as measured on the Brix hydrometer 15 days or more after the figs are canned, is not less than 50° and not more than 55°.

(d)(1) The name of the food is ''Preserved Figs—Precooked in Sirup''. For the purpose of label declaration, the words ''Precooked in Sirup'' may appear immediately below the words ''Preserved Figs'', but there shall be no intervening written, printed, or graphic matter, and the letters used for the words ''Precooked in Sirup'' shall be of the same type style and not less than one-half the height of the letters in the words ''Preserved Figs''.

(2) The label shall indicate which optional fig ingredient specified in paragraph (b) of this section is used.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words herein specified, showing the optional fig ingredient used, shall immediately and conspicuously precede or follow such name without intervening written,

printed, or graphic matter, except that the varietal name of the figs may so intervene.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

§ 145.135 Canned fruit cocktail.

(a) *Identity*—(1) *Ingredients.* Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail, is the food prepared from the mixture of fresh, frozen, or previously canned fruit ingredients of mature fruits in the forms and proportions as provided in paragraph (a)(2) of this section, and one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Ascorbic acid in an amount no greater than necessary to preserve color. Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Varietal types and styles.* The fruit ingredients referred to in paragraph (a)(1) of this section, the forms of each, and the percent by weight of each in the mixture of drained fruit from the finished canned fruit cocktail are as follows:

(i) *Peaches.* Any firm yellow variety of the species *Prunus persica* L., excluding nectarine varieties, which are pitted, peeled, and diced, not less than 30 percent and not more than 50 percent.

(ii) *Pears.* Any variety, of the species *Pyrus communis* L. or *Pyrus sinensis* L., which are peeled, cored, and diced, not less than 25 percent and not more than 45 percent.

(iii) *Pineapples.* Any variety, of the species *Ananas comosus* L., which are peeled, cored, and cut into sectors or into dice, not less than 6 percent and not more than 16 percent.

(iv) *Grapes.* Any seedless variety, of the species *Vitis vinifera* L., or *Vitis labrusca* L., not less than 6 percent and not more than 20 percent.

(v) *Cherries.* Approximate halves or whole pitted cherries of the species *Prunus cerasus* L., not less than 2 percent and not more than 6 percent, of the following types:

(*a*) Cherries of any light, sweet variety;

(*b*) Cherries artificially colored red; or

(*c*) Cherries artificially colored red and flavored, natural or artificial.

Provided, That each 127.5 grams (4½ ounces avoirdupois) of the finished canned fruit cocktail and each fraction thereof greater than 56.7 grams (2 ounces avoirdupois) contain not less than 2 sectors or 3 dice of pineapple and not less than 1 approximate half of the optional cherry ingredient.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in § 145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is 10 percent or more, but less than 14 percent, the medium shall be designated as ''slightly sweetened water''; or ''extra light sirup''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(*b*) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(*c*) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(*d*) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(4) *Labeling requirements.* (i) The name of the food is ''fruit cocktail'', ''cocktail fruits'', or ''fruits for cocktail''. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or in lieu of the word ''Spice'', the common name of the spice, ''Seasoned with vinegar'' or ''Seasoned with lemon juice''. When two or more of the optional ingredients specified in paragraphs (a)(1) (ii) and (iii) of this section are used, such words may be combined as for example, ''Seasoned with cider vinegar, cloves, cinnamon oil and lemon juice''.

(ii) The name of the packing medium as used in paragraphs (a)(3) (i) and (ii) of this section, preceded by ''In'' or ''Packed in'' shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example, in the case of a mixture of brown sugar and honey, an appropriate statement would be ''_____ sirup of brown sugar and honey'' the blank to be filled in with the word ''light'', ''heavy'', or ''extra heavy'' as the case may be. When the liquid portion of the packing media provided for in paragraphs (a)(3) (i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'';

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section; and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(*b*) of this section, such names and the words ''from concentrate'', as specified in paragraph (a)(4)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(iv) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned fruit cocktail is as follows:

(i) Not more than 20 percent by weight of the units in the container of peach or pear, or of pineapple if the units thereof are diced, are more than ¾ inch in greatest edge dimension, or pass through the meshes of a sieve designated as 5/16 inch that complies with the specifications for such cloth set forth in the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory

Notes,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* If the units of pineapple are in the form of sectors, not more than 20 percent of such sectors in the container fail to conform to the following dimensions: The length of the outside arc is not more than ¾ inch but is more than ⅜ inch; the thickness is not more than ½ inch but is more than 5⁄16 inch; the length (measured along the radius from the inside arc to the outside arc) is not more than 1¼ inches but is more than ¾ inch.

(ii) Not more than 10 percent of the grapes in a container containing 10 grapes or more, and not more than 1 grape in a container containing less than 10 grapes, are cracked to the extent of being severed into two parts or are crushed to the extent that their normal shape is destroyed.

(iii) Not more than 10 percent of the grapes in a container containing 10 grapes or more, and not more than a grape in a container containing less than 10 grapes, have the cap stem attached.

(iv) There is present in the finished canned fruit cocktail not more than 1 square inch of pear peel per each 1 pound of drained weight of units of pear plus the weight of a proportion of the packing medium which is the same proportion as the drained weight of the units of pear bears to the drained weight of the entire contents of the can. Such drained weights shall be determined by the method prescribed in paragraph (c) of this section.

(v) There is present in the finished canned fruit cocktail not more than 1 square inch of peach peel per each 1 pound of drained weight of units of peach plus the weight of a proportion of the packing medium which is the same proportion as the drained weight of units of peach bears to the drained weight of the entire contents of the can. Such drained weights shall be determined by the method prescribed in paragraph (c) of this section.

(vi) Not more than 15 percent of the units of cherry ingredient, and not more than 20 percent of the units of peach, pear, or grape, in the container are blemished with scab, hail injury, scar tissue or other abnormality.

(vii) If the cherry ingredient is artificially colored, the color of not more than 15 percent of the units thereof in a container containing more than six units and of not more than one unit in a container containing six units or less, is other than evenly distributed in the unit or other than uniform with the color of the other units of the cherry ingredient.

(2) If the quality of canned fruit cocktail falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified.

(c) *Fill of container.* (1) The standard of fill of container for canned fruit cocktail is a fill such that the total weight of drained fruit is not less than 65 percent of the water capacity of the container, as determined by the general method for water capacity of containers prescribed in §130.12(a) of this chapter. Such total weight of drained fruit is determined by the following method: Tilt the opened container so as to distribute the contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth under ''2.38 mm (No. 8)'' in Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' prescribed in paragraph (b)(1)(i) of this section, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1)(i) of this section. Without shifting the material on the sieve so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and drained fruit. The weight so found, less the

weight of the sieve, shall be considered to be the total weight of drained fruit.

(2) If canned fruit cocktail falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein prescribed.

[42 FR 14414, Mar. 15, 1977, as amended at 47 FR 11829, Mar. 19, 1982; 49 FR 10100, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2880, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 145.136 Artificially sweetened canned fruit cocktail.

(a) Artificially sweetened canned fruit cocktail is the food which conforms to the definition and standard of identity prescribed for canned fruit cocktail by §145.135(a), except that in lieu of a packing medium specified in §145.135(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is ''artificially sweetened fruit cocktail''.

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned fruit cocktail by §145.135(a). If the packing medium is thickened with pectin, the label shall bear the statement ''thickened with pectin''. When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

§ 145.140 Canned seedless grapes.

(a) *Ingredients.* Canned seedless grapes is the food prepared from one of the fresh or previously canned optional grape ingredients specified in paragraph (b) of this section which may be packed in one of the optional packing media specified in paragraph (c) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(1) Natural and artificial flavors.

(2) Spice.

(3) Vinegar, lemon juice, or organic acids.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(b) *Varietal types and styles.* The optional grape ingredients referred to in paragraph (a) of this section are prepared from stemmed grapes of the light or dark seedless varieties or from unstemmed clusters of such grapes. For the purposes of paragraph (d) of this section, the names of such optional grape ingredients are ''light seedless grapes'' or ''dark seedless grapes'', as the case may be, preceded by the words ''unstemmed clusters'' where applicable.

(c) *Packing media.* (1) The optional packing media referred to in paragraph (a) of this section, as defined in §145.3 are:

(i) Water.

(ii) Fruit juice(s) and water.

(iii) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in §145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in §145.3.

(2) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in §145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(i) When the density of the solution is less than 14 percent, the medium shall be designated as ''slightly sweetened water''; or ''extra light sirup''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(ii) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(iii) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(iv) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(d) *Labeling requirements.* (1) The name of the food is ''seedless grapes.'' The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or in lieu of the word ''Spice'', the common name of the spice, or ''Seasoned with lemon juice''. When two or more of the optional ingredients specified in paragraphs (a) (2) and (3) of this section are used, such words may be combined as for example, ''Seasoned with cider vinegar, cloves, and cinnamon oil''.

(2) The color type and style of the grape ingredient as provided in paragraph (b) of this section and the name of the packing medium specified in paragraphs (c) (1) and (2) of this section, preceded by ''In'' or ''Packed in'' or the words ''solid pack'', where applicable, shall be included as part of the name or in close proximity to the name of the food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be ''_____ sirup of brown sugar and honey'' the blank to be filled in with the word ''light'', ''heavy'', or ''extra heavy'' as the case may be. When the liquid portion of the packing media provided for in paragraphs (c) (1) and (2) of this section consists of fruit juice(s), such juice(s) shall be designated in the packing medium as:

(i) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'';

(ii) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (d)(3) of this section; and

(iii) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (d)(3) of this section.

(3) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (d)(2)(ii) of this section, such names and the words ''from concentrate'', as specified in paragraph (d)(2)(iii) of this section, shall appear in an ingredient statement pursuant to the requirements of § 101.3(d) of this chapter.

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

§ 145.145 Canned grapefruit.

(a) *Identity*—(1) *Product identification.* Canned grapefruit is the food prepared from one of the optional grapefruit ingredients specified in paragraph (a)(2) of this section and one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one or more of the following safe and suitable optional ingredients:

(i) Spices.

(ii) Natural and artificial flavoring.

(iii) Lemon juice.

(iv) Citric acid.

(v) Calcium chloride or calcium lactate or a mixture of the two calcium salts in a quantity reasonably necessary to firm the grapefruit sections, but in no case in a quantity such that the calcium contained in such calcium salt or mixture is more than 0.035 percent by weight of the finished food.

Such food is sealed in a container and, before or after sealing, is so processed by heat as to prevent spoilage.

(2) *Optional grapefruit ingredient.* The optional grapefruit ingredients referred to in paragraph (a)(1) of this section are prepared from sound, mature grapefruit (*Citrus paradisi* Macfadyen) of the color types white—produced from white-fleshed grapefruit, and pink—produced from pink or red-fleshed grapefruit and are in the following forms of units: Whole sections or broken sections. Each such form of units or a mixture of such forms of units prepared from a single varietal group (color type) is an optional grapefruit ingredient. The core, seeds, and major portions of membrane of such ingredient are removed. For the purpose of this section, a grapefruit section is considered whole when the unit is intact or an intact portion of such unit is not less than 75 percent of its apparent original size and is not excessively trimmed.

(i) For the purpose of paragraph (a)(4) of this section, the name of the optional grapefruit ingredient is:

(*a*) ''Section'' or ''segments'', if 50 percent or more of the drained weight of the food consists of whole sections.

(*b*) ''Broken sections'' or ''broken segments'', if less than 50 percent of the drained weight of the food consists of whole sections.

(ii) The drained weight is determined by the method prescribed in the standard of fill of container for canned grapefruit set forth in paragraph (c)(2) of this section.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section are:

(*a*) Water.

(*b*) Grapefruit juice and water.

(*c*) Grapefruit juice.

(*d*) Slightly sweetened sirup or slightly sweetened water.

(*e*) Light sirup.

(*f*) Heavy sirup.

(*g*) Slightly sweetened grapefruit juice and water.

(*h*) Lightly sweetened grapefruit juice and water.

(*i*) Heavily sweetened grapefruit juice and water.

(*j*) Slightly sweetened grapefruit juice.

(*k*) Lightly sweetened grapefruit juice.

(*l*) Heavily sweetened grapefruit juice.

As used in paragraph (a)(3)(i) of this section, the optional packing medium ''water'' means, in addition to water, any mixture of water and grapefruit juice in which there is less than 50 percent grapefruit juice; the optional packing medium ''grapefruit juice and water'' means the liquid packing medium in which juice of mature grapefruit and water are combined as a liquid packing medium with not less than 50 percent grapefruit juice and the term ''grapefruit juice'' means single strength expressed juice of sound, mature fruit. It may be fresh, canned, or made from concentrate. However, if it is made from concentrate, the juice shall be reconstituted with water to not less than the soluble solids the grapefruit juice had before concentration.

(ii) Each of the packing media in paragraph (a)(3)(i) (*d*) to (*l*) of this section is prepared with a liquid ingredient and one or more safe and suitable nutritive carbohydrate sweeteners. Water is the liquid ingredient from which packing media in paragraph (a)(3)(i) (*d*) to (*f*) of this section are prepared. Grapefruit juice and water are the liquid ingredients from which the packing media in paragraph (a)(3)(i) (*g*) to (*i*) of this section are prepared. Grapefruit juice is the liquid ingredient from which the packing media in paragraph (a)(3)(i) (*j*) to (*l*) of this section are prepared. If one or more liquid nutritive carbohydrate sweeteners and grapefruit juice are combined as a liquid packing medium with not less than 50 percent grapefruit juice, the packing medium is as set forth in paragraph (a)(3)(i) (*g*) to (*i*) of this section.

(iii) The respective densities of packing media in paragraph (a)(3)(i) (*d*) to (*i*) of this section as measured on the

refractometer, expressed as percent by weight sucrose (degrees Brix) with correction for temperature to the equivalent at 20 °C (68 °F), 15 days or more after the grapefruit are canned or the blended homogenized slurry of the comminuted entire contents of the container if canned for less than 15 days, according to the ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), section 31.011 under ''Solids By Means of Refractometer—Official Final Action,'' and Reference Tables, section 52.012 (Refractive indices (n) of sucrose solutions at 20°) and section 52.015 (Refractive indices of invert sugar solutions), which is incorporated by reference (copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*), but without correction for invert sugar or other substances, are as follows:

(*a*) Packing media in paragraph (a)(3)(i) (*d*), (*g*), and (*j*) of this section: Twelve percent or more but less than 16 percent.

(*b*) Packing media in paragraph (a)(3)(i) (*e*), (*h*), and (*k*) of this section: Sixteen percent or more but less than 18 percent.

(*c*) Packing media in paragraph (a)(3)(i) (*f*), (*i*), and (*l*) of this section: Eighteen percent or more. A lot shall be deemed to be in compliance for packing medium density based on the average value for all the samples analyzed according to paragraph (b)(2) of this section but no container may have a value lower than that of the next lower category or 2 percent by weight sucrose (degrees Brix) lower if no lower category exists.

(4) *Labeling requirements.* (i) The name of the food is ''grapefruit'' or ''pink grapefruit'', as appropriate for the color type of the grapefruit used. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''with added spice''. Whenever the word ''sirup'' is used, it may be alternatively spelled ''syrup''. When two or more of the optional ingredients specified in paragraphs (a)(1) (i), (ii), and (iii) of this section are used, such words may be combined; for example, ''with added cloves and cinnamon oil''.

(ii) The form and style of the grapefruit ingredient as provided for in paragraph (a)(2) of this section and the name of the packing medium as used in paragraph (a)(3) of this section preceded by ''In'' or ''Packed in'' shall be included as part of the name. When the packing medium is prepared from concentrated grapefruit juice, the words ''from concentrate'' shall follow the words ''grapefruit juice'' in the name of the packing medium.

(iii) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned grapefruit is as follows:

(i) The food is free from extraneous material such as leaves, portions of leaves, and pieces of peel.

(ii) The finished food contains per 500 grams (17.6 ounces) not more than:

(*a*) An aggregate area of 20 square centimeters (3.1 square inches) of tough membrane or albedo on the units.

(*b*) Four developed seeds. A seed is considered a developed seed when it measures more than 9.0 millimeters (0.35 inches) in any dimension.

(iii) Not more than 15 percent by weight of the drained grapefruit may be blemished units. A blemished unit is a grapefruit section or any portion thereof which is damaged by lye peeling, by discoloration, or by other visible injury. The drained weight is determined by the method prescribed in the standard of fill of container for canned grapefruit set forth in paragraph (c)(2) of this section.

(2) *Sampling and acceptance procedure.* A lot is to be considered acceptable when the number of ''defectives'' does not exceed the acceptance number in the sampling plans given in paragraph (b)(2)(ii) of this section.

(i) Definitions of terms to be used in the sampling plans in paragraph (b)(2)(ii) of this section are as follows:

(*a*) *Lot*. A collection of primary containers or units of the same size, type and style manufactured or packed under similar conditions and handled as a single unit of trade.

(*b*) *Lot size*. The number of primary containers or units in the lot.

(*c*) *Sample size* (*n*). The total number of sample units drawn for examination from a lot.

(*d*) *Sample unit*. A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(*e*) *Defective*. Any sample unit shall be regarded as defective when any of the defects or conditions specified in the quality standard (paragraph (b)(1) of this section) and paragraph (c)(3)(i) of this section for minimum fill of container are present in excess of the stated tolerances.

(*f*) *Accepted number* (*c*). The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(*g*) *Acceptable quality level* (*AQL*). The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(ii) Sampling plans and acceptance procedure:

Lot size (primary containers)	Size of container	
	n[1]	c[2]
NET WEIGHT EQUAL TO OR LESS THAN 1 KG (2.2 LB)		
4,800 or less	13	2
4,801–24,000	21	3
24,001–48,000	29	4
48,001–84,000	48	6
84,001–144,000	84	9
144,001–240,000	126	13
Over 240,000	200	19
NET WEIGHT GREATER THAN 1 KG (2.2 LB) BUT NOT MORE THAN 4.5 KG (10 LB)		
2,400 or less	13	2
2,401–15,000	21	3
15,001–24,000	29	4
24,001–42,000	48	6
42,001–72,000	84	9
72,001–120,000	126	13
Over 120,000	200	19
NET WEIGHT GREATER THAN 4.5 KG (10 LB)		
600 or less	13	2
601–2,000	21	3
2,001–7,200	29	4
7,201–15,000	48	6
15,001–24,000	84	9
24,001–42,000	126	13
Over 42,000	200	19

[1] n = number of primary containers in sample
[2] c = acceptance number

(3) If the quality of canned grapefruit falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned grapefruit falls below standard with respect to only one of the factors of quality specified by paragraph (b)(1) (i), (ii), or (iii) of this section, there may be substituted for the second line of such general statement of substandard quality, ''Good Food—Not High Grade'', a new line as specified after the corresponding designation of paragraph (b)(1) of this section which the canned grapefruit fail to meet:

(i) ''Contains extraneous material''.

(ii)(*a*) ''Excessive tough membrane''.

(*b*) ''Excessive seeds''.

(iii) ''Excessive blemished units''.

(c) *Fill of container*. (1) The standard of fill of container for canned grapefruit is:

(i) The fill of grapefruit and packing medium, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(ii) The drained weight of grapefruit ingredient is not less than 50 percent of the water capacity of the container, as determined by the method prescribed in paragraph (c)(2) of this section and the general method for water capacity of containers prescribed in §130.12(a) of this chapter.

(2) Drained weight is determined by the following method: Tilt the opened container so as to distribute the contents evenly over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve is

20.3 centimeters (8 inches) if the quantity of contents of the container is less than 1.4 kilograms (3 pounds) and 30.5 centimeters (12 inches) if such quantity is 1.4 kilograms (3 pounds) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for the No. 8 sieve set forth in the ''Definitions of Terms and Explanatory Notes'' of the AOAC, 13th Ed. (1980), Table 1, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(3)(iii) of this section. Without shifting the material on the sieve, incline the sieve at an angle of 17° to 20° to facilitate drainage. Two minutes after the drainage begins, weigh the sieve and drained grapefruit. The weight so found, less the weight of the sieve, shall be considered to be the weight of the drained grapefruit.

(3)(i) A container that falls below the requirement for minimum fill prescribed in paragraph (c)(1)(i) of this section shall be considered a ''defective''. The food will be deemed to fall below the standard of fill when the number of defectives exceeds the acceptance number (c) in the sampling plans prescribed in paragraph (b)(2) of this section.

(ii) Canned grapefruit will be deemed to fall below the standard of fill when the average drained weight of all containers analyzed when sampled according to the sampling plans prescribed in paragraph (b)(2) of this section is less than that prescribed in paragraph (c)(1)(ii) of this section.

(4) If canned grapefruit falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14414, Mar. 15, 1977, as amended at 47 FR 11830, Mar. 19, 1982; 49 FR 10100, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2880, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 145.170 Canned peaches.

(a) *Identity*—(1) *Ingredients.* Canned peaches is the food prepared from one of the fresh, frozen, or previously canned optional peach ingredients *Prunus persica* L., of commercial canning varieties, but excluding nectarine varieties, specified in paragraph (a)(2) of this section, which may be packed as a solid pack or in one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Peach pits, except in the cases of peeled whole peaches, in a quantity not more than 1 peach pit to each 227 grams (8 ounces) of finished canned peaches.

(v) Peach kernels, except in the cases of peeled whole peaches and except when the optional ingredient in paragraph (a)(1)(iv) of this section is used.

(vi) Ascorbic acid in an amount no greater than necessary to preserve color. Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Varietal types and styles.* The optional peach ingredients referred to in paragraph (a)(1) of this section are prepared from mature peaches of the following optional varietal and color types and styles of peach ingredients; namely:

(i) *The optional varietal types.* (*a*) Freestone is the distinct varietal type where the pit separates readily from the flesh.

(*b*) Clingstone is the distinct varietal type where the pit adheres to the flesh.

(ii) *The optional color types*—(*a*) *Yellow*—the varietal types in which the predominant color ranges from pale yellow to rich red orange.

(*b*) *White*—the varietal types in which the predominant color ranges from white to yellow-white.

(*c*) *Red*—the varietal types in which the predominant color ranges from pale yellow to orange red and with variegated red coloring other than that associated with the pit cavity.

(*d*) *Green*—varietal types in which the flesh has a green tint even when mature.

(iii) *The optional styles of the peach ingredients—(a) Whole*—consisting of whole peeled unpitted peaches.

(*b*) *Halves*—consisting of peeled pitted peaches cut into two approximately equal parts.

(*c*) *Halves and pieces*—consisting of a mixture in which the peeled pitted peach halves are more than 50 percent by weight.

(*d*) *Quarters*—consisting of peeled pitted peaches cut into four approximately equal parts.

(*e*) *Slices*—consisting of peeled pitted peaches cut into wedge-shaped sectors.

(*f*) *Dice*—consisting of peeled pitted peaches cut into cube-like parts.

(*g*) *Chunky*—consisting of peeled pitted peaches cut into parts 13 millimeters (0.5 inch) or greater in the smallest dimension and 44 millimeters (1.75 inches) or less in the largest dimension.

(*h*) *Pieces or irregular pieces*—consisting of peeled pitted peaches cut into parts of irregular shapes and sizes.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in §145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in §145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in §145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium, expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in §145.3(m), shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is 10 percent or more but less than 14 percent, the medium shall be designated as ''slightly sweetened water''; or ''extra light sirup''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(*b*) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(*c*) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(*d*) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'' as the case may be.

(4) *Labeling requirements.* (i) The name of the food is ''peaches''. The optional varietal type as set forth in paragraph (a)(2)(i) of this section shall be a part of the name. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or in lieu of the word ''Spice'', the common name of the spice, ''Seasoned with vinegar'' or ''Seasoned with peach kernels''. When two or more of the optional ingredients specified in paragraphs (a)(1)(ii) through (v) of this section are used, such words may be combined as for example, ''Seasoned with cider vinegar, cloves, cinnamon oil and peach kernels''.

(ii) The color type and style of the peach ingredient as provided for in paragraphs (a)(2) (ii) and (iii) of this section and the name of the packing medium specified in paragraphs (a)(3)(i) and (ii) of this section, preceded by ''In'' or ''Packed in'' or the words ''Solid pack'', where applicable, shall be included as part of the name or in close proximity to the name of the food, except that ''Halves'' may be alternately designated as ''Halved'', ''Halves and pieces'' as ''Halved and pieces'', ''Quarters'' as ''Quartered'', ''Slices'' as ''Sliced'', and ''Dice'' as ''Diced''. Pieces or irregular pieces

shall be designated ''Pieces'', ''Irregular pieces'', or ''Mixed pieces of irregular sizes and shapes''. ''Chunky'' may be designated as ''Chunks''. The terms ''Cling'' and ''Free'' may be used as optional designations for ''Clingstone'' and ''Freestone'', respectively. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor, or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s); as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be ''_____ sirup of brown sugar and honey'' the blank to be filled in with the word ''light'', ''heavy'', or ''extra heavy'' as the case may be. When the liquid portion of the packing media provided for in paragraphs (a)(3) (i) and (ii) of this section consists of fruit juices(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'';

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section; and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juices(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(*b*) of this section, such names and the words ''from concentrate'', as specified in paragraph (a)(4)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(iv) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned peaches is as follows:

(i) *Maturity.* All units tested in accordance with the method prescribed in paragraph (b)(2) of this section are pierced by weight of not more than 300 grams (10.6 ounces).

(ii) *Minimum size.* In the case of halves and quarters styles, the weight of each unit is not less than 17 grams (0.6 ounce) and 8.5 grams (0.3 ounce), respectively.

(iii) *Uniformity of size—*(*a*) *Whole, halves, and quarters.* In the case of whole, halves, and quarters styles, the diameter (width) of the largest unit is not more than 1.5 centimeters (0.6 inch) greater than the diameter (width) of the smallest unit. In containers with more than 20 units, 2 units may be disregarded in making the determination. Where a unit has broken in the container, the combined broken pieces are to be reassembled to approximate a single unit of the appropriate style.

(*b*) *Chunky.* In the case of chunky style, not more than 25 percent of the drained weight of the contents of the container consists of units that will pass through an opening 13 millimeters (0.5 inch) wide or that are more than 44 millimeters (1.75 inches) along the longest cut edge.

(iv) *Peel.* Not more than 15 square centimeters aggregate area of peel per 1,000 grams (1.05 square inches per 16 ounces) of net weight. Include any peel adhering to the peach or loose in the container.

(v) *Blemished units.* Not more than 20 percent by count of the units in the container are blemished, e.g., with scab, hail injury, discoloration, or other abnormalities. Blemished units are units which contain surface discolorations that definitely contrast with the overall color and may penetrate into the flesh.

(vi) *Trimmed units.* In the case of whole, halves, quarters, and slices styles, all units are untrimmed or are so trimmed as to preserve normal shape of the units.

(vii) *Crushed or broken units.* In the case of whole, halves, halves and pieces, quarters, slices, dice and chunky styles, not more than 5 percent

by count of the units in containers of 20 or more units and not more than 1 unit in containers of fewer than 20 units are crushed or broken. A unit that has lost its normal shape because of ripeness and bears no mark of crushing shall not be considered crushed or broken.

(viii) *Pits and pieces of pit.* In the case of all styles, except whole peaches and when whole peach pits or peach kernels are used as seasoning ingredients, there is not more than one loose pit or one loose large hard piece of pit (10 millimeters (⅜ inch) or larger) or one unit of peach (e.g., peach half or peach slice) to which one or more large hard pieces of pit are attached per 5.67 kilograms (200 ounces) net weight. In addition, there is not more than three of any one or any combination of two or more, per 2.83 kilograms (100 ounces) net weight of the following: (*a*) A unit to which one or more small hard pieces of pit less than 10 millimeters (⅜ inch) but not less than 1.6 millimeters (1/16 inch) are attached, (*b*) a unit to which three or more small pieces of pit less than 1.6 millimeters (1/16 inch) are attached, or (*c*) a loose small hard piece of pit less than 10 millimeters (⅜ inch).

(2) Canned peaches shall be tested by the following method to determine whether or not they meet the requirements of paragraph (b)(1)(i) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 29 millimeters (1.125 inches) inside diameter, with vertical sides; or rectangular in shape, 19 millimeters (0.75 inch) by 25 millimeters (1 inch) inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of 19 millimeters (0.75 inch). Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with a rectangular peel surface at least 13 millimeters (0.51 inch) by 25 millimeters (1 inch) cannot be trimmed. Test the piece by means of a round metal rod 4 millimeters (0.16 inch) in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams (3.53 ounces). Set the receptacle so that the surface of test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams (0.45 ounce) per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(3) Determine compliance as specified in §145.3(o) except that a lot shall be deemed to be in compliance for peel, pits, and pieces of pit based on the average of all samples analyzed according to the sampling plans set out in §145.3(p).

(4) If the quality of canned peaches falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality defined in §130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned peaches falls below standard with respect to only one of the factors of quality specified in paragraph (b)(1) (i) through (viii) of this section, there may be substituted for the second line of such general statement of substandard quality (''Good Food—Not High Grade'') a new line, as specified after the corresponding designation of paragraph (b)(1) of this section which the canned peaches fail to meet, as follows: (i) ''Not tender''; (ii) ''Small halves'' or ''Small quarters'' as the case may be; (iii) (*a*) ''Mixed sizes''; (*b*) ''Undersized and/or oversized pieces'', (iv) ''Excess peel''; (v) ''Blemished'';

(vi) ''Unevenly trimmed''; (vii) ''Partly crushed or broken''; (viii) ''Contains pits or pit fragments''. Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name ''peaches'' and any words and statements required or authorized to appear with such name by paragraph (a)(2) of this section.

(c) *Fill of container.* (1) The standard of fill of container for canned peaches is the maximum quantity of the optional peach ingredient that can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(2) If canned peaches fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14414, Mar. 15, 1977, as amended at 46 FR 33028, June 26, 1981; 50 FR 34677, Aug. 27, 1985; 51 FR 11434, Apr. 3, 1986; 58 FR 2880, Jan. 6, 1993]

§ 145.171 Artificially sweetened canned peaches.

(a) Artificially sweetened canned peaches is the food which conforms to the definition and standard of identity prescribed for canned peaches by §145.170(a), except that in lieu of a packing medium specified in §145.170(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is ''artificially sweetened _____'', the blank being filled in with the name prescribed by §145.170(a) for canned peaches having the same optional peach ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned peaches by §145.170(a). If the packing medium is thickened with pectin, the label shall bear the statement ''thickened with pectin''. When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

§ 145.175 Canned pears.

(a) *Identity*—(1) *Ingredients.* Canned pears is the food prepared from one of the fresh or previously canned optional pear ingredients *Pyrus communis* or *Pyrus sinensis* specified in paragraph (a)(2) of this section which may be packed in one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients.

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Artificial colors.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Styles and forms of units.* The optional pear styles and forms of units referred to in paragraph (a)(1) of this section are:

(i) *Whole*—consisting of peeled or unpeeled pears with cores removed or left in.

(ii) *Halves*—consisting of peeled or unpeeled pears with cores removed and cut into two approximately equal parts.

(iii) *Quarters*—consisting of peeled pears with cores removed and cut into four approximately equal parts.

(iv) *Slices*—consisting of peeled pears with cores removed and cut into wedge-shaped sectors.

(v) *Dice*—consisting of peeled pears with cores removed and cut into cube-like parts.

(vi) *Pieces or irregular pieces*—consisting of peeled pears with cores removed and cut into parts of irregular shapes and sizes.

(vii) *Chunky*—consisting of peeled pears with cores removed and cut into parts 13 millimeters (0.51 inch) or

greater in the smallest dimension and 44 millimeters (1.75 inches) or less in the largest dimension.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in §145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

(*d*) Clarified juice.

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in §145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in §145.30.

(ii) If the concentration of clarified juice is such that the packing medium forms to the density range for one of the sirups under paragraph (a)(3)(ii) (*a*), (*b*), (*c*), or (*d*) of this section, the concentrated clarified juice is considered to be light sirup, heavy sirup, or extra heavy sirup, as the case may be. When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure in §145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is less than 14 percent, the medium shall be designated as ''slightly sweetened water''; or ''extra light sirup''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(*b*) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'' as the case may be.

(*c*) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(*d*) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(4) *Labeling requirements.* (i) The name of the food is ''pears''. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or in lieu of the word ''Spice'', the common name of the spice, ''Seasoned with vinegar''. When two or more of the optional ingredients specified in paragraphs (a)(1) (ii) and (iii) of this section are used, such words may be combined as for example, ''Seasoned with cider vinegar, cloves, and cinnamon oil''.

(ii) The style and forms of units of the pear ingredient as provided in paragraph (a)(2) of this section and the name of the packing medium specified in paragraph (a)(3) (i) and (ii) of this section, preceded by ''In'' or ''Packed in'' or the words ''Solid pack'', where applicable, shall be included as part of the name or in close proximity to the name of the food, except that ''Halves'' may be alternatively designated as ''Halved'', ''Quarters'' as ''Quartered'', ''Slices'' as ''Sliced'', and ''Dice'' as ''Diced''. ''Pieces'' or ''Irregular pieces'' shall be designated as ''Pieces'', ''Irregular pieces'', or ''Mixed pieces of irregular sizes and shapes''. ''Chunky'' may be designated as ''Chunks''. The style of the pear ingredient shall be preceded or followed by ''Unpeeled'' when the units are whole or halves and are unpeeled. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be ''_____ sirup of brown sugar and honey'' the blank to be filled in with the word ''light'', ''heavy'', or ''extra

heavy'', as the case may be. When the liquid portion of the packing media provided for in paragraphs (a)(3) (i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'';

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section; and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(*b*) of this section, such names and the words ''from concentrate'', as specified in paragraph (a)(4)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(iv) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned pears is as follows:

(i) *Maturity.* All units tested in accordance with the method prescribed in paragraph (b)(2) of this section are pierced by a weight of not more than 300 grams (10.6 ounces).

(ii) *Minimum size.* In the case of halves and quarters styles, the weight of each unit is not less than 17 grams (0.6 ounce) and 8.5 grams (0.3 ounce), respectively.

(iii) *Uniformity of size—(a) Whole, halves, and quarters.* In the case of whole, halves, and quarters styles, among those units comprising 95 percent by count of those present in the container that are most uniform in size, the weight of the largest unit is not more than twice the weight of the smallest unit. In containers with fewer than 20 units, 1 unit may be disregarded in making the determination. Where a unit has broken in the container, reassemble the broken pieces to approximate a single unit of the appropriate style.

(*b*) *Chunky.* In the case of chunky style, not more than 25 percent of the drained weight of the contents of the container consists of units that will pass through an opening 13 millimeters (0.51 inch) wide or that are more than 44 millimeters (1.75 inches) along the longest cut edge.

(iv) *Peel (except unpeeled style).* Not more than 10 square centimeters (1.6 square inches) of peel adhering to pears or loose in the container per kilogram (35.3 ounces) of net weight.

(v) *Blemished units.* Not more than 20 percent by count of the units in the container are blemished with scab, hail injury, discoloration, or other abnormality aggregating the area of a circle more than 6.5 millimeters (0.25 inch) in diameter; corky or hard spots on outer surfaces aggregating the area of a circle more than 13 millimeters (0.51 inch) in diameter; or dark brown areas aggregating the area of a circle less than 6.5 millimeters (0.25 inch) in diameter which penetrate into the flesh or affect the appearance of the unit.

(vi) *Trimmed units.* In the case of whole, halves, and quarters styles, all units are untrimmed or are so trimmed as to preserve normal shape of the unit.

(vii) *Crushed or broken units.* In the case of whole, halves, quarter, slices, dice, and chunky styles, not more than 10 percent by count of the units in containers of 10 or more units and not more than 1 unit in containers of less than 10 units are crushed or broken. A unit that lost its normal shape because of ripeness and bears no mark of crushing shall not be considered to be crushed or broken.

(viii) *Loose core material in all styles except uncored whole style.* Not more than two units of loose core material per kilogram (35.3 ounces) of net weight. A unit of such material is defined as a portion of loose core, with or

without seeds, aggregating approximately one-half of a pear core.

(ix) *Partially cored units in all styles except uncored whole style.* Not more than 40 percent by count partially cored units in halves, quarters, slices, and pieces or irregular pieces styles and not more than 5 percent by weight in dice style. A partially cored unit is a unit of pear that contains an attached portion of the seed cell cavity.

(x) *Seeds in all styles except whole uncored style.* Not more than 8 seeds or the equivalent in pieces of seeds per kilogram (35.3 ounces) of net weight. Seeds included as cored material in paragraph (b)(1) (viii) and (ix) of this section shall not be counted a second time.

(2) Canned pears shall be tested by the following method to determine whether they meet the requirements of paragraph (b)(1)(i) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 28.6 millimeters (1.12 inches) inside diameter, with vertical sides; or rectangular in shape, 19 millimeters (0.75 inch) by 25.4 millimeters (1 inch) inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of 19 millimeters (0.75 inch). Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least 13 millimeters (0.51 inch) by 25.4 millimeters (1 inch) cannot be trimmed. Test the piece by means of a round metal rod 4 millimeters (0.16 inch) in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by the support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams (3.5 ounces). Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams (0.42 ounce) per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(3) Determine compliance as specified in §145.3(o) except that a lot shall be deemed to be in compliance for peel in all styles except unpeeled styles and seeds in all styles except whole uncored style based on the average of all samples analyzed according to the sampling plans set out in §145.3(p).

(4) If the quality of canned pears falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned pears falls below standard with respect to only one of the factors of quality specified in paragraph (b)(1) (i) through (x) of this section, there may be substituted for the second line of such general statement of substandard quality (''Good Food—Not High Grade'') a new line, as specified after the corresponding designation of paragraph (b)(1) of this section which the canned pears fail to meet, as follows:

(i) ''Not tender'';

(ii) ''Small halves'' or ''small quarters'', as the case may be;

(iii)(*a*) ''Mixed sizes'';

(*b*) ''Undersized and/or oversized pieces'';

(iv) ''Excessive peel'';

(v) ''Blemished'';

(vi) ''Unevenly trimmed'';

(vii) ''Partly crushed or broken'';

(viii) ''Excessive core'';

(ix) ''Excessive core'';

(x) ''Excessive seeds''.

Such alternative statement shall immediately and conspicuously precede or follow, without intervening written,

printed, or graphic matter, the name ''pears'' and any words and statements required or authorized to appear with such name by paragraph (a)(2) of this section.

(c) *Fill of container.* (1) The standard of fill of container for canned pears is the maximum quantity of the optional pear ingredient that can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(2) If canned pears fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14414, Mar. 15, 1977, as amended at 47 FR 41528, 41530, Sept. 21, 1982; 58 FR 2880, Jan. 6, 1993]

§ 145.176 Artificially sweetened canned pears.

(a) Artificially sweetened canned pears is the food which conforms to the definition and standard of identity prescribed for canned pears by §145.175(a) except that in lieu of a packing medium specified in §145.175(a)(3), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin and may contain any mixture of any edible organic salt or salts and any edible organic acid or acids as a flavor-enhancing agent, in a quantity not more than is reasonably required for that purpose.

(b)(1) The specified name of the food is ''artificially sweetened _____'', the blank being filled in with the name prescribed by §145.175(a) for canned pears having the same optional pear ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned pears by §145.175(a). If the packing medium is thickened with pectin, the label shall bear the statement ''thickened with pectin''. When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

§ 145.180 Canned pineapple.

(a) *Identity*—(1) *Ingredients.* Canned pineapple is the food prepared from mature, fresh or previously canned, pineapple conforming to the characteristics of *Ananas comosus* (L.) Merrill and from which peel and core have been removed. The food consists of one of the optional styles of the pineapple ingredient specified in paragraph (a)(2) of this section and may be packed in one of the optional packing media specified in paragraph (a)(3) of this section, except water is not a suitable packing medium for crushed style. Crushed style additionally may be packed as heavy or solid pack as specified in paragraph (a)(4) of this section. The food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural fruit flavors.

(ii) Mint flavor.

(iii) Spices, spice oils.

(iv) Vinegar or organic acids.

(v) Dimethylpolysiloxane in an amount not greater than 10 milligrams/kilogram (10 parts per million) by weight of the finished food as a defoaming agent.

The food is sealed in a container and, before or after sealing, is so processed by heat as to prevent spoilage.

(2) *Styles of pack.* The optional styles of the pineapple ingredients referred to in paragraph (a)(1) of this section are:

(i) *Slices or whole slices or rings*—consisting of uniformly cut circular slices or rings cut across the axis of the peeled, cored pineapple cylinders.

(ii) *Half slices*—consisting of uniformly cut, approximately semicircular halves of slices.

(iii) *Quarter slices*—consisting of uniformly cut, one-fourth portions of slices.

(iv) *Broken slices*—consisting of arc-shaped portions which may not be uniform in size and/or shape.

(v) *Spears or fingers*—consisting of long, slender pieces cut radially and

lengthwise of the cored pineapple cylinder, predominantly 65 millimeters (2.5 inches) or longer.

(vi) *Tidbits*—consisting of reasonably uniform, wedge-shaped sectors cut from slices or portions thereof, predominantly from 8 millimeters (0.31 inch) to 13 millimeters (0.51 inch) thick.

(vii) *Chunks*—consisting of short, thick pieces cut from thick slices and/or from peeled cored pineapple and predominantly more than 13 millimeters (0.51 inch) in both thickness and width, and less than 38 millimeters (1.5 inches) in length and does not include large cubes.

(viii) *Small cubes or dice*—consisting of reasonably uniform, cube-shaped pieces, predominately 14 millimeters (0.55 inch) or less in the longest edge dimensions.

(ix) *Pieces or irregular pieces*—consisting of irregular shapes and sizes not identifiable as a specific style and does not include chunks.

(x) *Crushed*—consisting of finely cut or finely shredded or grated or diced pieces of pineapple.

(xi) *Large cubes*—consisting of reasonably uniform, cube-shaped pieces, longer than 14 millimeters (0.55 inch) along any edge, but predominately 25 millimeters (1 inch) or less in the longest edge dimensions.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section and defined in § 145.3 are:

(*a*) Water.

(*b*) Pineapple juice and water.

(*c*) Pineapple juice.

(*d*) Clarified pineapple juice.

Such packing media may be used as such, or any one of the optional sweetening ingredients specified in paragraph (a)(3)(ii) of this section may be added.

(ii) The optional sweetening ingredients referred to in paragraph (a)(3)(i) of this section are:

(*a*) Sugar.

(*b*) Invert sugar sirup.

(*c*) Any mixture of optional sweetening ingredients designated in paragraph (a)(3)(ii)(*a*) and (*b*) of this section.

(*d*) Any of the optional sweetening ingredients designated in paragraph (a)(3)(ii)(*a*), (*b*), and (*c*) of this section with dextrose, as long as the weight of the solids of dextrose does not exceed one-third of the total weight of the solids of the combined sweetening ingredients.

(*e*) Any of the optional sweetening ingredients designated in paragraph (a)(3)(ii)(*a*), (*b*), and (*c*) of this section with corn sirup or with dried corn sirup or with glucose sirup or with dried glucose sirup, or with any two or more of these, as long as the weight of the solids of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup, or the sum of the weights of the solids of corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup, in case two or more of these are used, does not exceed one-fourth of the total weight of the solids of the combined sweetening ingredients.

(*f*) Any mixture of the optional ingredients designated in paragraph (a)(3)(ii)(*d*) and (*e*) of this section.

(iii) If the concentration of clarified pineapple juice is such that the packing medium conforms to the density range for one of the sirups provided for in paragraph (a)(3)(iv)(*b*), (*c*), or (*d*) of this section, the concentrated clarified juice is considered to be light sirup, heavy sirup, or extra heavy sirup, as the case may be.

(iv) When a sweetener is added as a part of any liquid packing medium as provided for in paragraph (a)(3)(i)(*a*), (*b*), and (*c*) of this section, the density range of the resulting packing medium, expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure in § 145.3(m), shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is 10 percent or more but less than 14 percent, the medium shall be designated as ''slightly sweetened water'' or ''extra light sirup''; ''slightly sweetened pineapple juice and water''; or ''slightly sweetened pineapple juice'', as the case may be.

(*b*) When the density of the solution is 14 percent or more but less than 18 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened pineapple juice and water''; or ''lightly sweetened pineapple juice,'' as the case may be.

(*c*) When the density of the solution is 18 percent or more but less than 22 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened pineapple juice and water''; or ''heavily sweetened pineapple juice'', as the case may be.

(*d*) When the density of the solution is 22 percent or more but not more than 35 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened pineapple juice and water''; or ''extra heavily sweetened pineapple juice'', as the case may be.

(v) Determine compliance as specified in §145.3(o).

(4) *Types of pack.* The optional types of pack for crushed style referred to in paragraph (a)(1) of this section are as follows:

(i) *Heavy pack.* Crushed style with or without sweetening ingredients and containing at least 73 percent drained fruit weight, as determined by the procedure set forth in §145.3(n).

(ii) *Solid pack.* Crushed style with or without sweetening ingredients and containing at least 78 percent drained fruit weight, as determined by the procedure set forth in §145.3(n).

(5) *Labeling requirements.* (i) The name of the food is ''pineapple''. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or, in lieu of the word ''Spice'', the common name of the spice; or ''Seasoned with vinegar'' or, in lieu of the word ''vinegar'', the name of the vinegar used. When two or more of the optional ingredients specified in paragraph (a)(1)(i) through (iv) of this section are used, such words may be combined, as, for example, ''Seasoned with cider vinegar, cloves, and cinnamon oil''.

(ii) The style of the pineapple ingredient as provided for in paragraph (a)(2) of this section and the name of the packing medium as specified in paragraph (a)(3)(i) and (ii) of this section, preceded by ''In'' or ''Packed in'' or the words ''Heavy pack'' or ''Solid pack'' as specified in paragraph (a)(4) of this section, where applicable, shall be included as part of the name or in close proximity to the name of the food. The word ''slices'' may be alternatively designated ''sliced,'' ''dice'' as ''diced,'' and ''pieces'' or ''irregular pieces'' as ''mixed pieces of irregular sizes and shapes.'' Whenever pineapple juice, as provided for in paragraph (a)(3)(i)(*c*) of this section, is used, the declaration may be preceded by an appropriate statement such as ''unsweetened''.

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned pineapple is as follows:

(i) *Core material.* In the case of all styles, not more than 7 percent of the drained weight of the contents of the container consists of core material as determined by the method prescribed in paragraph (b)(3)(ii) of this section.

(ii) *Uniformity of weight and shape*—(*a*) *Slices.* The drained weight of the largest unit in the container is not more than 1.4 times the drained weight of the smallest unit.

(*b*) *Half slices and quarter slices.* The drained weight of the largest unit in a container is not more than 1.75 times the drained weight of the smallest unit, except for an occasional broken piece due to splitting or an occasional whole slice not completely cut through.

(*c*) *Broken slices.* (*1*) Not more than 10 percent of the drained weight of the contents of the container consists of pieces having an arc of less than 90°.

(*2*) Not more than 5 percent of the drained weight of the contents of the container:

(*i*) Consists of pieces that measure in thickness less than 8 millimeters (0.31 inch) or more than 25 millimeters (1 inch); or

(*ii*) Consists of pieces that measure less than 19 millimeters (0.75 inch) in width as measured from the outer edge to the inner edge.

(*3*) Not more than 5 percent of the drained weight of the contents of the container consists of broken slices having an outside diameter differing by as much as 9.5 millimeters (0.37 inch) from that of those present in greatest proportion by weight.

(*d*) *Spears.* The drained weight of the largest unit in the container is not more than 1.4 times the drained weight of the smallest unit.

(*e*) *Tidbits.* Not more than 15 percent of the drained weight of the contents of the container consists of units each of which weighs less than three-fourths as much as the average drained weight of all the untrimmed units in the container.

(*f*) *Chunks.* Not more than 15 percent of the drained weight of the contents of the container consists of pieces weighing less than 5 grams (0.18 ounce) each.

(*g*) *Cubes.* (*1*) Not more than 10 percent of the drained weight of the contents of the container consists of pieces that will pass through a screen with square openings of 8 millimeters (0.31 inch) in the case of the small cubes or large cubes.

(*2*) Not more than 15 percent of the drained weight consists of pieces weighing more than 3 grams (0.11 ounce) each for small cubes and 18 grams (0.63 ounce) each for large cubes.

(*h*) *Pieces.* Not more than 20 percent of the drained weight of the contents of the container consists of units that will pass through a screen with square openings of 8 millimeters (0.31 inch).

(iii) *Blemishes.* Blemishes consist of surface areas and spots that contrast strongly in color or texture with the normal pineapple tissue or that may penetrate the flesh. Blemishes are normally removed in preparation of pineapple for culinary use and include any of the following, if in excess of 1.6 millimeters (0.06 inch) in the longest dimension on the exposed surface of the unit: deep fruit eyes, pieces of shell, brown spots, bruised portions, and other abnormalities.

(*a*) *Slices, half slices, quarter slices, broken slices, spears, tidbits, chunks, cubes, and pieces.* Not more than 12.5 percent by count of the units in the container may be blemished; but in containers having not more than 5 units, 1 unit may be blemished; in containers having more than 5 units, but not more than 10 units, 2 units may be blemished and in containers having more than 10 units, but not more than 32 units, 4 units may be blemished.

(*b*) *Crushed.* Not more than 1.5 percent of the drained weight of the contents of the container consists of fragments bearing blemishes.

(iv) *Excessively trimmed.* Slices, half slices, and quarter slices are considered excessively trimmed if the portion trimmed away exceeds 5 percent of the apparent physical bulk of the perfectly formed unit and if the trimming destroys the normal circular shape of the outer or inner edge of the unit. Broken slices, spears, and tidbits are excessively trimmed if the trimming destroys the normal shape of the unit.

(*a*) *Slices, half slices, and quarter slices.* Not more than 7.5 percent by count of the units in the container may be excessively trimmed, but in containers having not more than 10 units, 1 unit may be excessively trimmed; and in containers having more than 10 units, but not more than 27 units, 2 units may be excessively trimmed.

(*b*) *Broken slices and spears.* Not more than 15 percent by count of the total units in the container may be excessively trimmed.

(*c*) *Tidbits.* Not more than 15 percent of the drained weight of the contents of the container consists of excessively trimmed units.

(v) *Mashed.* A unit that has lost its normal shape because of ripeness that bears no mark of mechanical injury is not to be considered mashed.

(*a*) *Slices, half slices, and quarter slices.* Not more than one unit in containers of 25 units or less, and not more than 3 units in containers of more than 25 units, are mashed.

(*b*) *Broken slices.* Not more than 5 percent by count of the units in the container are mashed.

(*c*) *Spears.* Not more than 1 unit in the container is mashed.

(*d*) *Tidbits.* Not more than 3 units in containers of less than 150 units, and not more than 2 percent of the units in containers of 150 units or more, are mashed.

(*e*) *Chunks.* Not more than 3 units in containers of less than 70 units, and not more than 5 percent of the units in containers of 70 units or more, are mashed.

(vi) *Acidity.* In the case of all styles, not more than 1.35 grams of acid, calculated as anhydrous citric acid, is

contained in 100 milliliters of the liquid drained from the product 15 days or more after the pineapple is canned.

(vii) *Excessive liquid*. The drained weight of crushed pineapple is not less than 63 percent of the net weight of the contents of the container.

(2) *Sampling and acceptance*. Determine compliance as specified in § 145.3(o).

(3) *Methodology*. The method to be employed to determine whether canned pineapple meets the requirements of paragraph (b)(1) (i) through (vi) of this section are as follows:

(i) Determine the drained weight of the canned pineapple by the procedure prescribed in § 145.3(n).

(ii) Identify and separate any core material cleanly from each of the units in the container, and weigh the aggregate of the core material. Calculate the percent core material to determine compliance with paragraph (b)(1)(i) of this section.

(iii) In the case of slices, half slices, quarter slices, spears, tidbits, chunks, and pieces, check the weight of the units against the requirements of paragraph (b)(1)(ii) (*a*), (*b*), (*d*), (*e*), (*f*), and (*h*) of this section.

(iv) In the case of broken slices, check the dimensions of each unit against the requirements of paragraph (b)(1)(ii)(*c*) of this section.

(v) In the case of cubes, and pieces, determine compliance with paragraph (b)(1)(ii) (*g*) and (*h*) of this section by placing the units, a few at a time, on the mesh of a U.S. Standard No. 8 sieve (8-millimeter (0.31 inch)) mesh. After shaking gently, remove those units that remain on the sieve before testing the next portion. Continue portionwise until all units are tested, then determine the aggregate weight of those units that have passed through the sieve.

(vi) Except in the case of crushed pineapple, segregate and count each unit that is blemished as defined in paragraph (b)(1)(iii) of this section. In the case of crushed pineapple, segregate each fragment of crushed pineapple bearing a blemish and determine the aggregate weight of such fragments to determine compliance with paragraph (b)(1)(iii)(*b*) of this section.

(vii) Except in the case of chunks, cubes, pieces, and crushed pineapple, inspect all the units in the container to determine those that have been excessively trimmed, as defined in paragraph (b)(1)(iv) of this section.

(viii) Except in the case of cubes, pieces, and crushed pineapple, count the total units in the container and the number of mashed units to determine compliance with paragraph (b)(1)(v) of this section.

(ix) Determine the total acidity of the drained liquid by titration, using the following method: Measure with a pipette 10 milliliters of the unfiltered drained liquid into a 250-milliliter Erlenmeyer flask. Add 25 milliliters of distilled or deionized water and 0.3 milliliter of 1-percent phenolphthalein solution. Titrate with one-tenth normal sodium hydroxide solution to a faint, permanently pink coloration. Multiply the number of milliliters of one-tenth normal sodium hydroxide required by 0.064 to calculate the number of grams of anhydrous citric acid per 100 milliliters of drained liquid to determine compliance with paragraph (b)(3)(vi) of this section.

(4) If the quality of canned pineapple falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form specified in that section; however, if the quality of the canned pineapple falls below standard with respect to only one of the factors of quality specified in paragraph (b)(1)(i) through (vii) of this section, there may be substituted for the second line of the general statement of substandard quality (''Good Food—Not High Grade'') one of the following new lines, placed after the corresponding designation of paragraph (b)(1) of this section that the canned pineapple fails to meet:

(i) ''Poorly cored'' or ''Excessive core''.

(ii) ''Mixed sizes'' or ''Irregular small pieces'', as appropriate.

(iii) ''Blemished'' or ''Contains blemished pieces''.

(iv) ''Excessively trimmed''.

(v) ''Mashed units'' or ''Contains mashed units''.

(vi) ''Excessively tart''.

(vii) ''Contains excess liquid''.

(c) *Fill of Container.* (1) The standard of fill of container for canned crushed pineapple is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter.

(2) If canned crushed pineapple falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14414, Mar. 15, 1977, as amended at 44 FR 40279, July 10, 1979; 45 FR 43391 and 43392, June 27, 1980; 46 FR 57475, Nov. 24, 1981; 48 FR 39916, Sept. 2, 1983; 58 FR 2880, Jan. 6, 1993]

§ 145.181 Artificially sweetened canned pineapple.

(a) Artificially sweetened canned pineapple is the food that conforms to the definition and standard of identity prescribed for canned pineapple by §145.180(a), except that in lieu of a packing medium specified in §145.180(a)(2), the packing medium used is water artificially sweetened with saccharin, sodium saccharin, or a combination of both. Such packing medium may be thickened with pectin.

(b)(1) The specified name of the food is ''artificially sweetened _____'', the blank being filled in with the name prescribed by §145.180(a) for canned pineapple having the same optional pineapple ingredient.

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned pineapple by §145.180(a). If the packing medium is thickened with pectin, the label shall bear the statement ''thickened with pectin''.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

§ 145.185 Canned plums.

(a) *Identity*—(1) *Ingredients.* Canned plums is the food prepared from clean, sound, and mature fruit of plum varieties conforming to the characteristics of *Prunus domestica* L., greengage varieties conforming to the characteristics of *Prunus italica* L., mirabelle or damson varieties conforming to the characteristics of *Prunus insititia* L., or cherry varieties conforming to the characteristics of *Prunus cerasifera* Ehrh. The food consists of one of the optional styles of the plum ingredient, specified in paragraph (a)(2) of this section, and one of the optional packing media specified in paragraph (a)(3) of this section. Such food may also contain one, or any combination of two or more of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Spice.

(iii) Vinegar, lemon juice, or organic acids.

(iv) Artificial coloring.

Such food is sealed in a container and before or after sealing is so processed by heat so as to prevent spoilage.

(2) *Optional styles of the plum ingredient.* The optional plum ingredients specified in paragraph (a)(1) of this section are peeled or unpeeled:

(i) Whole.

(ii) Halves.

Peeled or unpeeled whole plums are pitted or, alternatively, unpitted. Peeled or unpeeled plum halves are pitted.

(3) *Packing media.* (i) The optional packing media referred to in paragraph (a)(1) of this section, as defined in §145.3 are:

(*a*) Water.

(*b*) Fruit juice(s) and water.

(*c*) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in §145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in §145.3.

(ii) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure

prescribed in §145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(*a*) When the density of the solution is 11 percent or more but less than 15 percent, the medium shall be designated as ''slightly sweetened water'', or ''extra light sirup'', ''slightly sweetened fruit juice(s) and water'' or ''slightly sweetened fruit juice(s)'', as the case may be.

(*b*) When the density of the solution is 15 percent or more, but less than 19 percent, the medium shall be designated as ''light sirup'', ''lightly sweetened fruit juice(s) and water'', or ''lightly sweetened fruit juice(s)'', as the case may be.

(*c*) When the density of the solution is 19 percent or more, but less than 25 percent, the medium shall be designated as ''heavy sirup'', ''heavily sweetened fruit juice(s) and water'', or ''heavily sweetened fruit juice(s)'', as the case may be.

(*d*) When the density of the solution is 25 percent or more, but less than 35 percent, the medium shall be designated as ''extra heavy sirup'', ''extra heavily sweetened fruit juice(s) and water'', or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(4) *Labeling requirements.* (i) The name of the food is ''plums'' accompanied by the color designation ''yellow'' or ''golden'' or ''red'' or ''purple'', as appropriate, or the specific name of the variety or ''Greengage plums'', ''Damson plums'', ''Cherry plums'', ''Mirabelle plums''. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or in lieu of the word ''Spice'', the common name of the spice; ''Seasoned with vinegar''. When two or more of the optional ingredients specified in paragraphs (a)(1) (ii) and (iii) of this section are used, such words may be combined as for example, ''Seasoned with cider vinegar, cloves, and cinnamon oil''.

(ii) The style of the plum ingredient as provided in paragraph (a)(2) of this section and the name of the packing medium specified in paragraphs (a)(3) (i) and (ii) of this section, preceded by ''In'' or ''Packed in'' shall be included as part of the name or in close proximity to the name of the food. The style of the plum ingredient shall be preceded or followed by ''Peeled'' when the plums are peeled and by ''Pitted'' in the case of whole pitted plums. ''Halves'' may be alternatively designated ''Halved''. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristics to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example, in the case of a mixture of brown sugar and honey, an appropriate statement would be ''_____ sirup of brown sugar and honey'', the blank to be filled in with the word ''light'', ''heavy'', or ''extra heavy'', as the case may be. When the liquid portion of the packing media provided for in paragraphs (a)(3) (i) and (ii) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(*a*) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'',

(*b*) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (a)(4)(iii) of this section, and

(*c*) In the case of a single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (a)(4)(iii) of this section.

(iii) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (a)(4)(ii)(*b*) of this section, such names and the words ''from concentrate'', as specified in paragraph (a)(4)(ii)(*c*) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(iv) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality*. (1) The standard of quality for canned plums is as follows:

(i) *Blemishes* (*damaged*). After draining in accordance with the procedure set out in §145.3(n) not more than 30 percent by weight of the drained plums consists of plums which have been blemished or damaged by any of the following factors either singly or in combination: Damaged by insects; appearance or eating quality materially affected by friction, disease, external stone gum or discoloration.

(ii) *Crushed or broken units in whole and halves styles*. In the case of the whole styles, not more than 25 percent by weight of the drained plums are deformed or broken to an extent that the normal shape of the fruit is seriously affected. In the case of the halves style, not more than 25 percent by weight of the drained plums are damaged or torn to such an extent that they are smaller than 50 percent of a plum half.

(iii) *Blemishes and crushed or broken units*. Not more than 35 percent by weight of the drained plums consist of both blemishes as specified in paragraph (b)(1)(i) of this section and crushed or broken units in the case of the whole and halves styles as specified in paragraph (b)(2)(ii) of this section.

(iv) *Extraneous plant material*. Not more than one piece of stalk or stem from the plum tree or other harmless extraneous plant material per 200 grams (7 ounces) of drained plums.

(v) *Loose pits in whole style*. Not more than three loose pits per 500 grams (17.6 ounces) of drained plums.

(vi) *Pits or pieces of pits in whole pitted and halves styles*. Not more than two pits or pieces of pits per 500 grams (17.8 ounces) of drained plums.

(2) Determine compliance as specified in §145.3(o) except that a lot shall be deemed to be in compliance for extraneous plant material, loose pits in whole style, and pits or pieces of pits in whole pitted and halves styles based on the average of all samples analyzed according to the sampling plans set out in §145.3(p).

(3) If the quality of canned plums falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned plums falls below standard with respect to only one of the factors of quality specified in paragraphs (b)(1) (i) through (vi) of this section, there may be substituted for the second line of such general statement of substandard quality (''Good Food—Not High Grade'') a new line, as specified after the corresponding designation of paragraph (b)(1) of this section which the canned plums fail to meet, as follows:

(i) ''Blemished'';

(ii) ''Partly crushed or broken'';

(iii) ''Blemished and partly crushed or broken'';

(iv) ''Contains extraneous plant material'';

(v) ''Contains loose pits''; or

(vi) ''Contains pits'' or ''Contains pieces of pits''.

(c) *Fill of container*. (1) The standard of fill of container for canned plums is:

(i) The fill of the plums and packing medium, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(ii) The drained weight of the plum ingredient as determined by the method prescribed in §145.3(n) is not less than 50 percent for whole styles and 55 percent for halves styles based on the water capacity of containers as determined in §130.12(a) of this chapter.

(2) Determine compliance for fill of container as specified in §145.3(o).

(3) If canned plums fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified. If canned plums fall below the standard of fill of container in respect to drained weight, the words ''Low drained weight'' shall follow the general statement of substandard fill on the label.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

§ 145.190 Canned prunes.

(a) *Ingredients.* Canned prunes is the food prepared from dried prunes, which may be packed as a solid pack or in one of the optional packing media specified in paragraph (b) of this section. Such food may also contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(1) Natural and artificial flavors.

(2) Spice.

(3) Vinegar, lemon juice, or organic acids.

(4) Unpeeled pieces of citrus fruits.

Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(b) *Packing media.* (1) The optional packing media referred to in paragraph (a) of this section, as defined in § 145.3 are:

(i) Water.

(ii) Fruit juice(s) and water.

(iii) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

(2) When a sweetener is added as a part of any such liquid packing medium, the density range of the resulting packing medium expressed as percent by weight of sucrose (degrees Brix) as determined by the procedure prescribed in § 145.3(m) shall be designated by the appropriate name for the respective density ranges, namely:

(i) When the density of the solution is less than 20 percent, the medium shall be designated as ''slightly sweetened water''; or ''extra light sirup''; ''slightly sweetened fruit juice(s) and water''; or ''slightly sweetened fruit juice(s)'', as the case may be.

(ii) When the density of the solution is 20 percent or more but less than 24 percent, the medium shall be designated as ''light sirup''; ''lightly sweetened fruit juice(s) and water''; or ''lightly sweetened fruit juice(s)'', as the case may be.

(iii) When the density of the solution is 24 percent or more but less than 30 percent, the medium shall be designated as ''heavy sirup''; ''heavily sweetened fruit juice(s) and water''; or ''heavily sweetened fruit juice(s)'', as the case may be.

(iv) When the density of the solution is 30 percent or more but not more than 45 percent, the medium shall be designated as ''extra heavy sirup''; ''extra heavily sweetened fruit juice(s) and water''; or ''extra heavily sweetened fruit juice(s)'', as the case may be.

(c) *Labeling requirements.* (1) The name of the food is ''prunes—prepared from dried prunes''. The words ''prepared from dried prunes'' shall be in close proximity to the word ''prunes'' and shall be of the same style and not less than ½ of the point size of the type used for the word ''prunes''. The name of the food shall also include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice or seasoning that characterizes the product; for example, ''Spice added'', or in lieu of the word ''Spice'', the common name of the spice, ''Seasoned with vinegar'' or ''Seasoned with unpeeled pieces of citrus fruit''. When two or more of the optional ingredients specified in paragraphs (a) (2) through (4) of this section are used, such words may be combined as for example, ''Seasoned with cider vinegar, cloves, cinnamon oil and unpeeled pieces of citrus fruit.''

(2) When the food is prepared with a packing medium, the name of the packing medium specified in paragraphs (b) (1) and (2) of this section, preceded by ''In'' or ''Packed in'' and the words ''cooked'', ''stewed'', or ''prepared'', shall be included as part of the name or in close proximity to the name of the food. When no packing medium is used, the words ''solid pack'' or ''moist pack'' or the word ''moistened'' followed by the words ''without sirup'' shall be included as part of the name or in close proximity to the name of the

food. When the packing medium is prepared with a sweetener(s) which imparts a taste, flavor or other characteristic to the finished food in addition to sweetness, the name of the packing medium shall be accompanied by the name of such sweetener(s), as for example in the case of a mixture of brown sugar and honey, an appropriate statement would be ''_____ sirup of brown sugar and honey'', the blank to be filled in with the word ''light'', ''heavy'', or ''extra heavy'' as the case may be. When the liquid portion of the packing media provided for in paragraphs (b) (1) and (2) of this section consists of fruit juice(s), such juice(s) shall be designated in the name of the packing medium as:

(i) In the case of a single fruit juice, the name of the juice shall be used in lieu of the word ''fruit'',

(ii) In the case of a combination of two or more fruit juices, the names of the juices in the order of predominance by weight shall either be used in lieu of the word ''fruit'' in the name of the packing medium, or be declared on the label as specified in paragraph (c)(3) of this section, and

(iii) In the case of the single fruit juice or a combination of two or more fruit juices any of which are made from concentrate(s), the words ''from concentrate(s)'' shall follow the word ''juice(s)'' in the name of the packing medium and in the name(s) of such juice(s) when declared as specified in paragraph (c)(3) of this section.

(3) Whenever the names of the fruit juices used do not appear in the name of the packing medium as provided in paragraph (c)(2)(ii) of this section, such names and the words ''from concentrate'', as specified in paragraph (c)(2)(iii) of this section, shall appear in an ingredient statement pursuant to the requirements of §101.3(d) of this chapter.

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14414, Mar. 15, 1977, as amended at 58 FR 2880, Jan. 6, 1993]

PART 146—CANNED FRUIT JUICES

Subpart A—General Provisions

Subpart B—Requirements for Specific Standardized Canned Fruit Juices and Beverages

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14433, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§146.3 Definitions.

For the purposes of this part:

(a) The term *corn sirup* means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup. The solids of corn sirup and of dried corn sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(b) The term *dextrose* means the hydrated or anhydrous, refined monosaccharide obtained from hydrolyzed starch.

(c) The term *dried glucose sirup* means the product obtained by drying glucose sirup.

(d) The term *glucose sirup* means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(e) The term *invert sugar sirup* means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless, except for sweetness.

(f) The term *sugar* means refined sucrose.

(g) Compliance means the following: Unless otherwise provided in a standard, a lot of canned fruits shall be deemed in compliance for the following factors, to be determined by the sampling and acceptance procedure as provided in paragraph (h) of this section, namely:

(1) *Quality.* The quality of a lot shall be considered acceptable when the number of defectives does not exceed the acceptance number in the sampling plans.

(2) *Fill of container.* A lot shall be deemed to be in compliance for fill of container when the number of defectives does not exceed the acceptance number (c) in the sampling plans.

(h) The sampling and acceptance procedure means the following:

(1) *Definitions*—(i) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(ii) *Lot size.* The number of primary containers or units in the lot.

(iii) *Sample size.* The total number of sample units drawn for examination from a lot.

(iv) *Sample unit.* A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(v) *Defective.* Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(vi) *Acceptance number* (*c*). The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(vii) *Acceptable quality level* (*AQL*). The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(2) *Sampling plans:*

Lot size (primary containers)	Size of container	
	n[1]	*c*[2]
NET WEIGHT EQUAL TO OR LESS THAN 1 KG (2.2 LB)		
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
NET WEIGHT GREATER THAN 1 KG (2.2 LB) BUT NOT MORE THAN 4.5 KG (10 LB)		
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
NET WEIGHT GREATER THAN 4.5 KG (10 LB)		
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

[1] *n* = number of primary containers in sample.
[2] *c* = acceptance number.

Subpart B—Requirements for Specific Standardized Canned Fruit Juices and Beverages

§ 146.114 Lemon juice.

(a) *Identity*—(1) *Description.* Lemon juice is the unfermented juice, obtained by mechanical process, from sound, mature lemons (*Citrus limon* (L.) Burm. f.), from which seeds (except embryonic seeds and small fragments of seed which cannot be separated by good manufacturing practice) and excess pulp are removed. The juice may be adjusted by the addition of the optional concentrated lemon juice ingredient

specified in paragraph (a)(2) of this section in such quantity so that the increase in acidity, calculated as anhydrous citric acid, does not exceed 15 percent of the acidity of the finished food. The lemon oil and lemon essence (derived from lemons) content may be adjusted in accordance with good manufacturing practice. The juice may have been concentrated and later reconstituted. When prepared from concentrated lemon juice, the finished food contains not less than 6 percent, by weight, of soluble solids taken as the refractometric sucrose value (of the filtrate), corrected to 20 °C, but uncorrected for acidity, in accordance with the ''International Scale of Refractive Indices of Sucrose Solutions'' in section 52.012 of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference, and has a titratable acidity content of not less than 4.5 percent, by weight, calculated as anhydrous citrus acid. Copies of the incorporation by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. The food may contain one or any combination of the safe and suitable optional ingredients specified in paragraph (a)(2) of this section. Lemon juice, as defined in this paragraph, may be preserved by heat sterilization (canning), refrigeration, freezing, or by the addition of safe and suitable preservatives. When sealed in a container to be held at ambient temperatures, it is preserved by the addition of safe and suitable preservatives or so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Optional ingredients.* The optional safe and suitable ingredients referred to in paragraph (a)(1) of this section are:

(i) Concentrated lemon juice (lemon juice from which part of the water has been removed).

(ii) Water and/or lemon juice to reconstitute concentrated lemon juice in the manufacture of lemon juice from concentrate.

(iii) Preservatives.

(3) *Labeling.* (i) The name of the food is:

(*a*) ''Lemon juice'' (*1*) if the food is prepared from unconcentrated, undiluted liquid extracted from mature lemons; or (*2*) if the food is prepared from unconcentrated, undiluted liquid extracted from mature lemons to which concentrated lemon juice is added to adjust acidity as provided for in paragraph (a)(1) of this section.

(*b*) ''Lemon juice from concentrate'' or ''reconstituted lemon juice'' (*1*) if the food is prepared from concentrated lemon juice and water and/or lemon juice; or (*2*) if the food is prepared from lemon juice from concentrate and lemon juice. The words ''from concentrate'' or ''reconstituted'' shall be shown in letters not less than one-half the height of the letters in the word ''lemon juice.''

(ii) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container.* (1) The standard of fill of container for lemon juice, except when the food is frozen, is not less than 90 percent of the total capacity of the container as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, except

(i) When the food is frozen or

(ii) When the food is packaged in individual serving-size packages, containing ½ fluid ounce or less, for use as described in §1.24(a)(3) of this chapter.

(2) Compliance is determined as specified in §146.3(g)(2).

(3) If the lemon juice fails to meet the standard of fill as prescribed in paragraph (c) (1) and (2) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein prescribed.

[45 FR 7786, Feb. 5, 1980, as amended at 47 FR 11830, Mar. 19, 1982; 49 FR 10100, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2881, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 146.120 Frozen concentrate for lemonade.

(a) Frozen concentrate for lemonade is the frozen food prepared from one or both of the lemon juice ingredients specified in paragraph (b) of this section together with one or any mixture of safe and suitable nutritive carbohydrate sweeteners. The product contains not less than 48.0 percent by weight of soluble solids taken as the sucrose value determined by refractometer and corrected for acidity prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 22.025, ''Frozen Concentrate for Lemonade (12),'' under the heading ''Soluble Solids by Refractometer—Official First Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html* When the product is diluted according to directions for making lemonade which shall appear on the label, the acidity of the lemonade, calculated as anhydrous citric acid, shall be not less than 0.70 gram per 100 milliliters, and the soluble solids, measured as described for the concentrate, shall be not less than 10.5 percent by weight.

(b) The lemon juice ingredients referred to in paragraph (a) of this section are:

(1) Lemon juice or frozen lemon juice or a mixture of these.

(2) Concentrated lemon juice or frozen concentrated lemon juice or a mixture of these.

For the purposes of this section, lemon juice is the undiluted juice expressed from mature lemons of an acid variety; and concentrated lemon juice is lemon juice from which part of the water has been removed. In the preparation of the lemon juice ingredients, the lemon oil content may be adjusted by the addition of lemon oil or concentrated lemon oil in accordance with good manufacturing practice, and the lemon pulp in the juice as expressed may be left in the juice or may be separated. Lemon pulp that has been separated, which may have been preserved by freezing, may be added in preparing frozen concentrate for lemonade, provided that the amount of pulp added does not raise the proportion of pulp in the finished food to a level in excess of that which would be present by using lemon juice ingredients from which pulp has not been separated. The lemon juice ingredients may be treated by heat, either before or after the other ingredients are added, to reduce the enzymatic activity and the number of viable microorganisms.

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14433, Mar. 15, 1977, as amended at 47 FR 11830, Mar. 19, 1982; 49 FR 10100, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2881, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 146.121 Frozen concentrate for artificially sweetened lemonade.

(a) Frozen concentrate for artificially sweetened lemonade conforms to the definition and standard of identity prescribed for frozen concentrate for lemonade by § 146.120, except that in lieu of nutritive sweeteners it is sweetened with one or more of the artificial sweetening ingredients listed in and complying with the requirements of parts 172, 180 or 184 of this chapter, and the soluble solids specifications prescribed in § 146.120(a) do not apply. When the product is diluted according to directions which shall appear on the label, the acidity of the artificially sweetened lemonade, calculated as anhydrous citric acid, shall be not less than 0.70 gram per 100 milliliters. It may contain one or more safe and suitable dispersing ingredients serving the function of distributing the lemon oil throughout the food. It may also contain one or more safe and suitable thickening ingredients. Such dispersing and thickening ingredients are not food additives as defined in section 201(s) of the Federal Food, Drug, and

Cosmetic Act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) [Reserved]

(c) The name of the food is ''Frozen concentrate for artificially sweetened lemonade''. The words ''artificially sweetened'' shall be of the same size and style of type as the word ''lemonade''.

(d) If an optional thickening or dispersing ingredient referred to in paragraph (a) of this section is used, the label shall bear the statement ''_____ added'' or ''with added _____'', the blank being filled in with the common name of the thickening or dispersing agent used. Such statement shall be set forth on the label with such prominence and conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase.

(e) Frozen concentrate for artificially sweetened lemonade is labeled to conform to the labeling requirements prescribed for foods which purport to be or are represented for special dietary use by regulations promulgated pursuant to section 403(j) of the act.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14433, Mar. 15, 1977, as amended at 58 FR 2881, Jan. 6, 1993]

§ 146.126 Frozen concentrate for colored lemonade.

(a) Frozen concentrate for colored lemonade conforms to the definition and standard of identity prescribed for frozen concentrate for lemonade by § 146.120, except that it is colored with a safe and suitable fruit juice, vegetable juice, or any such juice in concentrated form, or with any other color additive ingredient suitable for use in food, including artificial coloring, used in conformity with regulations established pursuant to section 721 of the Federal Food, Drug, and Cosmetic Act.

(b) The name of the food is ''Frozen concentrate for _____ lemonade'', the blank being filled in with the word describing the color: for example, ''Frozen concentrate for pink lemonade''.

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14433, Mar. 15, 1977, as amended at 58 FR 2881, Jan. 6, 1993]

§ 146.132 Grapefruit juice.

(a) *Identity*—(1) *Description.* Grapefruit juice is the unfermented juice, intended for direct consumption, obtained by mechanical process from sound, mature grapefruit (*Citrus paradisi* Macfadyen) from which seeds and peel (except embryonic seeds and small fragments of seeds and peel which cannot be separated by good manufacturing practice) and excess pulp are removed and to which may be added not more than 10 percent by volume of the unfermented juice obtained from mature hybrids of grapefruit. The juice may be adjusted by the addition of the optional concentrated grapefruit juice ingredients specified in paragraph (a)(2) of this section, but the quantity of such concentrated grapefruit juice ingredient added shall not contribute more than 15 percent of the grapefruit juice soluble solids in the finished food. The grapefruit pulp, grapefruit oil, and grapefuit essence (components derived from grapefruit) content may be adjusted in accordance with good manufacturing practice. The juice may have been concentrated and later reconstituted with water suitable for the purpose of maintaining essential composition and quality factors of the juice. It may be sweetened with the dry nutritive sweeteners referred to in paragraph (a)(2)(iii) of this section. If the grapefruit juice is prepared from concentrate, such sweeteners, in liquid form, referred to in paragraph (a)(2)(iii) of this section, also may be used. When prepared from concentrated grapefruit juice, exclusive of added sweeteners, the finished food contains not less than 10 percent, by weight, of soluble solids taken as the refractometric sucrose value (of the filtrate), corrected to 20 °C, and corrected for acidity by adding $(0.012 + 0.193x–0.0004x^2)$, where x equals the percent anhydrous citric acid in the sample, to the refractometrically

obtained sucrose value by the first method prescribed in ''Correction of Refractometer Sucrose Readings for Citric Acid Content for Lemonade,'' by Yeatman, Senzel, and Springer, ''Journal of the Association of Official Analytical Chemists,'' vol. 59 p. 368 (1976). Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The food may contain one or any combination of the optional ingredients specified in paragraph (a)(2) of this section. Grapefruit juice, as defined in this paragraph, may be preserved by heat sterlization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Optional ingredients*. The optional ingredients referred to in paragraph (a)(1) of this section are:

(i) Concentrated grapefruit juice (grapefruit juice from which part of the water has been removed).

(ii) Water and/or grapefruit juice to reconstitute concentrated grapefruit juice in the manufacture of grapefruit juice from concentrate.

(iii) One or any combination of two or more of the dry or liquid forms of sugar, invert sugar sirup, dextrose, glucose sirup, and fructose. Sweeteners defined in part 168 of this chapter shall be as defined therein.

(3) *Labeling*. (i) The name of the food is:

(*a*) ''Grapefruit juice'' (*1*) if the food is prepared from unconcentrated, undiluted liquid extracted from mature grapefruit; or (*2*) if the food is prepared from unconcentrated, undiluted liquid extracted from mature grapefruit to which concentrated grapefruit juice is added to adjust soluble solids as provided for in paragraph (a)(1) of this section.

(*b*) ''Grapefruit juice from concentrate'' (*1*) if the food is prepared from concentrated grapefruit juice and water and/or grapefruit juice; or (*2*) if the food is prepared from grapefuit juice from concentrate and grapefruit juice. The words ''from concentrate'' shall be shown in letters not less than one-half the height of the letters in the words ''grapefruit juice.''

(ii) If any nutritive sweetener is added, the principal display panel of the label shall bear the statement ''Sweetener added.'' If no sweetener is added, the word ''unsweetened'' may immediately precede or follow the words ''Grapefruit Juice'' or ''Grapefruit Juice from Concentrate.''

(iii) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container*. (1) The standard of fill of container for grapefruit juice, except when the food is frozen, is not less than 90 percent of the total capacity of the container as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter.

(2) Compliance is determined as specified in § 146.3(g)(2).

(3) If the grapefruit juice fails to meet the standard of fill as prescribed in paragraphs (c) (1) and (2) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein prescribed.

[46 FR 8464, Jan. 27, 1981; 46 FR 21359, Apr. 10, 1981; 46 FR 26300, May 12, 1981, as amended at 47 FR 11830, Mar. 19, 1982; 47 FR 24287, June 4, 1982; 47 FR 43364, Oct. 1, 1982; 58 FR 2881, Jan. 6, 1993; 66 FR 17359, Mar. 30, 2001]

§ 146.135 Orange juice.

(a) Orange juice is the unfermented juice obtained from mature oranges of the species *Citrus sinensis* or of the citrus hybrid commonly called ''Ambersweet'' (½ *Citrus sinensis* X ⅜ *Citrus reticulata* X ⅛ *Citrus paradisi* (USDA Selection:1–100–29: 1972 Whitmore Foundation Farm)). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by current good manufacturing practice) and excess pulp are removed. The juice may be chilled, but it is not frozen.

(b) The name of the food is ''orange juice''. The name ''orange juice'' may be preceded on the label by the varietal name of the oranges used, and if the oranges grew in a single State, the name of such State may be included in the name, as for example, ''California Valencia orange juice''.

[42 FR 14433, Mar. 15, 1977, as amended at 57 FR 57667, Dec. 7, 1992]

§ 146.137 Frozen orange juice.

(a) Frozen orange juice is orange juice as defined in § 146.135, except that it is frozen.

(b) The name of the food is ''Frozen orange juice''. Such name may be preceded on the label by the varietal name of the oranges used, and if the oranges grew in a single State, the name of such State may be included in the name, as for example, ''California Valencia frozen orange juice''.

§ 146.140 Pasteurized orange juice.

(a) Pasteurized orange juice is the food prepared from unfermented juice obtained from mature oranges as specified in § 146.135, to which may be added not more that 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in § 146.135). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed, and pulp and orange oil may be adjusted in accordance with good manufacturing practice. If the adjustment involves the addition of pulp, then such pulp shall not be of the washed or spent type. The solids may be adjusted by the addition of one or more of the optional concentrated orange juice ingredients specified in paragraph (b) of this section. One or more of the optional sweetening ingredients listed in paragraph (c) of this section may be added in a quantity reasonably necessary to raise the Brix or the Brix-acid ratio to any point within the normal range usually found in unfermented juice obtained from mature oranges as specified in § 146.135. The orange juice is so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms. Either before or after such heat treatment, all or a part of the product may be frozen. The finished pasteurized orange juice contains not less than 10.5 percent by weight of orange juice soluble solids, exclusive of the solids of any added optional sweetening ingredients, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 10 to 1.

(b) The optional concentrated orange juice ingredients referred to in paragraph (a) of this section are frozen concentrated orange juice as specified in § 146.146 and concentrated orange juice for manufacturing as specified in § 146.153 when made from mature oranges; but the quantity of such concentrated orange juice ingredients added shall not contribute more than one-fourth of the total orange juice solids in the finished pasteurized orange juice.

(c) The optional sweetening ingredients referred to in paragraph (a) of this section are sugar, invert sugar, dextrose, dried corn sirup, dried glucose sirup.

(d)(1) The name of the food is ''Pasteurized orange juice''. If the food is filled into containers and preserved by freezing, the label shall bear the name ''Frozen pasteurized orange juice''. The words ''pasteurized'' or ''frozen pasteurized'' shall be shown on labels in letters not less than one-half the height of the letters in the words ''orange juice''.

(2) If the pasteurized orange juice is filled into containers and refrigerated, the label shall bear the name of the food, ''chilled pasteurized orange juice''. If it does not purport to be either canned orange juice or frozen pasteurized orange juice, the word ''chilled'' may be omitted from the name. The words ''pasteurized'' or ''chilled pasteurized'' shall be shown in letters not less than one-half the height of the letters in the words ''orange juice''.

(e)(1) If a concentrated orange juice ingredient specified in paragraph (b) of this section is used in adjusting the orange juice solids of the pasteurized orange juice, the label shall bear the

statement ''prepared in part from concentrated orange juice'' or ''with added concentrated orange juice'' or ''concentrated orange juice added''.

(2) If one or more of the sweetening ingredients specified in paragraph (c) of this section are added to the pasteurized orange juice, the label shall bear the statement ''_____ added'', the blank being filled in with the name or an appropriate combination of the names of the sweetening ingredients used. However, for the purpose of this section, the name ''sweetener'' may be used in lieu of the specific name or names of the sweetening ingredients.

(f) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this section for naming the optional ingredients used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14433, Mar. 15, 1977, as amended at 57 FR 57667, Dec. 7, 1992; 58 FR 2881, Jan. 6, 1993]

§ 146.141 Canned orange juice.

(a) Canned orange juice is the food prepared from orange juice as specified in § 146.135 or frozen orange juice as specified in § 146.137, or a combination of both, to which may be added not more than 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in § 146.135). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed. Orange oil and pulp may be adjusted in accordance with good manufacturing practice. The adjustment of pulp referred to in this paragraph does not permit the addition of washed or spent pulp. Liquid condensate recovered from the deoiling operation may be added back. One or more of the optional sweetening ingredients named in paragraph (b) of this section may be added, in a quantity reasonably necessary to raise the Brix or the Brix-acid ratio to any point within the normal range usually found in unfermented juice obtained from mature oranges as specified in § 146.135. The food is sealed in containers and so processed by heat, either before or after sealing, as to prevent spoilage. The finished canned orange juice tests not less than 10° Brix, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 9 to 1.

(b) The optional sweetening ingredients referred to in paragraph (a) of this section are sugar, invert sugar, dextrose, dried corn sirup, dried glucose sirup.

(c) The name of the food is ''Canned orange juice''. All the words in the name shall appear in the same size, color, and style of type and on the same color-contrasting background. If the food is not sold under refrigeration and if it does not purport to be chilled pasteurized orange juice or frozen pasteurized orange juice, the word ''canned'' may be omitted from the name.

(d) If one or more of the sweetening ingredients specified in paragraph (b) of this section are added to the canned orange juice, the label shall bear the statement ''_____ added'', the blank being filled in with the name or an appropriate combination of the names of the sweetening ingredients used. However, for the purpose of this section, the name ''sweetener'' may be used in lieu of the specific name or names of the sweetening ingredients.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section for naming the optional ingredients used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the

applicable sections of parts 101 and 130 of this chapter.

[42 FR 14433, Mar. 15, 1977, as amended at 57 FR 57667, Dec. 7, 1992; 58 FR 2881, Jan. 6, 1993]

§ 146.145 Orange juice from concentrate.

(a) Orange juice from concentrate is the food prepared by mixing water with frozen concentrated orange juice as defined in §146.146 or with concentrated orange juice for manufacturing as defined in §146.153 (when made from mature oranges), or both. To such mixture may be added orange juice as defined in §146.135, frozen orange juice as defined in §146.137, pasteurized orange juice as defined in §146.140, orange juice for manufacturing as defined in §146.151 (when made from mature oranges and preserved by chilling or freezing but not by canning), orange oil, orange pulp, and one or more of the sweetening ingredients listed in paragraph (b) of this section. The finished orange juice from concentrate contains not less than 11.8 percent orange juice soluble solids, exclusive of solids of any added optional sweetening ingredients. It may be so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms.

(b) The sweetening ingredients referred to in paragraph (a) of this section are sugar, sugar sirup, invert sugar, invert sugar sirup, dextrose, corn sirup, dried corn sirup, glucose sirup, dried glucose sirup.

(c) The name of the food is ''Orange juice from concentrate''. The words ''from concentrate'' shall be shown in letters not less than one-half the height of the letters in the words ''orange juice''.

(d) When orange juice from concentrate contains any optional sweetening ingredient as listed in paragraph (b) of this section, whether added directly as such or indirectly as an added ingredient of any orange juice product used, the label shall bear the statement ''_____ added'', the blank being filled in with the name or an appropriate combination of the names of the sweetening ingredients added. However, for the purposes of this section the name ''sweetener'' may be used in lieu of the specific name or names of the sweetening ingredients.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this section for naming the optional ingredients used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14433, Mar. 15, 1977, as amended at 58 FR 2881, Jan. 6, 1993]

§ 146.146 Frozen concentrated orange juice.

(a) Frozen concentrated orange juice is the food prepared by removing water from the juice of mature oranges as provided in §146.135, to which may be added unfermented juice obtained from mature oranges of the species *Citrus reticulata*, other *Citrus reticulata* hybrids, or of *Citrus aurantium*, or both. However, in the unconcentrated blend, the volume of juice from *Citrus reticulata* or *Citrus reticulata* hybrids shall not exceed 10 percent (except that this limitation shall not apply to the hybrid species described in §146.135) and from *Citrus aurantium* shall not exceed 5 percent. The concentrate so obtained is frozen. In its preparation, seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) and excess pulp are removed, and a properly prepared water extract of the excess pulp so removed may be added. Orange oil, orange pulp, orange essence (obtained from orange juice), orange juice and other orange juice concentrate as provided in this section or concentrated orange juice for manufacturing provided in §146.153 (when made from mature oranges), water, and one or more of the optional sweetening ingredients specified in paragraph (b) of this section may be added to adjust the final composition. The juice of *Citrus reticulata* and *Citrus aurantium*, as permitted by this paragraph, may be

added in single strength or concentrated form prior to concentration of the *Citrus sinensis* juice, or in concentrated form during adjustment of the composition of the finished food. The addition of concentrated juice from *Citrus reticulata* or *Citrus aurantium,* or both, shall not exceed, on a single-strength basis, the 10 percent maximum for *Citrus reticulata* and the 5 percent maximum for *Citrus aurantium* prescribed by this paragraph. Any of the ingredients of the finished concentrate may have been so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms. The finished food is of such concentration that when diluted according to label directions the diluted article will contain not less than 11.8 percent by weight of orange juice soluble solids, exclusive of the solids of any added optional sweetening ingredients. The dilution ratio shall be not less than 3 plus 1. For the purposes of this section and §146.150, the term ''dilution ratio'' means the whole number of volumes of water per volume of frozen concentrate required to produce orange juice from concentrate having orange juice soluble solids of not less than 11.8 percent by weight exclusive of the solids of any added optional sweetening ingredients.

(b) The optional sweetening ingredients referred to in paragraph (a) of this section are sugar, sugar sirup, invert sugar, invert sugar sirup, dextrose, corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup.

(c) If one or more of the sweetening ingredients specified in paragraph (b) of this section are added to the frozen concentrated orange juice, the label shall bear the statement ''_____ added'', the blank being filled in with the name or an appropriate combination of names of the sweetening ingredients used. However, for the purpose of this section, the name ''sweetener'' may be used in lieu of the specific name or names of the sweetening ingredients.

(d) The name of the food concentrated to a dilution ratio of 3 plus 1 is ''frozen concentrated orange juice'' or ''frozen orange juice concentrate''. The name of the food concentrated to a dilution ratio greater than 3 plus 1 is ''frozen concentrated orange juice, _____ plus 1'' or ''frozen orange juice concentrate, _____ plus 1'', the blank being filled in with the whole number showing the dilution ratio; for example, ''frozen orange juice concentrate, 4 plus 1''. However, where the label bears directions for making 1 quart of orange juice from concentrate (or multiples of a quart), the blank in the name may be filled in with a mixed number; for example, ''frozen orange juice concentrate, 4⅓ plus 1''. For containers larger than 1 pint, the dilution ratio in the name may be replaced by the concentration of orange juice soluble solids in degrees Brix; for example, a 62° Brix concentrate in 3½-gallon cans may be named on the label ''frozen concentrated orange juice, 62° Brix''.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this section for naming the optional ingredients used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

(f) Nothing in this section is intended to interfere with the adoption and enforcement by any State, in regulating the production of frozen concentrated orange juice in such State, of State standards, consistent with this section, but which impose higher or more restrictive requirements than those set forth in this section.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14433, Mar. 15, 1977, as amended at 57 FR 57667, Dec. 7, 1992; 58 FR 2881, Jan. 6, 1993]

§ 146.148 Reduced acid frozen concentrated orange juice.

(a) Reduced acid frozen concentrated orange juice is the food that complies with the requirements for composition and label declaration of ingredients prescribed for frozen concentrated orange juice by §146.146, except that it may not contain any added sweetening ingredient. A process involving the use of anionic ion-exchange resins permitted by §173.25 of this chapter is used

to reduce the acidity of the food so that the ratio of the Brix reading to the grams of acid, expressed as anhydrous citric acid, per 100 grams of juice is not less than 21 to 1 or more than 26 to 1.

(b) The name of the food is ''Reduced acid frozen concentrated orange juice''.

[45 FR 12414, Feb. 26, 1980, as amended at 58 FR 2881, Jan. 6, 1993]

§ 146.150 Canned concentrated orange juice.

(a) Canned concentrated orange juice is the food that complies with the requirements of composition, definition of dilution ratio, and labeling of ingredients prescribed for frozen concentrated orange juice by §146.146, except that it is not frozen and it is sealed in containers and so processed by heat, either before or after sealing, so as to prevent spoilage.

(b) The name of the food when concentrated to a dilution ratio of 3 plus 1 is ''Canned concentrated orange juice'' or ''Canned orange juice concentrate''. The name of the food when concentrated to a dilution ratio greater than 3 plus 1 is ''Canned concentrated orange juice, _____ plus 1'' or ''Canned orange juice concentrate, _____ plus 1'', the blank being filled in with the whole number showing the dilution ratio; for example, ''Canned orange juice concentrate, 4 plus 1''. However, where the label bears directions for making 1 quart of single-strength diluted product (or multiples of a quart) the blank in the name may be filled in with a mixed number; for example, ''Canned orange juice concentrate, 4⅓ plus 1''. For containers larger than 1 pint, the dilution ratio in the name may be replaced by the concentration of orange juice soluble solids in degrees Brix; for example, a 62° Brix concentrate in 1-gallon cans may be named on the label ''canned concentrated orange juice, 62° Brix''. If the food does not purport to be frozen concentrated orange juice, the word ''canned'' may be omitted from the name.

[42 FR 14433, Mar. 15, 1977, as amended at 58 FR 2881, Jan. 6, 1993]

§ 146.151 Orange juice for manufacturing.

(a) Orange juice for manufacturing is the food prepared for further manufacturing use. It is prepared from unfermented juice obtained from oranges as provided in §146.135, except that the oranges may deviate from the standards for maturity in that they are below the minimum for Brix and Brix-acid ratio for such oranges, and to which juice may be added not more than 10 percent by volume of the unfermented juice obtained from oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in §146.135). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed, and pulp and orange oil may be adjusted in accordance with good manufacturing practice. If pulp is added it shall be other than washed or spent pulp. The juice or portions thereof may be so treated by heat as to reduce substantially the enzymatic activity and number of viable microorganisms, and it may be chilled or frozen, or it may be so treated by heat, either before or after sealing in containers, as to prevent spoilage.

(b) The name of the food is ''Orange juice for manufacturing''.

[42 FR 14433, Mar. 15, 1977, as amended at 57 FR 57667, Dec. 7, 1992]

§ 146.152 Orange juice with preservative.

(a) Orange juice with preservative is the food prepared for further manufacturing use. It complies with the requirements for composition of orange juice for manufacturing as provided for in §146.151, except that a preservative is added to inhibit spoilage. It may be heat-treated to reduce substantially the enzymatic activity and the number of viable microorganisms.

(b) The preservatives referred to in paragraph (a) of this section are any safe and suitable preservatives or combinations thereof.

(c) The name of the food is ''Orange juice with preservative''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the

applicable sections of parts 101 and 130 of this chapter. In addition, the name of each preservative shall be proceeded by a statement of the percent by weight of the preservative used. If the food is packed in container sizes that are less than 19 liters (5 gallons), the label shall bear a statement indicating that the food is for further manufacturing use only.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in paragraph (d) of this section for naming the preservative ingredient used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

[42 FR 14414, Mar. 15, 1977, as amended at 44 FR 36378, June 22, 1979; 58 FR 2881, Jan. 6, 1993]

§ 146.153 Concentrated orange juice for manufacturing.

(a) Concentrated orange juice for manufacturing is the food that complies with the requirements of composition and label declaration of ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it is either not frozen or is less concentrated, or both, and the oranges from which the juice is obtained may deviate from the standards for maturity in that they are below the minimum Brix and Brix-acid ratio for such oranges: *Provided,* however, that the concentration of orange juice soluble solids is not less than 20° Brix.

(b) The name of the food is ''Concentrated orange juice for manufacturing, _____'' or ''_____ orange juice concentrate for manufacturing'', the blank being filled in with the figure showing the concentration of orange juice soluble solids in degrees Brix.

[42 FR 14433, Mar. 15, 1977, as amended at 58 FR 2881, Jan. 6, 1993]

§ 146.154 Concentrated orange juice with preservative.

(a) Concentrated orange juice with preservative complies with the requirements for composition and labeling of optional ingredients prescribed for concentrated orange juice for manufacturing by § 146.153, except that a preservative is added to inhibit spoilage.

(b) The preservatives referred to in paragraph (a) of this section are any safe and suitable preservatives or combinations thereof.

(c) The name of the food is ''Concentrated orange juice with preservative, _____'', the blank being filled in with the figure showing the concentration of orange juice soluble solids in degrees Brix.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. In addition, the name of each preservative shall be preceded by a statement of the percent by weight of the preservative used. If the food is packed in container sizes that are less than 19 liters (5 gallons), the label shall bear a statement indicating that the food is for further manufacturing use only.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in paragraph (d) of this section for naming the preservative ingredient used shall immediately and conspicuously precede or follow the name of the food, without intervening written, printed, or graphic matter.

[42 FR 14414, Mar. 15, 1977, as amended at 44 FR 36378, June 22, 1979; 58 FR 2882, Jan. 6, 1993]

§ 146.185 Pineapple juice.

(a) *Identity.* (1) Pineapple juice is the juice, intended for direct consumption, obtained by mechanical process from the flesh or parts thereof, with or without core material, of sound, ripe pineapple (*Ananas comosus* L. Merrill). The juice may have been concentrated and later reconstituted with water suitable for the purpose of maintaining essential composition and quality factors of the juice. Pineapple juice may contain finely divided insoluble solids, but it does not contain pieces of shell, seeds, or other coarse or hard substances or excess pulp. It may be sweetened with any safe and suitable dry nutritive carbohydrate sweetener. However, if the pineapple juice is prepared from concentrate, such sweeteners, in liquid

form, also may be used. It may contain added vitamin C in a quantity such that the total vitamin C in each 4 fluid ounces of the finished food amounts to not less than 30 milligrams and not more than 60 milligrams. In the processing of pineapple juice, dimethylpolysiloxane complying with the requirements of §173.340 of this chapter may be employed as a defoaming agent in an amount not greater than 10 parts per million by weight of the finished food. Such food is prepared by heat sterilization, refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) The name of the food is ''Pineapple juice'' if the juice from which it is prepared has not been concentrated and/or diluted with water. The name of the food is ''Pineapple juice from concentrate'' if the finished juice has been made from pineapple juice concentrate as specified in paragraph (a) of this section. If a nutritive sweetener is added, the label shall bear the statement ''Sweetener added.'' If no sweetener is added, the word ''Unsweetened'' may immediately precede or follow the words ''Pineapple juice'' or ''Pineapple juice from concentrate.''

(3) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality*. (1) The standard of quality for pineapple juice is as follows:

(i) The soluble solids content of pineapple juice (exclusive of added sugars) without added water shall not be less than 10.5° Brix as determined by refractometer at 20 °C uncorrected for acidity and read as degrees Brix on International Sucrose Scales. Where the juice has been obtained using concentrated juice with addition of water, the soluble pineapple juice solids content (exclusive of added sugars) shall be not less than 12.8° Brix, uncorrected for acidity and read as degrees Brix on the International Sucrose Scales.

(ii) The acidity, as determined by the method prescribed in paragraph (b)(2)(ii) of this section, is not more than 1.35 grams of anhydrous citric acid per 100 milliliters of the juice.

(iii) The ratio of the degrees Brix to total acidity, as determined by the method prescribed in paragraph (b)(2)(iii) of this section, is not less than 12.

(iv) The quantity of finely divided ''insoluble solids'', as determined by the method prescribed in paragraph (b)(2)(iv) of this section, is not less than 5 percent nor more than 30 percent.

(2) The methods referred to in paragraph (b)(1) of this section are as follows:

(i) Determine the degrees Brix of the pineapple juice by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 31.009, ''Solids by Means of Spindle—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*.

(ii) Determine the total acidity of the pineapple juice by titration by the method prescribed in §145.180(b)(2)(ix) of this chapter.

(iii) Divide the degrees Brix determined as prescribed in paragraph (b)(2)(i) of this section by the grams of anhydrous citric acid per 100 milliliters of juice, determined as prescribed in paragraph (b)(2)(ii) of this section, and report the results as ratio of degrees Brix to total acidity.

(iv) Determine the quantity of ''insoluble solids'' in pineapple juice as follows: Measure 50 milliliters of thoroughly stirred pineapple juice into a cone-shaped graduated tube of the long-cone type, measuring approximately 4$\frac{3}{16}$ inches from tip to top calibration and having a capacity of 50 milliliters. Place the tube in a suitable centrifuge the approximate speed of which is related to diameter of swing in accordance with the table immediately below. The word ''diameter'' means the over-all distance between

the tips of opposing centrifuge tubes in operating position.

Diameter (inches)	Approximate revolutions per minute
10	1,609
10½	1,570
11	1,534
11½	1,500
12	1,468
12½	1,438
13	1,410
13½	1,384
14	1,359
14½	1,336
15	1,313
15½	1,292
16	1,271
16½	1,252
17	1,234
17½	1,216
18	1,199
18½	1,182
19	1,167
19½	1,152
20	1,137

The milliliter reading at the top of the layer of ''insoluble solids,'' after centrifuging 3 minutes, is multiplied by two to obtain the percentage of ''insoluble solids.''

(3) If the quality of pineapple juice falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14 (a) of this chapter, in the manner and form therein specified.

(c) *Fill of container.* (1) The standard of fill of container for pineapple juice, except when the food is frozen, is not less than 90 percent of the total capacity of the container, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter.

(2) If pineapple juice falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14433, Mar. 15, 1977, as amended at 47 FR 11831, Mar. 19, 1982; 47 FR 52694, Nov. 23, 1982; 49 FR 10101, Mar. 19, 1984; 50 FR 19524, May 9, 1985; 54 FR 24895, June 12, 1989; 58 FR 2882, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 146.187 Canned prune juice.

(a) Canned prune juice is the food prepared from a water extract of dried prunes and contains not less than 18.5 percent by weight of water-soluble solids extracted from dried prunes. The quantity of prune solids may be adjusted by the concentration, dilution, or both, of the water extract or extracts made. Such food may contain one or more of the optional acidifying ingredients specified in paragraph (b)(1) of this section, in a quantity sufficient to render the food slightly tart; it may contain honey added within the quantitative limits prescribed by paragraph (b)(2) of this section; and it may contain added vitamin C in a quantity prescribed by paragraph (b)(3) of this section. Such food is sealed in a container and so processed by heat, before or after sealing, as to prevent spoilage.

(b) The optional ingredients referred to in paragraph (a) of this section are:

(1) One or any combination of two or more of the following acidifying ingredients:

(i) Lemon juice.

(ii) Lime juice.

(iii) Citric acid.

(2) Honey, in a quantity not less than 2 percent and not more than 3 percent by weight of the finished food.

(3) Vitamin C, in a quantity such that the total vitamin C in each 6 fluid ounces of the finished food amounts to not less than 30 milligrams and not more than 50 milligrams.

(c)(1) The name of the food is ''Prune juice—a water extract of dried prunes''. For the purposes of the Federal Food, Drug, and Cosmetic Act concerning the label declaration of the name of the food, the explanatory statement ''A water extract of dried prunes'' may appear immediately below the words ''prune juice'', but there shall be no intervening written, printed, or graphic matter, and the type used for the words ''A water extract of dried prunes'' shall be of the same style and not less than half the print size of the type used for the words ''prune juice''.

(2)(i) When one or more of the acidifying ingredients specified in paragraph (b)(1) of this section are used, the label shall bear the statement ''_____ added'' or ''with added _____'', the blank being filled in with the name or names of the optional ingredients used.

(ii) When honey, as specified in paragraph (b)(2) of this section, is used the

label shall bear the statement ''with _____ honey'' or ''_____ honey added'', the blank to be filled in with the percent by weight of the honey in the finished food or with the statement ''between 2 and 3%''.

(iii) When one or more of the ingredients designated in paragraph (b)(1) of this section and the ingredient designated in paragraph (b)(2) of this section are used, the statements specified in paragraphs (c)(2) (i) and (ii) of this section may be combined, as for example, ''with lemon juice and between 2 and 3% honey added''.

(iv) When vitamin C is added as provided in paragraph (b)(3) of this section, it shall be designated on the label as ''vitamin C added'' or ''with added vitamin C''.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words specified in this paragraph, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14433, Mar. 15, 1977, as amended at 58 FR 2882, Jan. 6, 1993]

PART 150—FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Fruit Butters, Jellies, Preserves, and Related Products

Sec.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14445, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Fruit Butters, Jellies, Preserves, and Related Products

§ 150.110 Fruit butter.

(a) The fruit butters for which definitions and standards of identity are prescribed by this section are the smooth, semisolid foods each of which is made from a mixture of one or a permitted combination of the optional fruit ingredients specified in paragraph (b) of this section and one or any combination of the optional ingredients specified in paragraph (c) of this section, which meets the specifications in paragraph (d) of this section, and which is labeled in accordance with paragraph (e) of this section. Such mixture is concentrated with or without heat. The volatile flavoring materials or essence from such mixture may be captured during concentration, separately concentrated, and added back to any such mixture, together with any concentrated essence accompanying any optional fruit ingredient.

(b)(1) Each of the optional fruit ingredients referred to in paragraph (a) of this section is prepared by cooking one of the following fresh, frozen, canned, and/or dried (evaporated) mature fruits, with or without added water, and screening out skins, seeds, pits, and cores:

FACTOR REFERRED TO IN PARAGRAPH (D)(2) OF THIS SECTION

Name of fruit	
Apple	7.5
Apricot	7.0
Grape	7.0
Peach	8.5
Pear	6.5
Plum (other than prune)	7.0
Prune	7.0
Quince	7.5

(2) The permitted combinations are of two, three, four, and five of the fruit ingredients specified in paragraph (b)(1) of this section; the weight of each is not less than one-fifth of the weight of the combination. Each such fruit ingredient in any such combination is an optional ingredient.

(c) The following safe and suitable optional ingredients may be used:

(1) Nutritive carbohydrate sweeteners.

(2) Spice.

(3) Flavoring (other than artificial flavoring).

(4) Salt.

(5) Acidifying agents.

(6) Fruit juice or diluted fruit juice or concentrated fruit juice, in a quantity not less than one-half the weight of the optional fruit ingredient.

(7) Preservatives.

(8) Antifoaming agents except those derived from animal fats.

(9) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit ingredient.

(d) For the purposes of this section:

(1) The mixture referred to in paragraph (a) of this section shall contain not less than five parts by weight of the fruit ingredient as measured in accordance with paragraph (d)(2) of this section to each two parts by weight of nutritive carbohydrate sweetener as measured in accordance with paragraph (d)(4) of this section.

(2) Any requirement with respect to the weight of any optional fruit ingredient, whether concentrated, unconcentrated, or diluted, means the weight determined by the following method: (i) Determine the percent of soluble solids in the optional fruit ingredient by the method for soluble solids referred to in paragraph (d)(3) of this section; (ii) multiply the percent so found by the weight of such fruit ingredient; (iii) divide the result by 100; (iv) subtract from the quotient the weight of any nutritive sweetener solids or other added solids; and (v) multiply the remainder by the factor for such ingredient prescribed in paragraph (b)(1) of this section. The result is the weight of the optional fruit ingredient.

(3) The soluble solids content of the finished fruit butter is not less than 43 percent, as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), section 22.024, under ''Soluble Solids by Refractometer in Fresh and Canned Fruits, Fruit Jellies, Marmalades, and Preserves—Official Final Action,'' which is incorporated by reference, except that no correction is made for water-insoluble solids. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(4) The weight of any nutritive carbohydrate sweetener means the weight of the solids of such ingredient.

(5) The weight of fruit juice or diluted fruit juice or concentrated fruit juice (optional ingredient, paragraph (c)(6)) from a fruit specified in paragraph (b)(1) of this section is the weight of such juice, as determined by the method prescribed in paragraph (d)(2) of this section, except that the percent of soluble solids is determined by the method prescribed in the AOAC, 13th Ed. (1980), section 31.011, under ''Solids by Means of Refractometer—Official Final Action,'' which is incorporated by reference; the weight of diluted concentrated juice from any other fruits is the original weight of the juice before it was diluted or concentrated. The availability of this incorporation by reference is given in paragraph (d)(3) of this section.

(e)(1) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(i) In case the fruit butter is made from a single fruit ingredient, the name is ''Butter'', preceded by the name where by such fruit is designated in paragraph (b)(1) of this section.

(ii) In case the fruit butter is made from a combination of two, three, four, or five fruit ingredients, the name is ''Butter'', preceded by the words ''Mixed fruit'' or by the names whereby such fruits are designated in paragraph (b)(1) of this section, in the order of predominance, if any, of the weight of such fruit ingredients in the combination.

(2) Each of the optional ingredients specified in paragraphs (b) and (c) of this section shall be declared on the

label as required by the applicable sections of part 101 of this chapter, except that:

(i) Other than in the case of dried (evaporated) fruit the name(s) of the fruit or fruits used may be declared without specifying the particular form of the fruit or fruits used. When the optional fruit ingredient is prepared in whole or in part from dried fruit, the label shall bear the words ''prepared from'' or ''prepared in part from'', as the case may be, followed by the word ''evaporated'' or ''dried'', followed by the name whereby such fruit is designated in paragraph (c) of this section. When two or more such optional fruit ingredients are used, such names, each preceded by the word ''evaporated'' or ''dried'', shall appear in the order of predominance, if any, of the weight of such ingredients in the combination.

(ii) [Reserved]

[42 FR 14445, Mar. 15, 1977, as amended at 47 FR 11831, Mar. 19, 1982; 49 FR 10101, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2882, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 150.140 Fruit jelly.

(a) The jellies for which definitions and standards of identity are prescribed by this section are the jelled foods each of which is made from a mixture of one or a permitted combination of the fruit juice ingredients specified in paragraph (b) of this section and one or any combination of the optional ingredients specified in paragraph (c) of this section, which meets the specifications in paragraph (d) of this section and which is labeled in accordance with paragraph (e) of this section. Such mixture is concentrated with or without heat. The volatile flavoring materials or essence from such mixture may be captured during concentration, separately concentrated, and added back to any such mixture, together with any concentrated essence accompanying any optional fruit ingredient.

(b)(1) Each of the fruit juice ingredients referred to in paragraph (a) of this section is the filtered or strained liquid extracted with or without the application of heat and with or without the addition of water, from one of the following mature, properly prepared fruits which are fresh, frozen and/or canned:

FACTOR REFERRED TO IN PARAGRAPH (D)(2) OF THIS SECTION

Name of fruit	
Apple	7.5
Apricot	7.0
Blackberry (other than dewberry)	10.0
Black raspberry	9.0
Boysenberry	10.0
Cherry	7.0
Crabapple	6.5
Cranberry	9.5
Damson, damson plum	7.0
Dewberry (other than boysenberry, loganberry, and youngberry)	10.0
Fig	5.5
Gooseberry	12.0
Grape	7.0
Grapefruit	11.0
Greengage, greengage plum	7.0
Guava	13.0
Loganberry	9.5
Orange	8.0
Peach	8.5
Pineapple	7.0
Plum (other than damson, greengage, and prune)	7.0
Pomegranate	5.5
Prickly pear	11.0
Quince	7.5
Raspberry, red raspberry	9.5
Red currant, currant (other than black currant)	9.5
Strawberry	12.5
Youngberry	10.0

(2) The permitted combinations are of two, three, four, or five of the fruit juice ingredients specified in paragraph (b)(1) of this section, the weight of each is not less than one-fifth of the weight of the combination. Each such fruit juice ingredient in any such combination is an optional ingredient.

(c) The following safe and suitable optional ingredients may be used:

(1) Nutritive carbohydrate sweeteners.

(2) Spice.

(3) Acidifying agents.

(4) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit juice ingredient.

(5) Buffering agents.

(6) Preservatives.

(7) Antifoaming agents except those derived from animal fats.

(8) Mint flavoring and artificial green coloring, in case the fruit juice ingredient or combination of fruit juice ingredients is extracted from apple, crabapple, pineapple, or two or all of such fruits.

(9) Cinnamon flavoring, other than artificial flavoring, and artificial red

coloring in case the fruit juice ingredient or combination of fruit juice ingredients is extracted from apple or crabapple or both such fruits.

(d) For the purposes of this section:

(1) The mixture referred to in paragraph (a) of this section shall contain not less than 45 parts by weight of the fruit juice ingredients as measured in accordance with paragraph (d)(2) of this section to each 55 parts by weight of saccharine ingredient as measured in accordance with paragraph (d)(4) of this section.

(2) Any requirement with respect to the weight of any fruit juice ingredient, whether prepared from concentrated, unconcentrated, or diluted fruit juice means the weight determined by the following method: (i) Determine the percent of soluble solids in such fruit juice ingredient by the method for soluble solids referred to in paragraph (d)(3) of this section; (ii) multiply the percent so found by the weight of such fruit juice ingredient; (iii) divide the result by 100; (iv) subtract from the quotient the weight of any added saccharine ingredient solids or other added solids; and (v) multiply the remainder by the factor for such fruit juice ingredient prescribed in paragraph (b) of this section. The result is the weight of the fruit juice ingredient.

(3) The soluble-solids content of the finished jelly is not less than 65 percent, as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 31.011, under ''Solids by Means of Refractometer—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(4) The weight of any optional saccharine ingredient means the weight of the solids of such ingredient.

(e)(1) The name of each jelly for which a definition and standard of identity is prescribed by this section is as follows:

(i) In case the jelly is made with a single fruit juice ingredient, the name is ''Jelly'', preceded or followed by the name or synonym whereby the fruit from which such fruit juice ingredient was extracted is designated in paragraph (b) of this section.

(ii) In case the jelly is made with a combination of two, three, four, or five fruit juice ingredients, the name is ''Jelly'', preceded or followed by the words ''Mixed fruit'' or by the names or synonyms whereby the fruits from which the fruit juice ingredients were extracted are designated in paragraph (b) of this section, in the order of predominance, if any, of the weights of any such fruit juice ingredients in the combination.

(2) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(i) The name(s) of the fruit or fruits used may be declared without specifying the particular form of the fruit or fruits used.

(ii) When the optional ingredients listed in paragraphs (c) (3), (4), and (5) of this section are declared on the label, the declaration may be followed by the statement ''Used as needed'' on all jellies to which they are customarily, but not always, added to compensate for natural variations in the fruit juice ingredients used.

[42 FR 14445, Mar. 15, 1977, as amended at 47 FR 11831, Mar. 19, 1982; 49 FR 10101, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2882, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 150.160 Fruit preserves and jams.

(a) The preserves or jams for which definitions and standards of identity are prescribed by this section are the viscous or semi-solid foods, each of which is made from a mixture composed of one or a permitted combination of the fruit ingredients specified in paragraph (b) of this section and one or any combination of the optional ingredients specified in paragraph (c) of this section which meets the specifications in paragraph (d) of this section,

and which is labeled in accordance with paragraph (e) of this section. Such mixture, with or without added water, is concentrated with or without heat. The volatile flavoring material from such mixture may be captured during concentration, separately concentrated, and added back to any such mixture, together with any concentrated essence accompanying any optional fruit ingredient.

(b)(1) The fruit ingredients referred to in paragraph (a) of this section are the following mature, properly prepared fruits which are fresh, concentrated, frozen and/or canned:

GROUP I

Blackberry (other than dewberry), Black raspberry, Blueberry, Boysenberry, Cherry, Crabapple, Dewberry (other than boysenberry, loganberry, and youngberry) Elderberry, Grape, Grapefruit, Huckleberry, Loganberry, Orange, Pineapple, Raspberry, red raspberry, Rhubarb, Strawberry, Tangerine, Tomato, Yellow tomato, Youngberry

GROUP II

Apricot, Cranberry, Damson, damson plum, Fig, Gooseberry, Greengage, greengage plum, Guava, Nectarine, Peach, Pear, Plum (other than greengage plum and damson plum), Quince, Red currant, currant (other than black currant)

(2) The following combinations of fruit ingredients may be used:

(i) Any combination of two, three, four, or five of such fruits in which the weight of each is not less than one-fifth of the weight of the combination; except that the weight of pineapple may be not less than one-tenth of the weight of the combination.

(ii) Any combination of apple and one, two, three, or four of such fruits in which the weight of each is not less than one-fifth and the weight of apple is not more than one-half of the weight of the combination; except that the weight of pineapple may be not less than one-tenth of the weight of the combination.

In any combination of two, three, four, or five fruits, each such fruit is an optional ingredient. For the purposes of this section the word ''fruit'' includes the vegetables specified in this paragraph.

(c) The following safe and suitable optional ingredients may be used:

(1) Nutritive carbohydrate sweeteners.

(2) Spice.

(3) Acidifying agents.

(4) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit ingredient.

(5) Buffering agents.

(6) Preservatives.

(7) Antifoaming agents, except those derived from animal fat.

(d) For the purposes of this section:

(1) The mixture referred to in paragraph (a) of this section shall be composed of not less than: (i) In the case of a fruit ingredient consisting of a Group I fruit or a permitted combination exclusively of Group I fruits, 47 parts by weight of the fruit ingredient to each 55 parts by weight of the saccharine ingredient; and (ii) in all other cases, 45 parts by weight of the fruit ingredient to each 55 parts by weight of the saccharine ingredient. The weight of the fruit ingredient shall be determined in accordance with paragraph (d)(2) of this section, and the weight of the saccharine ingredient shall be determined in accordance with paragraph (d)(5) of this section.

(2) Any requirement with respect to the weight of any fruit, combination of fruits, or fruit ingredient means:

(i) The weight of fruit exclusive of the weight of any sugar, water, or other substance added for any processing or packing or canning, or otherwise added to such fruit.

(ii) In the case of fruit prepared by the removal, in whole or in part, of pits, seeds, skins, cores, or other parts; the weight of such fruit, exclusive of the weight of all such substances removed therefrom.

(iii) In the cases of apricots, cherries, grapes, nectarines, peaches, and all varieties of plums, whether or not pits and seeds are removed therefrom; the weight of such fruit, exclusive of the weight of such pits and seeds.

(iv) In the case of concentrated fruit, the weight of the properly prepared fresh fruit used to produce such concentrated fruit.

(3) The term *concentrated fruit* means a concentrate made from the properly prepared edible portion of mature fresh or frozen fruits by removal of moisture

with or without the use of heat or vacuum, but not to the point of drying. Such concentrate is canned or frozen without the addition of sugar or other sweetening agents and is identified to show or permit the calculation of the weight of the properly prepared fresh fruit used to produce any given quantity of such concentrate. The volatile flavoring material or essence from such fruits may be captured during concentration and separately concentrated for subsequent addition to the concentrated fruit either directly or during manufacture of the preserve or jam, in the original proportions present in the fruit.

(4) The weight of any optional saccharine ingredient means the weight of the solids of such ingredient.

(5) The soluble-solids content of the finished jam or preserve is not less than 65 percent, as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 22.024, under ''Soluble Solids by Refractometer in Fresh and Canned Fruits, Jellies, Marmalades, and Preserves—Official Final Action,'' which is incorporated by reference, except that no correction is made for water-insoluble solids. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(e)(1) The name of each preserve or jam for which a definition and standard of identity is prescribed by this section is as follows:

(i) If the fruit ingredient is a single fruit, the name is ''Preserve'' or ''Jam'', preceded or followed by the name or synonym whereby such fruit is designated in paragraph (b) of this section.

(ii) If the fruit ingredient is a combination of two, three, four, or five fruits, the name is ''Preserve'' or ''Jam'', preceded or followed by the words ''Mixed fruit'' or by the names or synonyms whereby such fruits are designated in paragraph (b) of this section, in the order of predominance, if any, of the weights of such fruits in the combination.

(2) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(i) The name(s) of the fruit or fruits used may be declared without specifying the particular form of the fruit or fruits used.

(ii) When the optional ingredients listed in paragraphs (c) (3), (4), and (5) of this section are declared on the label, the declaration may be followed by the statement ''used as needed'' on all preserves or jams to which they are customarily, but not always, added to compensate for natural variations in the fruit ingredients used.

[42 FR 14445, Mar. 15, 1977, as amended at 47 FR 11831, Mar. 19, 1982; 49 FR 10101, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2882, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

PART 152—FRUIT PIES

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Fruit Pies

§ 152.126 Frozen cherry pie.

(a) *Identity.* (1) Frozen cherry pie (excluding baked and then frozen) is the food prepared by incorporating in a filling contained in a pastry shell mature, pitted, stemmed cherries that are fresh, frozen, and/or canned. The top of the pie may be open or it may be wholly or partly covered with pastry or other suitable topping. Filling, pastry, and topping components of the food consist of optional ingredients as prescribed by paragraph (a)(2) of this section. The finished food is frozen.

(2) The optional ingredients referred to in paragraph (a)(1) of this section consist of suitable substances that are not food additives as defined in section 201(s) of the Federal Food, Drug, and

Cosmetic Act or color additives as defined in section 201(t) of the act; or if they are food additives or color additives as so defined, they are used in conformity with regulations established pursuant to section 409 or 721 of the act. Ingredients that perform a useful function in the formulation of the filling, pastry, and topping components, when used in amounts reasonably required to accomplish their intended effect, are regarded as suitable except that artificial sweeteners are not suitable ingredients of frozen cherry pie.

(3) The name of the food for which a definition and standard of identity is established by this section is frozen cherry pie; however, if the maximum diameter of the food (measured across opposite outside edges of the pastry shell) is not more than 4 inches, the food alternatively may be designated by the name frozen cherry tart. The word ''frozen'' may be omitted from the name on the label if such omission is not misleading.

(4)(i) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(ii) The label shall not bear any misleading pictorial representation of the cherries in the pie.

(b) *Quality.* (1) The standard of quality for frozen cherry pie is as follows:

(i) The fruit content of the pie is such that the weight of the washed and drained cherry content is not less than 25 percent of the weight of the pie when determined by the procedure prescribed by paragraph (b)(2) of this section.

(ii) Not more than 15 percent by count of the cherries in the pie are blemished with scab, hail injury, discoloration, scar tissue, or other abnormality. A cherry showing skin discoloration (other than scald) having an aggregate area exceeding that of a circle nine thirty-seconds of an inch in diameter is considered to be blemished. A cherry showing discoloration of any area but extending into the fruit tissue is also considered to be blemished.

(2) Compliance with the requirement for the weight of the washed and drained cherry content of the pie, as prescribed by paragraph (b)(1)(i) of this section, is determined by the following procedure:

(i) Select a random sample from a lot:

(*a*) At least 24 containers if they bear a weight declaration of 16 ounces or less.

(*b*) Enough containers to provide a total quantity of declared weight of at least 24 pounds if they bear a weight declaration of more than 16 ounces.

(ii) Determine net weight of each frozen pie.

(iii) Temper the pie until the top crust can be removed.

(iv) Remove the filling and cherries from the pie and transfer to the surface of a previously weighed 12-inch diameter U.S. No. 8 sieve (0.094-inch openings) stacked on a U.S. No. 20 sieve (0.033-inch openings).

(v) Distribute evenly over the surface and wash with a gentle spray of water at 70°–75 °F to free the cherries and cherry fragments from the adhering material.

(vi) Remove the U.S. No. 8 sieve and examine the U.S. No. 20 sieve and transfer all cherry fragments to the U.S. No. 8 sieve.

(vii) Drain the cherry contents on the No. 8 sieve for 2 minutes in an inclined position (15°–30° slope). Weigh the U.S. No. 8 sieve and the washed and drained cherries to the nearest 0.01 ounce.

(viii) The weight of the washed and drained cherries is the weight of the sieve and the cherry material less the weight of the sieve. Calculate the percent of the cherry content of each pie with the following formula, and then calculate the average percent of the entire random sample:

$$\text{Percent of the cherry content of the pie} = [(\text{Weight of washed and drained cherries}) / (\text{Net weight of pie})] \times 100.$$

(3) If the quality of the frozen cherry pie falls below the standard of quality prescribed by paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form specified therein; but in lieu of the words prescribed for the second line inside the rectangle, the label may bear the alternative statement ''Below standard in quality _____'', the blank being filled in with the following words, as applicable:

Subpart B—Requirements for Specific Standardized Canned Vegetables

§ 155.120 Canned green beans and canned wax beans.

(a) *Identity*—(1) *Definition*. Canned green beans and canned wax beans are the foods prepared from succulent pods of fresh green bean or wax bean plants conforming to the characteristics of *Phaseolus vulgaris* L. *and Phaseolus coccineus* L. The optional color and varietal types and styles of the bean ingredient are set forth in paragraph (a)(2) of this section. The product is packed with water or other suitable aqueous liquid medium to which may be added one or more of the other optional ingredients set forth in paragraph (a)(3) of this section. Such food is so processed by heat, in an appropriate manner before or after being sealed in a container, as to prevent spoilage.

(2) *Optional color and varietal types and styles of pack*. The optional color and varietal types and styles of the bean ingredient referred to in paragraph (a)(1) of this section are:

(i) *Optional color types*. The beans shall be one of the following distinct color types: (*a*) Green; or (*b*) Wax.

(ii) *Optional varietal types*—(*a*) *Round*. Beans having a width not greater than 1½ times the thickness of the bean; or

(*b*) *Flat*. Beans having a width greater than 1½ times the thickness of the bean.

(iii) *Optional styles of pack*—(*a*) *Whole*. Whole pods of any length.

(*b*) *Shoestring or sliced lengthwise or French style*. Pods sliced lengthwise.

(*c*) *Cuts*. Transversely cut pods not less than 19 mm (0.75 in) long as measured along the longitudinal axis, which may contain the shorter end pieces that result from cutting such pods.

(*d*) *Short cuts*. Pieces of pods cut transversely of which 75 percent, by count, or more are less than 19 mm (0.75 in) in length and not more than 1 percent by count are more than 32 mm (1¼ in) in length.

(*e*) *Diagonal cuts*. Pods cut in lengths as specified in paragraph (a)(2)(iii)(*c*) of this section, except the pods are cut at an angle approximately 45° to the longitudinal axis.

(*f*) *Diagonal short cuts*. Pods cut in lengths as specified in paragraph (a)(2)(iii)(*d*) of this section, except the pods are cut at an angle approximately 45° to the longitudinal axis.

(*g*) *Mixture*. Any mixture of two or more of the styles specified in paragraph (a)(2)(iii)(*a*) to (*f*), inclusive, of this section.

(3) *Optional ingredients*. In addition to the optional packing media listed in paragraph (a)(1) of this section and the optional types and styles of beans ingredient listed in paragraph (a)(2) of this section, the following safe and suitable optional ingredients may be used:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate.

(iv) Disodium guanylate.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(vii) Nutritive carbohydrate sweeteners.

(viii) Spice.

(ix) Flavoring (except artificial).

(x) Pieces of green or red peppers or mixtures of both, either of which may be dried, or other vegetables not exceeding in total 15 percent by weight of the finished product.

(xi) Vinegar.

(xii) Lemon juice or concentrated lemon juice.

(xiii) Glucono delta-lactone.

(xiv) Mint leaves.

(xv) Butter or margarine in a quantity of not less than 3 percent by weight of the finished product. When butter or margarine is added, emulsifiers or stabilizers, or both, may be added. No spice or flavoring simulating the color or flavor imparted by butter or margarine is used.

(4) *Labeling*. (i) The name of the food is ''green beans'' or ''wax beans'' as appropriate. Wax beans may be additionally designated ''golden'' or ''yellow''.

(ii) The following shall be included as part of the name or in conjunction with the name of the food:

(*a*) A declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter.

(*b*) A declaration of any spice, seasoning, or garnishing that characterizes the product, e.g., ''with added spice'', or, in lieu of the word ''spice'',

the common name of the spice, e.g., ''seasoned with green peppers''.

(*c*) The words ''vacuum pack'' or ''vacuum packed'' when the weight of the liquid in the container, as determined by the method prescribed in paragraph (b)(2)(i) of this section is not more than 25 percent of the net weight, and the container is closed under conditions creating a high vacuum in the container.

(*d*) The name of the optional style of bean ingredient as set forth in paragraph (a)(2)(iii) of this section or, if a product consists of a mixture of such styles, the words ''mixture of '' the blank to be filled in with the names of the styles present, arranged in the order of decreasing predominance, if any, by weight of such ingredients. If the product consists of whole beans and the pods are packed parallel to the sides of the container, the word ''whole'' may be preceded or followed by the words ''vertical pack'', or if the pods are cut at both ends and are of substantially equal lengths, the words ''asparagus style'' may be used in lieu of the words ''vertical pack''. If the product consists of short cuts or diagonal short cuts, a numerical expression indicating the predominate length of cut in the finished food may be used in lieu of the word ''short'', e.g., ''½ inch cut''.

(iii) The following may be included in the name of the food:

(*a*) The word ''stringless'' where the beans are in fact stringless.

(*b*) The name of the optional varietal type as specified in paragraph (a)(2)(ii) of this section, or the specific varietal name, e.g., ''Blue Lake Green Beans'', or both.

(iv) If a term designating diameter is used, it shall be supported by an exact graphic representation of the cross section of the bean pod or by a statement of the maximum diameter in common or decimal fractions of an inch and, optionally, by the millimeter equivalent stated parenthetically. The diameter of a whole, cut, diagonal cut, or short cut is determined by measuring the thickest portion of the pod at the shorter diameter of the bean perpendicular to the longitudinal axis.

(5) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) When tested by the method prescribed in paragraph (b)(2) of this section:

(i) In the case of cut beans and diagonal cut beans under paragraphs (a)(2)(iii) (*c*) and (*d*) of this section and mixtures of two or more optional forms under paragraph (a)(2)(iii)(*g*) of this section, not more than 60 units per 340 g (12 oz) drained weight are less than 13 mm (0.50 in) long: *Provided*, That where the number of units per 340 g (12 oz) drained weight exceeds 240, not more than 25 percent by count of the total units are less than 13 mm (0.50 in) long.

(ii) In case there are present pods or pieces of pods 10.7 mm ($^{27}/_{64}$-inch) or more in diameter, there are not more than 12 strings per 340 gm (12 ounces) of drained weight which will support 227 gm (one-half pound) for 5 seconds or longer.

(iii) The deseeded pods contain not more than 0.15 percent by weight of fibrous material.

(iv) There are not more than 10 percent by weight of blemished units of which amount not more than one-half may be materially damaged by insect or pathological injury. A unit is considered blemished when the aggregate blemished area exceeds the area of a circle 3 mm (⅛ in) in diameter. Materially damaged means that the unit is damaged to the extent that the appearance or eating quality of the unit is seriously affected.

(v) There are not more than 8 unstemmed units per 340 g (12 oz) drained weight.

(vi) The combined number of leaves, detached stems, and other extraneous vegetable matter shall not average more than 3 pieces per 340 g (12 oz) drained beans.

(2) Canned beans shall be tested by the following method to determine whether they meet the requirements of paragraph (b)(1) of this section:

(i) Determine the gross weight of the container. Open and distribute the contents of the container over the meshes of a U.S. No. 8 circular sieve with openings of 2.36 mm (0.0937 in), which has been previously weighed. The diameter

of the sieve is 20.3 cm (8 in) if the quantity of contents of the container is less than 1.36 kg (3 lb) and 30.5 cm (12 in) if such quantity is 1.36 kg (3 lb) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications of such cloth set forth in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th ed. (1990), vol. 2, p. xii, Table 1, ''Nominal Dimensions of Standard Test Sieves (USA Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Without shifting the material on the sieve, incline the sieve 17 to 20° to facilitate drainage. Two minutes after drainage begins, weigh the sieve and the drained material. Record in grams (ounces) the weight so found, less the weight of the sieve, as the drained weight. Dry and weigh the empty container and subtract this weight from the gross weight to obtain the net weight. Calculate the percent of drained liquid in the net weight.

(ii) Pour the drained material from the sieve into a flat tray and spread it in a layer of fairly uniform thickness. Count the total number of units. For the purpose of this count, loose seeds, pieces of seed, loose stems, and extraneous material are not to be included. Divide the number of units by the drained weight recorded in paragraph (b)(2)(i) of this section and multiply by 340 to obtain the number of units per 340 g (12 oz) drained weight.

(iii) Examine the drained material in the tray, weigh and record weight of blemished units, count and record the number of unstemmed units; and, in case the material consists of the optional ingredient specified in paragraph (a)(2)(iii) (*c*), (*d*) or (*f*) of this section, count and record the number of units which are less than 13 mm (0.50 in.) long. If the number of units per 340 g (12 oz.) is 240 or less, divide the number of units which are less than 13 mm (0.50 in.) by the drained weight recorded in paragraph (b)(2)(i) of this section and multiply by 340 to obtain the number of such units per 340 g (12 oz.) drained weight. If the number of units per 340 g (12 oz.) exceeds 240, divide the number of units less than 13 mm (0.50 in.) long by the total number of units and multiply by 100 to determine the percentage by count of the total units which are less than 13 mm (0.50 in.) long.

(*a*) Divide the weight of blemished units by the drained weight recorded in paragraph (b)(2)(i) of this section and multiply by 100 to obtain the percentage by weight of blemished units in the container.

(*b*) Divide the number of unstemmed units by the drained weight recorded in paragraph (b)(2)(i) of this section and multiply by 340 to obtain the number of unstemmed units per 340 g (12 oz.) of drained weight.

(iv) Remove from the tray the extraneous vegetable material, count, record count, and return to tray.

(v) Remove from the tray one or more representative samples of 99 to 113 g (3½ to 4 ounces) covering each sample as taken to prevent evaporation.

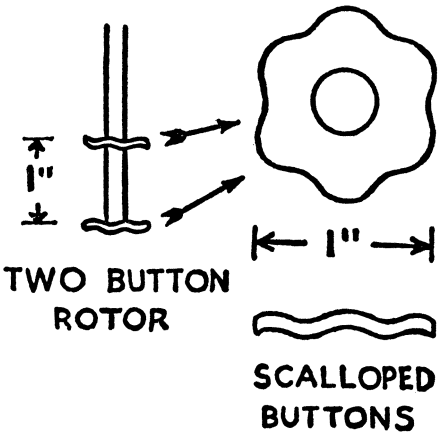
(vi) From each representative sample selected in paragraph (b)(2)(v) of this section, discard any loose seed and extraneous vegetable material and detach and discard any attached stems. Except with optional style of ingredient specified in paragraph (a)(2)(iii)(*b*) of this section (pods sliced lengthwise), trim off, as far as the end of the space formerly occupied by the seed, any portion of pods from which the seed has become separated. Remove and discard any portions of seed from the trimmings and reserve the trimmings for paragraph (b)(2)(viii) of this section. Weigh and record the weight of the trimmed pods. Deseed the trimmed pods and reserve the deseeded pods for paragraph (b)(2)(viii) of this section. Remove strings from the pods during the deseeding operation. Reserve these strings for testing as prescribed in paragraph (b)(2)(vii) of this section. In

the case of pods sliced lengthwise, remove seed and pieces of seed and reserve the deseeded pods for use as prescribed in paragraph (b)(2)(viii) of this section.

(vii) If strings have been removed for testing, as prescribed in paragraph (b)(2)(vi) of this section, test them as follows:

Fasten clamp, weighted to 250 g (8.8 oz.), to one end of the string, grasp the other end with the fingers (a cloth may be used to aid in holding the string), and lift gently. Count the string as tough if it supports the 250 g (8.8 oz.) weight for at least 5 seconds. If the string breaks before 5 seconds, test such parts into which it breaks as are 13 mm (½ in.) or more in length; and if any such part of the string supports the 250 g (8.8 oz.) weight for at least 5 seconds, count the string as tough. Divide the number of tough strings by the weight of the sample recorded in paragraph (b)(2)(v) of this section and multiply by 340 to obtain the number of tough strings per 340 g (12 oz.) drained weight.

(viii) Combine the deseeded pods with the trimmings reserved in paragraph (b)(2)(vi) of this section, and, if strings were tested as prescribed in paragraph (b)(2)(vii) of this section, add such strings broken or unbroken. Weigh and record weight of combined material. Transfer to the metal cup of a malted-milk stirrer and mash with a pestle. Wash material adhering to the pestle back into cup with 200 cc of boiling water. Bring mixture nearly to a boil, add 25 cc of 50 percent (by weight) sodium hydroxide solution and bring to a boil. (If foaming is excessive, 1 cc of capryl alcohol may be added.) Boil for 5 minutes, then stir for 5 minutes with a malted-milk stirrer capable of a no-load speed of at least 7,200 rpm. Use a rotor with two scalloped buttons shaped as shown in exhibit 1 as follows:



Transfer the material from the cup to a previously weighed 30-mesh monel metal screen having a diameter of about 9–10 cm (3½ to 4 in.) and side walls about 2.5 cm (1 in.) high, and wash fiber on the screen with a stream of water using a pressure not exceeding a head (vertical distance between upper level of water and outlet of glass tube) of 152 cm (60 in.), delivered through a glass tube 7.6 cm (3 in.) long and 3 mm (⅛ in.) inside diameter inserted into a rubber tube of 6 mm (¼ in.) inside diameter. Wash the pulpy portion of the material through the screen and continue washing until the remaining fibrous material, moistened with phenolphthalein solution, does not show any red color after standing 5 minutes. Again wash to remove phenolphthalein. Dry the screen containing the fibrous material for 2 hours at 100 °C, cool, weigh, and deduct weight of screen. Divide the weight of fibrous material by the weight of combined deseeded pods, trimmings, and strings and multiply by 100 to obtain the percentage of fibrous material.

(ix) If the drained weight recorded in paragraph (b)(2)(i) of this section was less than 340 g (12 oz.), open and examine separately for extraneous material, as directed in paragraph (b)(2)(iv) of this section, additional containers until a total of not less than 340 g (12 oz.) of drained material is obtained. To determine the number of pieces of extraneous vegetable material per 340 g (12 oz.) of drained weight, total the

number of pieces of extraneous vegetable material found in all containers opened, divide this sum by the sum of the drained weights in these containers and multiply by 340.

(3) Determine compliance as specified in §155.3(b) except that a lot shall be deemed to be in compliance for extraneous plant material based on an average of all containers examined.

(4) If the quality of the canned green beans or canned wax beans falls below the standard of quality prescribed by paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified; but in lieu of the words prescribed for the second line inside the rectangle the following words may be used, when the quality of canned green beans or canned wax beans falls below the standard in one only of the following respects:

(i) ''Excessive number very short pieces'', if the canned green beans or canned wax beans fail to meet the requirements of paragraph (b)(1)(i) of this section.

(ii) ''Excessive number blemished units'', if they fail to meet the requirements of paragraph (b)(1)(iv) of this section.

(iii) ''Excessive number unstemmed units'', if they fail to meet the requirements of paragraph (b)(1)(v) of this section.

(iv) ''Excessive foreign material'', if they fail to meet the requirements of paragraph (b)(1)(vi) of this section.

[42 FR 14449, Mar. 15, 1977, as amended at 42 FR 30359, 30360, June 14, 1977; 45 FR 43398, June 27, 1980; 47 FR 11831, Mar. 19, 1982; 49 FR 10101, Mar. 19, 1984; 57 FR 34245, Aug. 4, 1992; 58 FR 2882, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 155.130 Canned corn.

(a) *Identity*—(1) *Definition.* Canned sweet corn is the product prepared from clean, sound kernels of sweet corn packed with a suitable liquid packing medium which may include water and the creamy component from corn kernels. The tip caps are removed. The product is of the optional styles specified in paragraph (a)(2) of this section. It may contain one, or any combination of two or more, of the optional ingredients set forth in paragraph (a)(3) of this section. Such food is processed by heat, in an appropriate manner, before or after being sealed in a container, so as to prevent spoilage.

(2) *Styles.* The optional styles referred to in paragraph (a)(1) of this section consist of succulent sweet corn of the yellow (golden) or white color type, conforming to *Zea mays* L. having the sweet corn characteristic as follows:

(i) Whole kernel or whole grain or cut kernel consisting of whole or substantially whole cut kernels packed with a liquid medium.

(ii) Cream style consisting of whole or partially whole cut kernels packed in a creamy component from the corn kernels and other liquid or other ingredients to form a product of creamy consistency.

(3) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate.

(iv) Disodium guanylate.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(vii) Nutritive carbohydrate sweeteners.

(viii) Spice.

(ix) Flavoring (except artificial).

(x) Citric acid.

(xi) Starch or food starch-modified in cream style corn when necessary to ensure smoothness.

(xii) Seasonings and garnishes.

(*a*) Mint leaves.

(*b*) Pieces of green peppers or red peppers, or mixtures of both, either of which may be sweet or hot and may be dried, or other vegetables, not exceeding 15 percent by weight of the finished food.

(*c*) Lemon juice or concentrated lemon juice.

(*d*) Butter or margarine in a quantity not less than 3 percent by weight of the finished food. When butter or margarine is added, emulsifiers or stabilizers, or both, may be added. When butter or margarine is added, no spice, or flavoring simulating the color or flavor imparted by butter or margarine is used.

(4) *Labeling.* The name of the food is ''corn'' or ''sweet corn'' or ''sugar corn'' and shall include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter and a declaration of any spice, seasoning or garnishing that characterizes the product; for example, ''With added spice'', ''Seasoned with red peppers'', ''Seasoned with butter''. The name of the food shall also include the following:

(i) The optional style of the corn ingredient as specified in paragraph (a)(2) of this section.

(ii) The words ''vacuum pack'' or ''vacuum packed'' when the corn ingredient is as specified in paragraph (a)(2)(i) of this section and the weight of the liquid in the container, as determined by the method prescribed in paragraph (b)(2)(i) of this section, is not more than 20 percent of the net weight, and the container is closed under conditions creating a high vacuum in the container.

(iii) The color type used only when the product consists of white corn.

(iv) The color type used only when the product consists of white corn.

(5) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned corn is as follows:

(i) When tested by the method prescribed in paragraph (b)(2) of this section, canned whole-kernel corn (paragraph (a)(2)(i) of this section):

(*a*) Contains not more than seven brown or black discolored kernels or pieces of kernel per 400 g. (14 ounces) of drained weight;

(*b*) Contains not more than 1 cubic centimeter of pieces of cob for each 400 g. (14 ounces) of drained weight;

(*c*) Contains not more than 7 square centimeters (1.1 square inch) of husk per 400 g. (14 ounces) of drained weight; and

(*d*) Contains not more than 180 mm. (7 inches) of silk per 28 g. (1 ounce) of drained weight.

(ii) When tested by the method prescribed in paragraph (b)(3) of this section, canned cream style corn (paragraph (a)(2)(ii) of this section):

(*a*) Contains not more than 10 brown or black discolored kernels or pieces of kernel per 600 g. (21.4 ounces) of net weight;

(*b*) Contains not more than 1 cubic centimeter of pieces of cob per 600 g. (21.4 ounces) of net weight;

(*c*) Contains not more than 7 square centimeters (1.1 square inch) of husk per 600 g. (21.4 ounces) of net weight;

(*d*) Contains not more than 150 mm. (6 inches) of silk for each 28 g. (1 ounce) of net weight; and

(*e*) Has a consistency such that the average diameter of the approximately circular area over which the prescribed sample spreads does not exceed 30.5 cm. (12 inches), except that when the washed drained material contains more than 20 percent of alcohol-insoluble solids, the average diameter of the approximately circular area over which the prescribed sample spreads does not exceed 25.4 cm. (10 inches).

(iii)(*a*) The weight of the alcohol-insoluble solids of whole-kernel corn (paragraph (a)(2)(i) of this section) does not exceed 27 percent of the drained weight, when tested by the method prescribed in paragraph (b)(2) of this section.

(*b*) The weight of the alcohol-insoluble solids of the washed drained material of cream style corn (paragraph (a)(2)(ii) of this section) does not exceed 27 percent of the drained weight of such material, when tested by the method prescribed in paragraph (b)(3) of this section.

(2) The method referred to in paragraph (b)(1) of this section for testing whole-kernel corn (paragraph (a)(2)(i) of this section) is as follows:

(i) Determine the gross weight of the container. Open and distribute the contents of the container over the meshes of a U.S. No. 8 circular sieve which has previously been weighed. The diameter of the sieve is 20.3 cm. (8 inches) if the quantity of the contents of the container is less than 1.36 kg. (3 pounds), and 30.5 cm. (12 inches) if such quantity is 1.36 kg. (3 pounds) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such sieve set forth in the ''Definitions of Terms and Explanatory Notes'' prescribed in ''Official Methods of Analysis of the Association of Official

Analytical Chemists,'' 13th Ed. (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. Without shifting the material on the sieve, so incline the sieve at approximately 17–20° angle to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained material. Record, in g. (ounces), the weight so found, less the weight of the sieve, as the drained weight. Dry and weigh the empty container and subtract this weight from the gross weight to obtain the net weight. Calculate the percent of drained liquid in the net weight.

(ii) Pour the drained material from the sieve into a flat tray and spread it in a layer of fairly uniform thickness. Count, but do not remove, the brown or black discolored kernels or pieces of kernel and calculate the number per 400 g. (14 ounces) of drained material. Remove pieces of silk more than 12.7 mm. (one-half inch) long, husk, cob, and any pieces of material other than corn. Measure the aggregate length of such pieces of silk and calculate the length of silk per 28 g. (1 ounce) of drained weight. Spread the husk flat, measure its aggregate area, and calculate the area of husk per 400 g. (14 ounces) of drained weight. Place all pieces of cob under a measured amount of water in a cylinder which is so graduated that the volume can be measured to 0.1 cubic centimeter. Take the increase in volume as the aggregate volume of the cob and calculate the volume of cob per 400 g. (14 ounces) of drained weight.

(iii) Comminute representative 100 g. sample of the drained corn from which the silk, husk, cob, and other material which is not corn (i.e., peppers) have been removed. An equal amount of water is used to facilitate this operation. Weigh to nearest 0.01 g. a portion of the comminuted material equivalent to approximately 10 g. of the drained corn into a 600 cubic centimeter beaker. Add 300 cubic centimeters of 80 percent alcohol (by volume), stir, cover beaker, and bring to a boil. Simmer slowly for 30 minutes. Fit a Buchner funnel with a previously prepared filter paper of such sizes that its edges extend 12.7 mm. (one-half inch) or more up the vertical sides of the funnel. The previous preparation of the filter paper consists of drying it in a flat-bottomed dish for 2 hours at 100 °C, covering the dish with a tight fitting cover, cooling it in a desiccator, and promptly weighing to the nearest 0.001 g. After the filter paper is fitted to the funnel, apply suction and transfer the contents of the beaker to the funnel. Do not allow any of the material to run over the edge of the paper. Wash the material on the filter with 80 percent alcohol (by volume) until the washings are clear and colorless. Transfer the filter paper with the material retained thereon to the dish used in preparing the filter paper. Dry the material in a ventilated oven, without covering the dish, for 2 hours at 100 °C. Place the cover on the dish, cool it in a desiccator, and promptly weigh to the nearest 0.001 g. From this weight subtract the weight of the dish, cover, and paper as previously found. Calculate the remainder to percentage.

(3) The method referred to in paragraph (b)(1) of this section for testing cream-style corn (paragraph (a)(2)(ii) of this section) is as follows:

(i) Allow the container to stand at least 24 hours at a temperature of 68 °F to 85 °F. Determine the gross weight, open, transfer the contents into a pan, and mix thoroughly in such a manner as not to incorporate air bubbles. (If the net contents of a single container is less than 510 g. (18 ounces) determine the gross weight, open, and mix the contents of the least number of containers necessary to obtain 510 g. (18 ounces). Fill level full a hollow, truncated cone so placed on a polished horizontal plate as to prevent leakage. The cone has an inside bottom diameter of 7.62 cm. (3 inches), inside top diameter of 5.08 cm. (2 inches), and height of

12.30 cm. ($4\frac{27}{32}$ inches). As soon as the cone is filled, lift it vertically. Determine the average of the longest and shortest diameters of the approximately circular area on the plate covered by the sample 30 seconds after lifting the cone. Dry and weigh each empty container and subtract the weight so found from the gross weight to obtain the net weight.

(ii) Transfer the material from the plate, cone, and pan onto a U.S. No. 8 sieve as prescribed in paragraph (b)(2)(i) of this section. The diameter of the sieve is 20.3 cm. (8 inches) if the quantity of the contents of the container is less than 1.36 kg. (3 pounds), and 30.5 cm. (12 inches) if such quantity is 1.36 kg. (3 pounds) or more. Set the sieve in a pan. Add enough water to bring the level within 9.53 mm. (three-eighth inch) to 6.35 mm. (one-fourth inch) of the top of the sieve. Gently wash the material on the sieve by combined up-and-down and circular motion for 30 seconds. Repeat washing with a second portion of water. Remove sieve from pan, incline to facilitate drainage, and drain for 2 minutes.

(iii) From the material remaining on the U.S. No. 8 sieve, count, but do not remove, the brown or black discolored kernels or pieces of kernel and calculate the number per 600 g. (21.4 ounces) of net weight. Remove pieces of silk more than 12.7 mm. (one-half inch) long, husk, cob, and other material which is not corn (i.e., peppers). Measure aggregate length of such pieces of silk and calculate the length per 28 g. (ounce) of net weight. Spread the husk flat and measure its aggregate area and calculate the area per 600 g. (21.4 ounces) of net weight. Place all pieces of cob under a measured amount of water in a cylinder which is so graduated that the volume may be measured to 0.1 cubic centimeter. Take the increase in volume as the aggregate volume of the cob and calculate the volume of cob per 600 g. (21.4 ounces) of net weight. Take a representative 100 g. sample of the material remaining on the U.S. No. 8 sieve (if such material weighs less than 100 g. take all of it) and determine the alcohol-insoluble solids as prescribed in paragraph (b)(2)(iii) of this section for whole kernel corn.

(4) Determine compliance as specified in §155.3(b).

(5) If the quality of canned corn falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned corn falls below standard with respect to only one of the factors of quality specified by paragraphs (b)(1)(i) (*a*) to (*d*) of this section, or by paragraphs (b)(1)(ii) (*a*) to (*e*) of this section, there may be substituted for the second line of such general statement of substandard quality, ''Good food—not high grade'', a new line as specified after the corresponding subdivision designation of paragraph (b)(1) of this section, which the canned corn fails to meet:

(i)(*a*) or (ii)(*a*) ''Excessive discolored kernels''.
(i)(*b*) or (ii)(*b*) ''Excessive cob''.
(i)(*c*) or (ii)(*c*) ''Excessive husk''.
(i)(*d*) or (ii)(*d*) ''Excessive silk''.
(ii)(*e*) ''Excessively liquid''.

(c) *Fill of container.* (1) The standard of fill of container for canned corn is:

(i) Except in the case of vacuum pack corn the fill of the corn ingredient and packing medium, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(ii) In whole kernel corn, the drained weight of the corn ingredient, determined by the procedure set forth in §155.3, shall not be less than 61 percent of the water capacity of the container.

(2) Determine compliance as specified in §155.3(b).

(3) If canned corn falls below the standard of fill of container prescribed in paragraphs (c)(1) and (2) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14449, Mar. 15, 1977, as amended at 45 FR 43398, June 27, 1980; 47 FR 11831, 11832, Mar. 19, 1982; 49 FR 10101, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2882, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 155.131 Canned field corn.

(a) *Identity.* (1) Canned field corn conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for canned corn by § 155.130(a), except that the corn ingredient consists of succulent field corn or a mixture of succulent field corn and succulent sweet corn.

(2) The name of the food conforms to the name specified in § 155.130(a)(5), except that the words ''Corn'', ''Sweet corn'', and ''Sugar corn'' are replaced by the words ''Field corn'', and the term ''Golden field corn'' is not used.

(b) [Reserved]

(c) *Fill of container.* Canned cream-style field corn conforms to the standard of fill of container and label statement of substandard fill prescribed for canned cream-style corn by § 155.130(c).

[42 FR 14449, Mar. 15, 1977, as amended at 58 FR 2882, Jan. 6, 1993]

§ 155.170 Canned peas.

(a) *Identity*—(1) *Definition.* Canned peas is the food prepared from fresh or frozen succulent seeds of the pea plant of the species *Pisum sativum* L. but excluding the subspecies *macrocarpum.* Only sweet wrinkled varieties, smooth-skin varieties, or hybrids thereof may be used. The product is packed with water or other suitable aqueous liquid medium to which may be added one or more of the other optional ingredients set forth in paragraph (a)(2) of this section. Such food is sealed in a container and, before or after sealing, is so processed by heat as to prevent spoilage.

(2) *Optional ingredients.* In addition to the optional packing media provided for in paragraph (a)(1) of this section, the following safe and suitable optional ingredients may be used:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate.

(iv) Disodium guanylate.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(vii) One or any combination of two or more of the dry or liquid forms of sugar, invert sugar sirup, dextrose, glucose sirup, and fructose.

(viii) Spice.

(ix) Flavoring (except artificial).

(x) Color additives.

(xi) Calcium salts, the total amount of which added to firm the peas shall not result in more than 350 milligrams/kilogram (0.01 ounce/2.2 pounds) of calcium in the finished food.

(xii) Magnesium hydroxide, magnesium oxide, magnesium carbonate, or any mixture or combination of these in such quantity that the pH of the finished canned peas is not more than 8, as determined by the glass electrode method for the hydrogen ion concentration.

(xiii) Seasonings and garnishes:

(*a*) Pieces of green or red peppers or mixtures of both, either of which may be dried, or other vegetables not exceeding in total 15 percent of the drained weight of the finished food.

(*b*) Lemon juice or concentrated lemon juice.

(*c*) Mint leaves.

(*d*) Butter or margarine in a quantity not less that 3 percent by weight of the finished food, or other vegetable or animal fats or oils in a quantity not less than 2.4 percent by weight of the finished foods. When butter, margarine, or other vegetable or animal fats or oils are added, emulsifiers or stabilizers or both may be added, but no color, spice, or flavoring simulating the color or flavor imparted by butter or margarine may be used.

(3) *Labeling.* (i) The name of the food is ''peas'' and may include the designation ''green.'' The term ''early,'' ''June,'' or ''early June'' shall precede or follow the name in the case of smooth-skin peas or substantially smooth-skin peas, such as Alaska-type peas or hybrids having similar characteristics. Where the peas are of sweet green wrinkled varieties or hybrids having similar characteristics, the name may include the designation ''sweet,'' ''wrinkled,'' or any combination thereof. The term ''petit pois'' may be used in conjunction with the name of the food when an average of 80 percent or more of the peas will pass through a circular opening of a diameter of 7.1 millimeters (0.28 inch). If any color additive has been added, the name of the food shall include the term ''artificially colored.''

(ii) The following shall be included as part of the name or in close proximity to the name of the food:

(*a*) A declaration of any flavoring that characterizes the food, as specified in § 101.22 of this chapter.

(*b*) A declaration of any spice, seasoning, or garnishing that characterizes the product, e.g., ''seasoned with green peppers'', ''seasoned with butter'', ''seasoned with _____ oil'', the blank to be filled in with the common or usual name of the oil, ''with added spice'', or, in lieu of the word spice, the common or usual name of the spice.

(*c*) The words ''vacuum pack'' or ''vacuum packed'' when the weight of the liquid in the container, as determined by the method prescribed in § 155.3(a) is not more than 20 percent of the net weight, and the container is closed under conditions creating a high vacuum in the container.

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned peas is as follows:

(i) *Blond and yellow peas.* Not more than 2 percent of the drained weight is blond and/or yellow peas, i.e., white or yellow but edible peas.

(ii) *Blemished peas.* Not more than 5 percent of the drained weight is blemished peas, i.e., slightly stained or spotted peas.

(iii) *Seriously blemished peas.* Not more than 1 percent of the drained weight is seriously blemished peas, i.e., peas that are hard, shrivelled, spotted, discolored, or otherwise blemished to an extent that the appearance or eating quality is seriously affected.

(iv) *Pea fragments.* Not more than 10 percent of the drained weight is pea fragments, i.e., portions of peas, separated or individual cotyledons, crushed, partial or broken cotyledons, and loose skins, but excluding entire intact peas with skins detached.

(v) *Extraneous vegetable material.* Not more than 0.5 percent of the drained weight is extraneous vegetable material, i.e., vine or leaf or pod material from the pea plant or other such material.

(vi) *Alcohol-insoluble solids.* The alcohol-insoluble solids of smooth-skin or substantially smooth-skin peas, such as Alaska-type peas or hybrids having similar characteristics, may not be more than 23.5 percent and, of sweet green wrinkled varieties or hybrids having similar characteristics, not more than 21 percent based on the procedure set forth in the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 30.012, which is incorporated by reference. Copies are available from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(vii) *Limitation.* The sum of the pea material described in paragraphs (b)(1)(i), (ii), (iii), (iv), and (v) of this section shall not exceed 12 percent.

(2) Determine compliance as specified in § 155.3(b).

(3) If the quality of canned peas falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality when the quality of canned peas falls below the standard in only one respect, the label may bear the alternative statement, ''Below standard in quality ___'', the blank to be filled in with the words specified after the corresponding paragraph under paragraph (b)(1) of this section which such canned peas fail to meet, as follows: (i) ''Excessive blond and/or yellow peas''; (ii) ''Excessive blemished peas''; (iii) ''Excessive seriously blemished peas''; (iv) ''Excessive pea fragments''; (v) ''Excessive vegetable material''; (vi) ''Excessive mealy''. Such alternative statement shall immediately and conspicuously precede or follow without intervening written, printed, or graphic matter, the name ''peas'' and any words and statements required

or authorized to appear with such name by paragraph (a)(3) of this section.

(c) *Fill of container.* (1) Except in the case of vacuum pack peas, the fill of pea ingredient and packing medium, as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(2) When the peas and liquid are removed from the container and returned thereto, the leveled peas (irrespective of the quantity of the liquid), 15 seconds after they are so returned, completely fill the container. A container with lid attached by double seam shall be considered to be completely filled when it is filled to 5 millimeters (0.2 inch) vertical distance below the top of the double seam; and a glass container shall be considered to be completely filled when it is filled to 13 millimeters (0.5 inch) vertical distance below the top of the container.

(3) Determine compliance for fill of container as specified in § 155.3(b).

(4) If canned peas fall below the standard of fill of container prescribed in paragraph (c)(1) and/or (2) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

[45 FR 43398, June 27, 1980, as amended at 47 FR 11832, Mar. 19, 1982; 48 FR 15241, Apr. 8, 1983; 54 FR 24895, June 12, 1989; 58 FR 2882, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

EFFECTIVE DATE NOTE: In § 155.170, those portions of paragraph (a)(2) pertaining to the deletion of magnesium, hydroxide, magnesium oxide, and magnesium carbonate were stayed until further notice at 46 FR 35086, July 1, 1981, effective June 30, 1981.

§ 155.172 Canned dry peas.

(a) *Identity.* Canned dry peas conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for canned peas by § 155.170(a), except that:

(1) The optional pea ingredient is the dry seeds of the pea plant of the species *Pisum sativum* L. but excluding the subspecies *macrocarpum.*

(2) The optional ingredients specified in § 155.170(a)(2)(xii) shall not be used.

(3) The name of the food is ''cooked dry peas'' or ''soaked dry peas''. The optional terms specified by § 155.170(a)(3), ''early'', ''June'', ''sweet'', ''green'', ''wrinkled'', or any combination thereof, shall not be used on the labels.

(b) *Quality.* (1) The standard of quality for canned dry peas is that specified for canned peas by § 155.170(b) except that:

(i) The alcohol-insoluble solids maximums specified in § 155.170(b)(1)(vi) do not apply.

(ii) The skins of not more than 25 percent by count of the peas in the container are ruptured to a width of 1.6 millimeters (0.06 inch) or more.

(2) If the quality of canned dry peas falls below the standard of quality prescribed by paragraph (b)(1) of this section, the label shall bear the statement of substandard quality in the manner and form specified in § 155.170(b)(3) for canned peas, except that the words ''Excessively mealy'' shall not be used.

(c) *Fill of container.* (1) The standard of fill of container for canned dry peas is that prescribed for canned peas by § 155.170(c).

(2) If canned dry peas fall below the standard of fill of container prescribed by paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein specified.

[45 FR 43399, June 27, 1980, as amended at 48 FR 15241, Apr. 8, 1983; 58 FR 2883, Jan. 6, 1993]

§ 155.190 Canned tomatoes.

(a) *Identity*—(1) *Description.* (i) Canned tomatoes is the food prepared from mature tomatoes conforming to the characteristics of the fruit *Lycopersicum esculentum* P. Mill, of red or reddish varieties. The tomatoes may or may not be peeled, but shall have had the stems and calicies removed and shall have been cored, except where the internal core is insignificant to texture and appearance.

(ii) Canned tomatoes may contain one or more of the safe and suitable optional ingredients specified in paragraph (a)(2) of this section, be packed without any added liquid or in one of the optional packing media specified in paragraph (a)(3) of this section and be

prepared in one of the styles specified in paragraph (a)(4) of this section. Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

(2) *Optional ingredients.* One or more of the following safe and suitable ingredients may be used:

(i) Calcium salts in a quantity reasonably necessary to firm the tomatoes, but the amount of calcium in the finished canned tomatoes is not more than 0.045 percent of the weight, except that when the tomatoes are prepared in one of the styles specified in paragraphs (a)(4) (ii) to (iv) of this section the amount of calcium is not more than 0.08 percent of the weight of the food.

(ii) Organic acids for the purpose of acidification.

(iii) Dry nutritive carbohydrate sweeteners whenever any organic acid provided for in paragraph (a)(2)(ii) of this section is used, in a quantity reasonably necessary to compensate for the tartness resulting from such added acid.

(iv) Salt.

(v) Spices, spice oils.

(vi) Flavoring and seasoning.

(vii) Vegetable ingredients such as onion, peppers, and celery, that may be fresh or preserved by physical means, in a quantity not more than 10 percent by weight of the finished food.

(3) *Packing media.* (i) The liquid draining from the tomatoes during or after peeling or coring.

(ii) The liquid strained from the residue from preparing tomatoes for canning consisting of peels and cores with or without tomatoes or pieces thereof.

(iii) The liquid strained from mature tomatoes (tomato juice).

(iv) Tomato paste, or tomato puree, or tomato pulp complying with the compositional requirements of §155.191.

(4) *Styles.* (i) Whole.

(ii) Diced.

(iii) Sliced.

(iv) Wedges.

(5) *Name of the food.* (i) The name of the food is ''tomatoes'', except that when the tomatoes are not peeled the name is ''unpeeled tomatoes''.

(ii) The following shall be included as part of the name or in close proximity to the name of the food:

(*a*) A declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter.

(*b*) A declaration of any added spice, seasoning, or vegetable ingredient that characterizes the product, (e.g., ''with added _____'' or, ''with _____'' the blank to be filled in with the word(s) ''spice(s)'', ''seasoning(s)'', or the name(s) of the vegetable(s) used or in lieu of the word(s) ''spice(s)'' or ''seasoning (s)'' the common or usual name(s) of the spice(s) or seasoning(s) used) except that no declaration of the presence of onion, peppers, and celery is required for stewed tomatoes.

(*c*) The word ''stewed'' if the tomatoes contain characterizing amounts of at least the three optional vegetables listed in paragraph (a)(2)(vii) of this section.

(*d*) The styles: ''Diced'', ''sliced'', or ''wedges'' as appropriate.

(*e*) The name of the packing medium: ''tomato paste'', ''tomato puree'', or ''tomato pulp'' as provided in paragraph (a)(3)(iv) of this section, or ''strained residual tomato material from preparation for canning'' as provided for in paragraph (a)(3)(ii) of this section, as appropriate. The name of the packing medium shall be preceded by the word ''with''.

(iii) The following may be included as part of the name or in close proximity to the name:

(*a*) The word ''whole'' if the tomato ingredient is whole or almost whole, and the weight of such ingredient is not less than 80 percent of the drained weight of the finished food as determined in accordance with the method prescribed in paragraph (b)(2) of this section.

(*b*) The words ''solid pack'' when none of the optional packing media specified in paragraph (a)(3) of this section are used.

(*c*) The words ''in tomato juice'' if the packing medium specified in paragraph (a)(3)(iii) of this section is used.

(6) *Label declaration.* The name of each ingredient used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for canned tomatoes is as follows:

(i) The drained weight, as determined by the method prescribed in paragraph (b)(2)(i) of this section, is not less than 50 percent of the weight of water required to fill the container, as determined by the general method for water capacity of containers prescribed in §130.12(a) of this chapter;

(ii) The strength and redness of color as determined by the method prescribed in paragraph (b)(2) of this section, are not less than that of the blended color of any combination of the color discs described in such method in which one-third the area of disc 1, and not more than one-third the area of disc 2, is exposed;

(iii) Peel per kilogram (2.2 pounds) of the finished food covers an area of not more than 15 cm^2 (2.3 square inches) which is equivalent to 6.8 cm^2 (1.06 square inches) per pound based on an average of all containers examined provided, however, that the area of peel is not a factor of quality for canned unpeeled tomatoes labeled in accordance with paragraph (a)(5)(i) of this section; and

(iv) Blemishes per kilogram (2.2 pounds) of the finished food cover an area of not more than 3.5 cm^2 (0.54 square inch) which is equivalent to 1.6 cm^2 (0.25 square inch) per pound based on an average of all containers examined.

(2) Canned tomatoes shall be tested by the following method to determine whether or not they meet the requirements of paragraphs (b)(1) (i) and (ii) of this section:

(i) Remove lid from container, but in the case of a container with lid attached by double seam, do not remove or alter the height of the double seam. Tilt the opened container so as to distribute the contents over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve used is 20.3 centimeters (8 inches) if the quantity of the contents of the container is less than 1.4 kilograms (3 pounds) or 30.5 centimeters (12 inches) if such quantity is 1.4 kilograms (3 pounds) or more. The meshes of such sieve are made by so weaving wire of 1.4 mm (0.054 inch) diameter as to form square openings 11.3 mm by 11.3 mm (0.446 inch by 0.446 inch). Without shifting the tomatoes, so incline the sieve as to facilitate drainage of the liquid. Two minutes from the time drainage begins, weigh the sieve and drained tomatoes. The weight so found, less the weight of the sieve, shall be considered to be the drained weight.

(ii) Remove from the sieve the drained tomatoes, cut out and segregate successively those portions of least redness until 50 percent of the drained weight has been so segregated. Comminute the segregated portions to a uniform mixture without removing or breaking the seeds. Fill the mixture into a black container to a depth of at least 25.4 mm (1 inch). Free the mixture from air bubbles, and skim off or press below the surface all visible seeds. Compare the color of the mixture, in full diffused daylight or its equivalent, with the blended color of combinations of the following concentric Munsell color discs of equal diameter, or the color equivalent of such discs:

(*a*) Red—Munsell 5 R 2.6/13 (glossy finish).

(*b*) Yellow—Munsell 2.5 YR 5/12 (glossy finish).

(*c*) Black—Munsell N 1/ (glossy finish).

(*d*) Grey—Munsell N 4 (mat finish).

(3) Determine compliance as specified in §155.3(b).

(4) If the quality of canned tomatoes falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter in the manner and form therein specified; if, however, the quality of canned tomatoes falls below standard with respect to only one of the factors of quality specified by paragraphs (b)(1) (i) to (iii) of this section, there may be substituted for the second line of such general statement of substandard quality (''Good Food—Not High Grade'') a new line, appropriate for the corresponding subparagraph designation of paragraph (b)(1) of this section which the canned tomatoes fail to meet, to read as follows:

(i) ''Poor color'' or

(ii) ''Excessive peel'' or

(iii) ''Excessive blemishes''.

(c) *Fill of container.* (1) The standard of fill of container for canned tomatoes

is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of containers prescribed in §130.12(b) of this chapter.

(2) Determine compliance as specified in §155.3(b).

(3) If canned tomatoes fall below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14449, Mar. 15, 1977, as amended at 43 FR 12858, Mar. 28, 1978; 43 FR 30274, July 14, 1978; 45 FR 43400, June 27, 1980; 58 FR 17103, Apr. 1, 1993; 59 FR 15051, Mar. 31, 1994]

§ 155.191 Tomato concentrates.

(a) *Identity*—(1) *Definition*. Tomato concentrates are the class of foods each of which is prepared by concentrating one or any combination of two or more of the following optional tomato ingredients:

(i) The liquid obtained from mature tomatoes of the red or reddish varieties (*Lycopersicum esculentum* P. Mill).

(ii) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(iii) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is obtained by so straining the tomatoes, with or without heating, as to exclude skins (peel), seeds, and other coarse or hard substances in accordance with good manufacturing practice. Prior to straining, food-grade hydrochloric acid may be added to the tomato material in an amount to obtain a pH no lower than 2.0. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2±0.2. Water may be added to adjust the final composition. The food contains not less than 8.0 percent tomato soluble solids as defined in §155.3(e). The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Optional ingredients*. One or any combination of two or more of the following safe and suitable ingredients may be used in the foods:

(i) Salt (sodium chloride formed during acid neutralization shall be considered added salt).

(ii) Lemon juice, concentrated lemon juice, or organic acids.

(iii) Sodium bicarbonate.

(iv) Water, as provided for in paragraph (a)(1) of this section.

(v) Spices.

(vi) Flavoring.

(3) *Labeling*. (i) The name of the food is:

(*a*) ''Tomato puree'' or ''tomato pulp'' if the food contains not less than 8.0 percent but less than 24.0 percent tomato soluble solids.

(*b*) ''Tomato paste'' if the food contains not less than 24.0 percent tomato soluble solids.

(*c*) The name ''tomato concentrate'' may be used in lieu of the name ''tomato puree,'' ''tomato pulp,'' or ''tomato paste'' whenever the concentrate complies with the requirements of such foods; except that the label shall bear the statement ''for remanufacturing purposes only'' when the concentrate is packaged in No. 10 containers (3.1 kilograms or 109 avoirdupois ounces total water capacity) or containers that are smaller in size.

(*d*) ''Concentrated tomato juice'' if the food is prepared from the optional tomato ingredient described in paragraph (a)(1)(i) of this section and is of such concentration that upon diluting the food according to label directions as set forth in paragraph (a)(3)(iii) of this section, the diluted article will contain not less than 5.0 percent by weight tomato soluble solids.

(ii) The following shall be included as part of the name or in close proximity to the name of the food:

(*a*) The statement ''Made from'' or ''Made in part from,'' as the case may be, ''residual tomato material from canning'' if the optional tomato ingredient specified in paragraph (a)(1)(ii) of this section is present.

(*b*) The statement ''Made from'' or ''Made in part from,'' as the case may be, ''residual tomato material from partial extraction of juice'' if the optional tomato ingredient specified in

paragraph (a)(1)(iii) of this section is present.

(*c*) A declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product, e.g., ''Seasoned with _____,'' the blank to be filled in with the words ''added spice'' or, in lieu of the word ''spice,'' the common name of the spice.

(iii) The label of concentrated tomato juice shall bear adequate directions for dilution to result in a diluted article containing not less than 5.0 percent by weight tomato soluble solids; except that alternative methods may be used to convey adequate dilution directions for containers that are larger than No. 10 containers (3.1 kilograms or 109 avoirdupois ounces total water capacity).

(iv) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter; except that water need not be declared in the ingredient statement when added to adjust the tomato soluble solids content of tomato concentrates within the range of soluble solids levels permitted for these foods.

(v) Determine percent tomato soluble solids as specified in § 155.3(e). Determine compliance as specified in § 155.3(b). A lot shall be deemed to be in compliance for tomato soluble solids as follows:

(*a*) The sample average meets or exceeds the required minimum.

(*b*) The number of sample units that are more than 1 percent tomato soluble solids below the minimum required does not exceed the acceptance number in the sampling plans set forth in § 155.3(c)(2).

(b) *Quality.* (1) The standard of quality for tomato concentrate (except for concentrated tomato juice, which when diluted to 5.0 percent tomato soluble solids shall conform to the standard of quality for tomato juice set forth in § 156.145 of this chapter) is as follows:

(i) The strength and redness of color of the food, when diluted with water (if necessary) to 8.1±0.1 percent tomato soluble solids is not less than the composite color produced by spinning the Munsell color discs in the following combination:

53 percent of the area of Disc 1;
28 percent of the area of Disc 2; and
19 percent of the area of either Disc 3 or Disc 4; or
9½ percent of the area of Disc 3 and 9½ percent of the area of Disc 4, whichever most nearly matches the appearance of the sample.

(ii) Not more than one whole seed per 600 grams (21 ounces).

(iii) Not more than 36 of the following defects, either singly or in combination, per 100 grams (3.5 ounces) of the product when diluted with water to 8.1±0.1 percent tomato soluble solids:

(*a*) Pieces of peel 5 millimeters (0.20 inch) or greater in length (without unrolling).

(*b*) Pieces of seed (seed particles) 1 millimeter (0.039 inch) or greater in length.

(*c*) Blemishes, such as dark brown or black particles (specks)—not more than four exceed 1.6 millimeters (0.0625 inch) in length of which not more than one exceeds 3.2 millimeters (0.125 inch) and none exceed 6.4 millimeters (0.25 inch).

(2) *Methodology.* Dilute with water, if necessary, to 8.1±0.1 percent tomato soluble solids. (i) Determine strength and redness of color as prescribed in § 155.3(d).

(ii) Whole seeds—Weigh out 600 grams (21 ounces) of the well-mixed, diluted concentrate; place a U.S. No. 12 screen (1.68 millimeters (0.066 inch) openings) over the sink drain; transfer the product sample onto the screen; rinse container thoroughly with water and pour through screen; flush sample through screen by using an adequate spray of water; check screen for whole seeds; apply the appropriate allowance.

(iii) Peel, pieces of seed, and blemishes—Spread the prepared concentrate evenly on a large white tray and remove the individual defects, identify, classify, and measure.

(3) *Sampling and acceptance.* Determine compliance as specified in § 155.3(b).

(4) If the quality of the tomato concentrate falls below the standard prescribed in paragraph (b) (1) and (3) of this section, the label shall bear the

general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified, but in lieu of such general statement of substandard quality when the quality of the tomato concentrate falls below the standard in one or more respects, the label may bear the alternative statement, ''Below Standard in Quality _____,'' the blank to be filled in with the words specified after the corresponding paragraph(s) under paragraph (b)(1) of this section which such tomato concentrate fails to meet, as follows:

(i) ''Poor color.''

(ii) ''Excessive seeds.''

(iii)(*a*) ''Excessive pieces of peel.''

(*b*) ''Excessive pieces of seed.''

(*c*) ''Excessive blemishes.''

(c) *Fill of container.* (1) The standard of fill of container for tomato concentrate, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, is not less than 90 percent of the total capacity, except when the food is frozen.

(2) Determine compliance as specified in §155.3(b).

(3) If the tomato concentrate falls below the standard of fill prescribed in paragraph (c) (1) and (2) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein prescribed.

[48 FR 3954, Jan. 28, 1983, as amended at 49 FR 15073, Apr. 17, 1984; 58 FR 2883, Jan. 6, 1993; 58 FR 17104, Apr. 1, 1993]

§ 155.194 Catsup.

(a) *Identity*—(1) *Definition.* Catsup, ketchup, or catchup is the food prepared from one or any combination of two or more of the following optional tomato ingredients:

(i) Tomato concentrate as defined in §155.191(a)(1), except that lemon juice, concentrated lemon juice, or safe and suitable organic acids may be used in quantities no greater than necessary to adjust the pH, and in compliance with §155.191(b).

(ii) The liquid derived from mature tomatoes of the red or reddish varieties *Lycopersicum esculentum* P. Mill.

(iii) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(iv) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is strained so as to exclude skins, seeds, and other coarse or hard substances in accordance with current good manufacturing practice. Prior to straining, food-grade hydrochloric acid may be added to the tomato material in an amount to obtain a pH no lower than 2.0. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2±0.2. The final composition of the food may be adjusted by concentration and/or by the addition of water. The food may contain salt (sodium chloride formed during acid neutralization shall be considered added salt) and is seasoned with ingredients as specified in paragraph (a)(2) of this section. The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Ingredients.* One or any combination of two or more of the following safe and suitable ingredients in each of the following categories is added to the tomato ingredients specified in paragraph (a)(1) of this section:

(i) Vinegars.

(ii) Nutritive carbohydrate sweeteners. Such sweeteners if defined in part 168 of this chapter shall be as defined therein.

(iii) Spices, flavoring, onions, or garlic.

(3) *Labeling.* (i) The name of the food is ''Catsup,'' ''Ketchup,'' or ''Catchup.''

(ii) The following shall be included as part of the name or in close proximity to the name of the food:

(*a*) The statement ''Made from'' or ''Made in part from,'' as the case may be, ''residual tomato material from canning'' if the optional tomato ingredient specified in paragraph (a)(1)(iii) of this section or tomato concentrate containing the ingredient specified in §155.191(a)(1)(ii) is present.

(*b*) The statement ''Made from'' or ''Made in part from,'' as the case may be, ''residual tomato material from

partial extraction of juice'' if the optional tomato ingredient specified in paragraph (a)(1)(iv) of this section or tomato concentrate containing the ingredient specified in §155.191(a)(1)(iii) is present.

(iii) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter; except that the name ''tomato concentrate'' may be used in lieu of the names ''tomato puree,'' ''tomato pulp,'' or ''tomato paste'' and when tomato concentrates are used, the labeling requirements of §155.191(a)(3)(ii)(*a*) and (a)(3)(ii)(*b*) do not apply.

(b) *Quality*. (1) The standard of quality for catsup is as follows: The consistency of the finished food is such that its flow is not more than 14 centimeters in 30 seconds at 20 °C when tested in a Bostwick Consistometer in the following manner: Check temperature of mixture and adjust to 20±1 °C. The trough must also be at a temperature close to 20 °C. Adjust end-to-end level of Bostwick Consistometer by means of the spirit level placed in trough of instrument. Side-to-side level may be adjusted by means of the built-in spirit level. Transfer sample to the dry sample chamber of the Bostwick Consistometer. Fill the chamber slightly more than level full, avoiding air bubbles as far as possible. Pass a straight edge across top of chamber starting from the gate end to remove excess product. Release gate of instrument by gradual pressure on lever, holding the instrument down at the same time to prevent its movement as the gate is released. Immediately start the stop watch or interval timer, and after 30 seconds read the maximum distance of flow to the nearest 0.1 centimeter. Clean and dry the instrument and repeat the reading on another portion of sample. Do not wash instrument with hot water if it is to be used immediately for the next determination, as this may result in an increase in temperature of the sample. For highest accuracy, the instrument should be maintained at a temperature of 20±1 °C. If readings vary more than 0.2 centimeter, repeat a third time or until satisfactory agreement is obtained. Report the average of two or more readings, excluding any that appear to be abnormal.

(2) Determine compliance as specified in §155.3(b).

(3) If the quality of catsup falls below the standard prescribed in paragraphs (b) (1) and (2) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified, but in lieu of such general statement of substandard quality when the quality of the catsup falls below the standard, the label may bear the alternative statement, ''Below Standard in Quality—Low Consistency.''

(c) *Fill of container*. (1) The standard of fill of container for catsup, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, is not less than 90 percent of the total capacity except:

(i) When the food is frozen, or

(ii) When the food is packaged in individual serving-size packages containing 56.7 grams (2 ounces) or less.

(2) Determine compliance as specified in §155.3(b).

(3) If the catsup falls below the standard of fill prescribed in paragraphs (c) (1) and (2) of this section, the label shall bear the general statement of substandard fill as specified in §130.14(b) of this chapter, in the manner and form therein specified.

[48 FR 3956, Jan. 28, 1983, as amended at 49 FR 15073, Apr. 17, 1984; 58 FR 2883, Jan. 6, 1993]

§ 155.200 Certain other canned vegetables.

(a) The canned vegetables for which definitions and standards of identity are prescribed by this section are those named in column I of the table set forth in paragraph (b) of this section. The vegetable ingredient in each such canned vegetable is obtained by proper preparation from the succulent vegetable prescribed in column II of such table. If two or more forms of such ingredient are designated in column III of such table, the vegetable in each such form is an optional ingredient. To the vegetable ingredient additional ingredients as required or permitted by paragraph (c) of this section are added,

and the food is sealed in a container and so processed by heat as to prevent spoilage.

(b) The table referred to in paragraph (a) of this section is as follows:

I—Name or synonym of canned vegetable	II—Source	III—Optional forms of vegetable ingredient
Artichokes	Flower buds of the artichoke plant	Whole; half or halves or halved; whole hearts; halved hearts; quartered hearts.
Asparagus	Edible portions of sprouts of the asparagus plant, as follows:.	
	3 and ¾ in or more of upper end	Stalks or spears.
	3 and ¾ in or more of peeled upper end	Peeled stalks or peeled spears.
	Not less than 2 and ¾ in but less than 3 and ¾ in of upper end.	Tips.
	Less than 2 and ¾ in of upper end	Points.
	Sprouts cut in pieces	Cut stalks or cut spears.
	Sprouts from which the tip has been removed, cut in pieces.	Bottom cuts or cuts—tips removed.
Bean sprouts	Sprouts of the Mung bean.	
Shelled beans	Seed shelled from green or wax bean pods, with or without snaps (pieces of immature unshelled pods).	
Lima beans or butter beans	Seed shelled from the pods of the lima bean plant.	
Beets	Root of the beet plant	Whole; slices or sliced; quarters or quartered; dice or diced; cut; shoestring or French style or julienne.
Beet greens	Leaves, or leaves and immature root, of the beet plant.	
Broccoli	Heads of the broccoli plant.	
Brussels sprouts	Sprouts of the brussels sprouts plant.	
Cabbage	Cut pieces of the heads of the cabbage plant.	
Carrots	Root of the carrot plant	Do.
Cauliflower	Cut pieces of the head of the cauliflower plant.	
Celery	Stalks of the celery plant	Cut; hearts.
Collards	Leaves of the collard plant.	
Dandelion greens	Leaves of the dandelion plant.	
Kale	Leaves of the kale plant.	
Mustard greens	Leaves of the mustard plant.	
Okra	Pods of the okra plant	Whole; cut.
Onions	Bulb of the onion plant	Do.
Parsnips	Root of the parsnip plant	Whole; quarters or quartered; slices or sliced; cut; shoestring or French style or julienne.
Black-eye peas or black-eyed peas.	Seed shelled from pods of the black-eye pea plant, with or without snaps (pieces of immature unshelled pods).	
Field peas	Seed shelled from pods of the field pea plant (other than the black-eye pea plant), with or without snaps (pieces of immature unshelled pods).	
Green sweet peppers	Green pods of the sweet pepper plant	Whole; halves or halved; pieces; dice or diced; strips; chopped.
Red sweet peppers	Red-ripe pods of the sweet pepper plant	Do.
Pimientos or pimentos	Red-ripe pods of the pimiento, pimento, pepper plant.	Whole; halves or halved; pieces; dice or diced; slices or sliced; chopped.
Potatoes	Tuber of the potato plant	Whole; slices or sliced; dice or diced; pieces; shoestring or French style or julienne; French fry cut.
Rutabagas	Root of the rutabaga plant	Whole; quarters or quartered; slices or sliced; dice or diced; cut.
Salsify	Root of the salsify plant.	
Spinach	Leaves of the spinach plant	Whole leaf; cut leaf or sliced; chopped.
Sweet potatoes	Tuber of the sweet potato plant	Whole; mashed; pieces or cuts or cut (longitudinally cut halves may be named on labels as halves or halved in lieu of pieces or cuts or cut).
Swiss chard	Leaves of the Swiss chard plant.	
Truffles	Fruit of the truffle.	
Turnip greens	Leaves of the turnip plant.	
Turnips	Root of the turnip plant	Whole; quarters or quartered; slices or sliced; dice or diced; cut.

(c) Water is added to the vegetable ingredient, except that pimientos may be canned with or without added water, and sweet potatoes in mashed form are canned without added water. Asparagus may be canned with added water, asparagus juice, or a mixture of both. For the purposes of this section, asparagus juice is the clear, unfermented liquid expressed from the washed and heated sprouts or parts of sprouts of the asparagus plant, and mixtures of asparagus juice and water are considered to be water when such mixtures are used as a packing medium for canned asparagus. In the case of artichokes, a vinegar or any safe and suitable organic acid, which either is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act, or if it is a food additive as so defined, is used in conformity with regulations established pursuant to section 409 of the act, is added in such quantity as to reduce the pH of the finished canned vegetable to 4.5 or below. The following optional ingredients, in the case of the vegetables specified, may be added:

(1) An edible vegetable oil, in the cases of artichokes and pimientos.

(2) Snaps, in the cases of shelled beans, black-eyed peas, and field peas.

(3) In the case of all vegetables (except canned mashed sweet potatoes as regards the seasonings listed in paragraph (c)(3)(iii) of this section) one or more of the following optional seasoning ingredients may be added in a quantity sufficient to season the food.

(i) Refined sugar (sucrose).

(ii) Refined corn sugar (dextrose).

(iii) Corn sirup, glucose sirup.

(iv) Dried corn sirup, dried glucose sirup.

(v) Spice.

(vi) A vinegar.

(vii) Green peppers or red peppers which may be dried.

(viii) Mint leaves.

(ix) Onions, which may be dried.

(x) Garlic, which may be dried.

(xi) Horseradish.

(xii) Lemon juice or concentrated lemon juice.

(xiii) Butter or margarine in a quantity not less than 3 percent by weight of the finished food. When butter or margarine is added, safe and suitable emulsifiers or stabilizers, or both, may be added. When butter or margarine is added, no spice or flavoring simulating the color or flavor imparted by butter or margarine is used.

(4) In the case of all vegetables, the following optional ingredients may be added:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate complying with the provisions of §172.535 of this chapter.

(iv) Disodium guanylate complying with the provisions of §172.530 of this chapter.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(5) In the case of all vegetables flavoring (except artificial) may be added.

(6) In the case of bean sprouts, lima beans, carrots, green sweet peppers, red sweet peppers, and potatoes, any safe and suitable calcium salts may be added as a firming agent.

(7) In the case of canned artichokes packed in glass containers, ascorbic acid may be added in a quantity not to exceed 32 milligrams per 100 grams of the finished food.

(8) In the case of canned asparagus, ascorbic acid, erythorbic acid, or the sodium salts of ascorbic acid or erythorbic acid may be added in an amount necessary to preserve color in the ''white'' and ''green-tipped and white'' color types.

(9) In the case of canned asparagus packed in glass containers, stannous chloride may be added in a quantity not to exceed 15 parts per million calculated as tin (Sn), except that in the case of asparagus packed in glass containers with lids lined with an inert material the quantity of stannous chloride added may exceed 15 parts per million but not 20 parts per million calculated as tin (Sn).

(10) In the case of canned black-eyed peas, disodium EDTA may be added in a quantity not to exceed 145 parts per million.

(11) In the case of potatoes, calcium disodium EDTA may be added in a quantity not to exceed 110 parts per million.

(12) A vinegar or any safe and suitable organic acid for all vegetables (except artichokes, in which the quantity

of such optional ingredient is prescribed by the introductory text of paragraph (c) of this section) in a quantity which, together with the amount of any lemon juice or concentrated lemon juice that may be added, is not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article.

(d) The name of each canned vegetable for which a definition and standard of identity is prescribed by this section is the name or any synonym thereof whereby such vegetable is designated in column I of the table in paragraph (b) of this section.

(e) When two or more forms of the vegetable are specified in column III of the table in paragraph (b) of this section, the label shall bear the specified word or words, or in case synonyms are so specified, one of such synonyms, showing the form of the vegetable ingredient present; except that in the case of canned spinach, if the whole leaf is the optional form used, the word ''spinach'' unmodified may be used in lieu of the words ''whole leaf spinach''.

(f)(1) If the optional ingredient specified in paragraph (c)(1) of this section is present, the label shall bear the statement ''_____ oil added'' or ''With added _____ oil'', the blank being filled in with the common or usual name of the oil.

(2) If asparagus juice is used as a packing medium in canned asparagus, the label shall bear the statement ''Packed in asparagus juice''.

(3) If the optional ingredient specified in paragraph (c)(2) of this section is present, the label shall bear the statement ''With snaps''.

(g) The name of the food shall include a declaration of any flavoring that characterizes the product as specified in §101.22 of this chapter, and a declaration of any spice or seasoning that characterizes the product; for example, ''with added spice'', ''seasoned with red peppers'', ''seasoned with butter''. Wherever the name of the vegetable appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in paragraphs (e) and (f) (1) through (3) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the vegetable may so intervene.

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14449, Mar. 15, 1977, as amended at 42 FR 30358, June 14, 1977; 46 FR 56410, Nov. 17, 1981; 48 FR 10813, Mar. 15, 1983; 49 FR 6711, Feb. 23, 1984; 58 FR 2883, Jan. 6, 1993; 59 FR 15052, Mar. 31, 1994]

§ 155.201 Canned mushrooms.

(a) *Identity*—(1) *Definition.* Canned mushrooms is the food properly prepared from the caps and stems of succulent mushrooms conforming to the characteristics of the species *Agaricus (Psalliota) bisporus* or *A. bitorquis*, in one of the optional styles specified in paragraph (a)(2) of this section, packed with a suitable liquid medium which may include water; and may contain one or more safe and suitable optional ingredients specified in paragraph (a)(3) of this section. The food is sealed in a container and, before or after sealing, is so processed by heat as to prevent spoilage.

(2) *Styles.* The optional styles of the mushroom ingredient referred to in paragraph (a)(1) of this section are:

(i) *Buttons*—consisting of whole mushrooms with attached stems not exceeding 5 millimeters (0.2 inch) in length, measured from the bottom of the veil.

(ii) *Whole*—consisting of whole mushrooms with attached stems cut to a length not exceeding the diameter of the cap, measured from the bottom of the veil.

(iii) *Quarters*—consisting of buttons or whole style cut into four approximately equal parts.

(iv) *Slices or sliced*—consisting of buttons or whole style of which not less than 50 percent are cut parallel to the longitudinal axis of the stem and 2 millimeters to 8 millimeters (0.08 inch to 0.32 inch) in thickness.

(v) *Random sliced*—consisting of buttons or whole style sliced in a random manner.

(vi) *Pieces and stems*—consisting of pieces of caps and stems of irregular shapes and sizes.

(3) *Optional ingredients.* One or any combination of two or more of the following safe and suitable optional ingredients as provided for in paragraph (a)(1) of this section may be used:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Disodium inosinate complying with the provisions of §172.535 of this chapter.

(iv) Disodium guanylate complying with the provisions of §172.530 of this chapter.

(v) Hydrolyzed vegetable protein.

(vi) Autolyzed yeast extract.

(vii) Ascorbic acid (vitamin C) in a quantity not to exceed 132 milligrams for each 100 grams (37.5 milligrams for each ounce) of drained weight of mushrooms.

(viii) Organic acids (except no vinegar is permitted), only where the inside metal of the container is fully enamel-lined and in glass containers with fully enamel-lined caps. Ascorbic acid as provided for in paragraph (a)(3)(vii) of this section.

(ix) Calcium disodium ethylenediaminetetraacetate ($CaNa_2$ EDTA) in a quantity not to exceed 200 parts per million for use to promote color retention.

(4) *Labeling requirements.* (i) The name of the food is mushrooms. The style as provided for in paragraph (a)(2) of this section shall be included as part of the name or in close proximity to the name of the food.

(ii) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container.* (1) The standard of fill of container for canned mushrooms is:

(i) The fill of the mushroom ingredient and packing medium, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, is not less than 90 percent of the total capacity of the container.

(ii) The drained weight of the mushroom ingredient is not less than 56 percent of the water capacity of the container.

(iii) Determine drained weight as specified in §155.3(a).

(2) Determine compliance for minimum fill and drained weight as specified in §155.3(b).

(3) If the canned mushrooms fall below the standard of fill prescribed in paragraph (c)(1) (i) and/or (ii) and (2) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein prescribed.

[48 FR 10813, Mar. 15, 1983, as amended at 58 FR 2883, Jan. 6, 1993]

PART 156—VEGETABLE JUICES

Subpart A—General Provisions

Subpart B—Requirements for Specific Standardized Vegetable Juices

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371.

Subpart A—General Provisions

§156.3 Definitions.

For the purpose of this part:

(a) *Strength and redness of color* means at least as much red as obtained by comparison of the prepared product, with the blended color produced by spinning a combination of the following concentric Munsell color discs of equal diameter, or the color equivalent of such discs:

Disc 1—Red (5R 2.6/13) (glossy finish)
Disc 2—Yellow (2.5 YR 5/12) (glossy finish)
Disc 3—Black (N1) (glossy finish)
Disc 4—Grey (N4) (mat finish)

Such comparison is to be made in full diffused daylight or under a diffused light source of approximately 2691 lux (250 footcandles) and having a spectral quality approximating that of daylight under a moderately overcast sky, with a correlated color temperature of 7,500 degrees Kelvin ±200 degrees. With the light source directly over the disc and product, observation is made at an angle of 45 degrees from a distance of

ACCEPTABLE QUALITY LEVEL (AQL) 6.5—Continued

Lot size (primary containers)	Size of container	
	n	*c*
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
NET WEIGHT GREATER THAN 1 KG (2.2 LB) BUT NOT MORE THAN 4.5 KG (10 LB)		
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
NET WEIGHT GREATER THAN 4.5 KG (10 LB)		
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

n = number of primary containers in sample.
c = acceptance number.

[48 FR 3956, Jan. 28, 1983, as amended at 54 FR 24895, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

Subpart B—Requirements for Specific Standardized Vegetable Juices

§ 156.145 Tomato juice.

(a) *Identity*—(1) *Definition.* Tomato juice is the food intended for direct consumption, obtained from the unfermented liquid extracted from mature tomatoes of the red or reddish varieties of *Lycopersicum esculentum* P. Mill, with or without scalding followed by draining. In the extraction of such liquid, heat may be applied by any method which does not add water thereto. Such juice is strained free from peel, seeds, and other coarse or hard substances, but contains finely divided insoluble solids from the flesh of the tomato in accordance with current good manufacturing practice. Such juice may be homogenized, may be seasoned with salt, and may be acidified with any safe and suitable organic acid. The juice may have been concentrated and later reconstituted with water and/or tomato juice to a tomato soluble solids content of not less than 5.0 percent by weight as determined by the method prescribed in § 156.3(b). The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Labeling.* (i) The name of the food is:

(*a*) ''Tomato juice'' if it is prepared from unconcentrated undiluted liquid extracted from mature tomatoes of reddish varieties.

(*b*) ''Tomato juice from concentrate'' if the finished juice has been prepared from concentrated tomato juice as specified in paragraph (a)(1) of this section or if the finished juice is a mixture of tomato juice and tomato juice from concentrate.

(ii) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for tomato juice is as follows:

(i) The strength and redness of color is not less than the composite color produced by spinning the Munsell color discs in the following combination: 53 percent of the area of Disc 1; 28 percent of the area of Disc 2; and 19 percent of the area of either Disc 3 or Disc 4; or 9½ percent of the area of Disc 3 and 9½ percent of the area of Disc 4, whichever most nearly matches the appearance of the tomato juice.

(ii) Not more than two defects for peel and blemishes, either singly or in combination, in addition to three defects for seeds or pieces of seeds, defined as follows, per 500 milliliters (16.9 fluid ounces):

(*a*) Pieces of peel 3.2 millimeters (0.125 inch) or greater in length.

(*b*) Blemishes such as dark brown or black particles (specks) greater than 1.6 millimeters (0.0625 inch) in length.

(*c*) Seeds or pieces of seeds 3.2 millimeters (0.125 inch) or greater in length.

(2) *Methodology.* (i) Determine strength and redness of color as specified in § 156.3(a).

(ii) Examine a total of 500 milliliters for peel, blemishes, and seeds. Divide the 500-milliliter sample into two 250-

milliliter aliquots and pour each aliquot onto separate 30.5 × 45.7 centimeters (12 × 18 inches) white grading trays. Remove defects and evaluate for color and size as defined in paragraph (b)(1)(ii) of this section.

(3) Determine compliance as specified in §156.3(d).

(4) If the quality of the tomato juice falls below the standard prescribed in paragraph (b)(1) and (3) of this section, the label shall bear the general statement of substandard quality specified in §130.14(a) of this chapter, in the manner and form therein specified, but in lieu of such general statement of substandard quality when the quality of the tomato juice falls below the standard in one or more respects, the label may bear the alternative statement, ''Below Standard in Quality _____'', the blank to be filled in with the words specified after the corresponding paragraph (s) under paragraph (b)(1) of this section which such tomato juice fails to meet, as follows:

(i) ''Poor color''.

(ii)(*a*) ''Excessive pieces of peel''.

(*b*) ''Excessive blemishes''.

(*c*) ''Excessive seeds'' or ''excessive pieces of seed''.

(c) *Fill of container.* (1) The standard of fill of container for tomato juice, as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, is not less than 90 percent of the total capacity, except when the food is frozen.

(2) Determine compliance as specified in §156.3(d).

(3) If the tomato juice falls below the standard of fill prescribed in paragraph (c)(1) and (2) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein prescribed.

[48 FR 3957, Jan. 28, 1983, as amended at 58 FR 2883, Jan. 6, 1993]

PART 158—FROZEN VEGETABLES

Subpart A—General Provisions

Sec.

Subpart B—Requirements for Specific Standardized Frozen Vegetables

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371.

Subpart A—General Provisions

§158.3 Definitions.

For the purposes of this part the following definitions shall apply:

(a) *Lot.* A collection of primary containers or units of the same size, type and style manufactured or packed under similar conditions and handled as a single unit of trade.

(b) *Lot size.* The number of primary containers or units (pounds when in bulk) in the lot.

(c) *Sample size.* The total number of sample units drawn for examination from a lot.

(d) *Sample unit.* A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(e) *Defective.* Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(f) *Acceptance number.* The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements. The following acceptance numbers shall apply:

Lot size (primary container)	Size container	
	n[1]	*c*[2]
NET WEIGHT EQUAL TO OR LESS THAN 1 KG (2.2 LB)		
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
NET WEIGHT GREATER THAN 1 KG (2.2 LB)		
Number of Pounds		
20,000 or less	13	2
More than 20,000 to 100,000	21	3
More than 100,000 to 200,000	29	4
More than 200,000 to 400,000	48	6
More than 400,000 to 600,000	84	9
More than 600,000 to 1,000,000	126	13
More than 1,000,000	200	19

[1] *n* = number of sample units.
[2] *c* = acceptance number.

(g) *Acceptable quality level* (*AQL*). The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

[42 FR 14461, Mar. 15, 1977]

Subpart B—Requirements for Specific Standardized Frozen Vegetables

§ 158.170 Frozen peas.

(a) *Identity*—(1) *Product definition.* Frozen peas is the food in ''package'' form as that term is defined in § 1.20 of this chapter, prepared from the succulent seed of the pea plant of the species *Pisum sativum* L. Any suitable variety of pea may be used. It is blanched, drained, and preserved by freezing in such a way that the range of temperature of maximum crystallization is passed quickly. The freezing process shall not be regarded as complete until the product temperature has reached −18 °C (0 °F) or lower at the thermal center, after thermal stabilization. Such food may contain one, or any combination of two or more, of the following safe and suitable optional ingredients:

(i) Natural and artificial flavors.

(ii) Condiments such as spices and mint leaves.

(iii) Dry nutritive carbohydrate sweeteners.

(iv) Salt.

(v) Monosodium glutamate and other glutamic acid salts.

(2) *Size specifications.* If size graded, frozen peas shall contain not less than 80 percent by weight of peas of the size declared or of smaller sizes. The sample unit may not contain more than 20 percent by weight of peas of the next two larger sizes, of which not more than one quarter by weight of such peas may be of the larger of these two sizes, and may contain no peas larger than the next two larger sizes, if such there be. The following sizes and designations shall apply:

Size designation	Round hole sieve size through which peas will pass	
	Millimeters	Inch
Extra small	Up to 7.5	0.295
Very small	Up to 8.2	.32
Small	Up to 8.75	.34
Medium	Up to 10.2	.40
Large	Over 10.2	.40

(3) *Labeling.* The name of the product is ''peas''. The term ''early'', ''June'', or ''early June'' shall precede or follow the name in the case of smooth-skin or substantially smooth-skin peas, such as Alaska-type peas. Where the peas are of sweet green wrinkled varieties, the name may include the designation ''sweet'', ''green'', ''wrinkled'', or any combination thereof. The label shall contain the words ''frozen'' or ''quick frozen''. The name of the food shall include a declaration of any flavoring that characterizes the product as specified in § 101.22 of this chapter and a declaration of any condiment such as spices and mint leaves that characterizes the product, e.g., ''Spice added''. Where a statement of pea size is made, such statement shall indicate either the size designation as specified in paragraph (a)(2) of this section or the applicable sieve size. However, the optional descriptive words ''petite'' or ''tiny'' may be used in conjunction with the product name when an average of 80 percent or more of the peas will pass through a circular opening of a diameter of 8.75 mm (0.34 in) or less for sweet green wrinkled peas and 8.2 mm (0.32 in) for smooth-skin or substantially smooth-skin peas, such as Alaska-type peas.

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) *Quality.* (1) The standard of quality for frozen peas is as follows:

(i) Not more than 4 percent by weight blond peas, i.e., yellow or white but edible peas;

(ii) Not more than 10 percent by weight blemished peas, i.e., slightly stained or spotted peas;

(iii) Not more than 2 percent by weight seriously blemished peas, i.e., peas that are hard, shrivelled, spotted, discolored or otherwise blemished to an extent that the appearance or eating quality is seriously affected.

(iv) Not more than 15 percent by weight pea fragments, i.e., portions of peas, separated or individual cotyledons, crushed, partial or broken cotyledons and loose skins, but excluding entire intact peas with skins detached;

(v) Not more than 0.5 percent by weight, or more than 12 sq cm (2 sq in) in area, extraneous vegetable material, i.e., vine or leaf or pod material from the pea plant or other such material per sample unit as defined in paragraph (b) of this section.

(vi) The sum of the pea material described in paragraphs (b)(1) (i), (ii), (iii), and (iv) of this section shall not exceed 15 percent.

(vii) For peas that meet the organoleptic and analytical characteristics of sweet green wrinkled varieties:

(*a*) The alcohol-insoluble solids may not be more than 19 percent based on the procedure set forth in paragraph (b)(3) of this section.

(*b*) Not more than 15 percent by count of the peas may sink in a solution containing 16 percent salt by weight according to the brine flotation test set forth in paragraph (b)(4) of this section;

(viii) For smooth-skin or substantially smooth-skin varieties the alcohol insoluble solids may not be more than 23 percent based on the procedure set forth in paragraph (b)(3) of this section.

(ix) The quality of a lot shall be considered acceptable when the number of defectives does not exceed the acceptance number in the sampling plans set forth in §158.3(f).

(2) The sample unit for determining compliance with the requirements of paragraph (b)(1) of this section other than those of paragraphs (b)(1)(vii)(*a*) and (b)(1)(viii) of this section, shall be 500 g (17.6 oz). For the determination of alcohol-insoluble solids as specified in paragraph (b)(3) of this section, the container may be the sample unit.

(3) *Alcohol-insoluble solids determination.* (i) Extracting solutions:

(*a*) One hundred parts of ethanol denatured with five parts of methanol volume to volume (formula 3A denatured alcohol), or

(*b*) A mixture of 95 parts of formula 3A denatured alcohol and five parts of isopropanol v/v.

(ii) Eighty percent alcohol (8 liters of extracting solutions, specified in paragraph (b)(3)(i) (*a*) or (*b*) of this section, diluted to 9.5 liters with water).

(iii) Drying dish—a flat-bottom dish with a tight fitting cover.

(iv) Drying oven—a properly ventilated oven thermostatically controlled at 100±2 °C.

(v) Procedure—Transfer frozen contents of package to plastic bag; tie bag securely and immerse in water bath with continuous flow at room temperature. Avoid agitation of bag during thawing by using clamps or weights. When sample completely thaws, remove bag, blot off adhering water, and transfer peas to U.S. No. 8 sieve, using (20 cm.) size for container of less than 3 lb. net weight and (30.5 cm.) for larger quantities. Without shifting peas, incline sieve to aid drainage, drain 2 minutes. With cloth wipe surplus water from lower screen surface. Weigh 250 g. of peas into high-speed blender, add 250 g. of water and blend to smooth paste. For less than 250 g. sample, use entire sample with equal weight of water. Weight 20 g.±10 mg. of the paste into 250 ml. distillation flask, add 120 ml. of extracting solutions specified in paragraph (b)(3)(i) (*a*) or (*b*) of this section, and reflux 30 minutes on steam or water bath or hotplate. Fit into a buchner funnel a filter paper of appropriate size (previously prepared by drying in flatbottom dish for 2 hours in drying oven, covering, cooling in desiccator, and weighing). Apply vacuum to buchner funnel and transfer contents of beaker so as to avoid running over edge of paper. Aspirate to dryness and wash material on filter with 80 percent alcohol until washings are clear and colorless. Transfer paper and alcohol-insoluble solids to drying dish used to prepare paper, dry uncovered for 2 hours in drying oven, cover, cool in desiccator, and weigh at once. From this weight deduct weight of dish, cover, and paper. Calculate percent by weight of alcohol-insoluble solids.

(4) *Brine flotation test.* (i) Explanation—The brine flotation test utilizes salt solutions of various specific

gravities to separate the peas according to maturity. The brine solutions are based on the percentage by weight of pure salt (NaCl) in solution at 20 °C. In making the test the brine solutions are standardized to the proper specific gravity equivalent to the specified ''percent of salt solutions at 20 °C'' by using a salometer spindle accurately calibrated at 20 °C. A 250 ml glass beaker or similar receptacle is filled with the brine solution to a depth of approximately 50 mm. The brine solution and sample (100 peas per container) must be at the same temperature and should closely approximate 20 °C.

(ii) Procedure—After carefully removing the skins from the peas, place the peas into the solution. Pieces of peas and loose skins should not be used in making the brine flotation test. If cotyledons divide, use both cotyledons in the test and consider the two separated cotyledons as 1 pea; and, if an odd cotyledon sinks, consider it as one pea. Only peas that sink to the bottom of the receptacle within 10 seconds after immersion are counted as ''peas that sink''.

(5) If the quality of the frozen peas falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in the Code of Federal Regulations but in lieu of the words prescribed in the second line of the rectangle the following words may be used where the frozen peas fall below the standard in only one respect: ''Below standard in quality _____'', the blank to be filled in with the specific reason for substandard quality as listed in the standard.

[42 FR 14461, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 58 FR 2883, Jan. 6, 1993]

PART 160—EGGS AND EGG PRODUCTS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Eggs and Egg Products

Sec.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14462, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Eggs and Egg Products

§ 160.100 Eggs.

No regulation shall be promulgated fixing and establishing a reasonable definition and standard of identity for the food commonly known as eggs.

§ 160.105 Dried eggs.

(a) Dried eggs, dried whole eggs are prepared by drying liquid eggs that conform to § 160.115, with such precautions that the finished food is free of viable *Salmonella* microorganisms. They may be powdered. Before drying, the glucose content of the liquid eggs may be reduced by one of the optional procedures set forth in paragraph (b) of this section. Either silicon dioxide complying with the provisions of § 172.480 of this chapter or sodium silicoaluminate may be added as an optional anticaking ingredient, but the amount of silicon dioxide used is not more than 1 percent and the amount of sodium silicoaluminate used is less than 2 percent by weight of the finished food. The finished food shall contain not less than 95 percent by weight total egg solids.

(b) The optional glucose-removing procedures are:

(1) *Enzyme procedure.* A glucose-oxidase-catalase preparation and hydrogen peroxide solution are added to the liquid eggs. The quantity used and the time of reaction are sufficient to substantially reduce the glucose content of the liquid eggs. The glucose-oxidase-catalase preparation used is one that is generally recognized as safe within the meaning of section 201(s) of the Federal

Food, Drug, and Cosmetic Act. The hydrogen peroxide solution used shall comply with the specifications of the United States Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain a preservative.

(2) *Yeast procedure.* The pH of the liquid eggs is adjusted to the range of 6.0 to 7.0, if necessary, by the addition of dilute, chemically pure hydrochloric acid, and controlled fermentation is maintained by adding food-grade baker's yeast (*Saccharomyces cerevisiae*). The quantity of yeast used and the time of reaction are sufficient to substantially reduce the glucose content of the liquid eggs.

(c) The name of the food for which a definition and standard of identity is prescribed by this section is ''Dried eggs'' or ''Dried whole eggs'' and if the glucose content was reduced, as provided in paragraph (b) of this section, the name shall be followed immediately by the statement ''Glucose removed for stability'' or ''Stabilized, glucose removed''.

(d)(1) When either of the optional anticaking ingredients specified in paragraph (a) of this section is used, the label shall bear the statement ''Not more than 1 percent silicon dioxide added as an anticaking agent'' or ''Less than 2 percent sodium silicoaluminate added as an anticaking agent'', whichever is applicable.

(2) The name of any optional ingredient used, as provided in paragraph (d)(1) of this section, shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render such statement likely to be read and understood by the ordinary individual under customary conditions of purchase.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 58 FR 2883, Jan. 6, 1993]

§ 160.110 Frozen eggs.

(a) Frozen eggs, frozen whole eggs, frozen mixed eggs is the food prepared by freezing liquid eggs that conform to § 160.115, with such precautions that the finished food is free of viable *Salmonella* microorganisms.

(b) Monosodium phosphate or monopotassium phosphate may be added either directly or in a water carrier, but the amount added does not exceed 0.5 percent of the weight of the frozen eggs. If a water carrier is used, it shall contain not less than 50 percent by weight of such monosodium phosphate or monopotassium phosphate.

(c) When one of the optional ingredients specified in paragraph (b) of this section is used, the label shall bear the statement ''Monosodium phosphate (or monopotassium phosphate) added to preserve color'', or, in case the optional ingredient used is added in a water carrier, the statement shall be ''Monosodium phosphate (or monopotassium phosphate), with __ percent water as a carrier, added to preserve color'', the blank being filled in to show the percent by weight of water used in proportion to the weight of the finished food. The statement declaring the optional ingredient used shall appear on the principal display panel or panels with such prominence and conspicuousness as to render it likely to be read and understood under customary conditions of purchase.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 58 FR 2883, Jan. 6, 1993]

§ 160.115 Liquid eggs.

(a) Liquid eggs, mixed eggs, liquid whole eggs, mixed whole eggs are eggs of the domestic hen broken from the shells and with yolks and whites in their natural proportion as so broken. They may be mixed, or mixed and strained, and they are pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those that perform a useful function in the pasteurization or other

treatment to render the liquid eggs free of viable *Salmonella* microorganisms, and that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or, if they are food additives, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 58 FR 2883, Jan. 6, 1993]

§ 160.140 Egg whites.

(a) Egg whites, liquid egg whites, liquid egg albumen is the food obtained from eggs of the domestic hen, broken from the shells and separated from yolks. The food may be mixed, or mixed and strained, and is pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. Safe and suitable substances that aid in protecting or restoring the whipping properties of liquid egg whites may be added. For the purposes of this paragraph, safe and suitable substances are those that perform a useful function as whipping aids or in the pasteurization or other treatment to render liquid egg whites free of viable *Salmonella* microorganisms and that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or, if they are food additives, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) Any optional ingredients used as whipping aids, as provided for in paragraph (a) of this section, shall be named on the principal display panel or panels of labels with such prominence and conspicuousness as to render such names likely to be read and understood by ordinary individuals under customary conditions of purchase.

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 58 FR 2883, Jan. 6, 1993]

§ 160.145 Dried egg whites.

(a) The food dried egg whites, egg white solids, dried egg albumen, egg albumen solids is prepared by drying liquid egg whites conforming to the requirements of § 160.140 (or deviating from that section only by not being *Salmonella* free). As a preliminary step to drying, the lysozyme and avidin contents may be reduced. If lysozyme and avidin levels are reduced, cation exchange resins regulated for use under § 173.25 of this chapter shall be used. As a further preliminary step to drying, the glucose content of the liquid egg whites is reduced by adjusting the pH, where necessary, with food-grade acid and by following one of the optional procedures set forth in paragraph (b) of this section. If the food is prepared from liquid egg whites conforming in all respects to the requirements of § 160.140, drying shall be done with such precautions that the finished food is free of viable *Salmonella* microorganisms. If the food is prepared from liquid egg whites that are not *Salmonella* free, the dried product shall be so treated by heat or otherwise as to render the finished food free of viable *Salmonella* microorganisms. Dried egg whites may be powdered.

(b) The optional glucose-removing procedures are:

(1) *Enzyme procedure.* A glucose-oxidase-catalase preparation and hydrogen peroxide solution are added to liquid egg whites. The quantity used and the time of reaction are sufficient to substantially reduce the glucose content. The glucose-oxidase-catalase preparation used is one that is generally recognized as safe within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act. The hydrogen peroxide solution used shall comply with the specifications of the United States Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain a preservative.

(2) *Controlled fermentation procedures*—(i) *Yeast procedure.* Food-grade

baker's yeast (*Saccharomyces cerevisiae*) is added to the liquid egg whites and controlled fermentation is maintained. The quantity of yeast used and the time of reaction are sufficient to substantially reduce the glucose content.

(ii) *Bacterial procedure.* The liquid egg whites are subjected to the action of a culture of glucose-fermenting bacteria either generally recognized as safe within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act or the subject of a regulation established pursuant to section 409 of the act, and the culture is used in conformity with such regulation. The quantity of the culture used is sufficient to predominate in the fermentation and the time and temperature of reaction are sufficient to substantially reduce the glucose content.

(c)(1) Dried egg whites in which the lysozyme and avidin have been reduced shall not be nutritionally inferior, as defined in §101.3(e)(4)(i) of this chapter, and shall be considered nutritionally equivalent to untreated egg whites if they meet the conditions that the biological quality of the protein contained is equal to or greater than that of untreated egg white from the same batch of liquid egg white.

(2) Compliance with the biological quality of protein requirement of paragraph (c)(1) of this section shall be determined by the analytical method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 14th Ed. (1984), section 43.253–43.257, ''Protein Efficiency Ratio, Rat Bioassay, Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(d) When the dried egg whites are prepared from liquid egg whites containing any optional ingredients added as whipping aids, as provided for in §160.140(a), the common names of such optional ingredients shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render the names likely to be read and understood by ordinary individuals under customary conditions of purchase.

(e) The name of the food for which a definition and standard of identity is prescribed in this section is alternatively ''Dried egg whites'', Egg white solids'', ''Dried egg albumen'', or ''Egg albumen solids''. If the lysozyme and avidin content is reduced as provided in paragraph (a) of this section, the name shall be immediately preceded or followed by the statement ''lysozyme and avidin reduced'' when the dried egg whites are sold as such. When the dried egg whites are used in a fabricated food, the statement ''lysozyme and avidin reduced'' may be omitted from any declaration of ingredients required under §101.4 of this chapter.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 51 FR 11435, Apr. 3, 1986; 51 FR 25362, July 14, 1986; 54 FR 24895, June 12, 1989; 58 FR 2883, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§160.150 Frozen egg whites.

(a) Frozen egg whites, frozen egg albumen is the food prepared by freezing liquid egg whites that conform to §160.140, with such precautions that the finished food is free of viable *Salmonella* microorganisms.

(b) When frozen egg whites are prepared from liquid egg whites containing any optional ingredients added as whipping aids, as provided for in §160.140(a), the common names of such optional ingredients shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render such names likely to be read and understood by ordinary individuals under customary conditions of purchase.

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 58 FR 2883, Jan. 6, 1993]

§ 160.180 Egg yolks.

(a) Egg yolks, liquid egg yolks, yolks, liquid yolks are yolks of eggs of the domestic hen so separated from the whites thereof as to contain not less than 43 percent total egg solids, as determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), sections 17.006 and 17.007 under ''Total Solids, Vacuum Method (3)—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. They may be mixed, or mixed and strained, and they are pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those that perform a useful function in the pasteurization or other treatment to render the egg yolks free of viable *Salmonella* microorganisms, and that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or, if they are food additives, they are used in conformity with regulations established pursuant to section 409 of the act.

(b) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 47 FR 11832, Mar. 19, 1982; 49 FR 10102, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2883, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 160.185 Dried egg yolks.

(a) Dried egg yolks, dried yolks is the food prepared by drying egg yolks that conform to § 160.180, with such precautions that the finished food is free of viable *Salmonella* microorganisms. Before drying, the glucose content of the liquid egg yolks may be reduced by one of the optional procedures set forth in paragraph (b) of this section. Either silicon dioxide complying with the provisions of § 172.480 of this chapter or sodium silicoaluminate may be added as an optional anticaking ingredient, but the amount of silicon dioxide used is not more than 1 percent and the amount of sodium silicoaluminate used is less than 2 percent by weight of the finished food. The finished food shall contain not less than 95 percent by weight total egg solids.

(b) The optional glucose-removing procedures are:

(1) *Enzyme procedure.* A glucose-oxidase-catalase preparation and hydrogen peroxide solution are added to the liquid egg yolks. The quantity used and the time of reaction are sufficient to substantially reduce the glucose content of the liquid egg yolks. The glucose-oxidase-catalase preparation used is one that is generally recognized as safe within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act. The hydrogen peroxide solution used shall comply with the specification of the United States Pharmacopeia, except that it may exceed the concentration specified therein and it does not contain a preservative.

(2) *Yeast procedure.* The pH of the liquid egg yolks is adjusted to the range of 6.0 to 7.0, if necessary, by the addition of dilute, chemically pure hydrochloric acid, and controlled fermentation is maintained by adding food-grade baker's yeast (*Saccharomyces cerevisiae*). The quantity of yeast used and the time of reaction are sufficient to substantially reduce the glucose content of the liquid egg yolks.

(c) The name of the food for which a definition and standard of identity is prescribed by this section is ''Dried egg yolks'', or ''Dried yolks'', and if the glucose content was reduced, as provided in paragraph (b) of this section, the name shall be followed immediately by the statement ''Glucose removed for stability'' or ''Stabilized, glucose removed''.

(d)(1) When either of the optional anticaking ingredients specified in paragraph (a) of this section is used, the label shall bear the statement ''Not more than 1 percent silicon dioxide added as an anticaking agent'' or ''Less than 2 percent sodium silicoaluminate added as an anticaking agent'', whichever is applicable.

(2) The name of any optional ingredient used, as provided in paragraph (d)(1) of this section, shall be listed on the principal display panel or panels of the label with such prominence and conspicuousness as to render such statement likely to be read and understood by the ordinary individual under customary conditions of purchase.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 58 FR 2883, Jan. 6, 1993]

§ 160.190 Frozen egg yolks.

(a) Frozen egg yolks, frozen yolks is the food prepared by freezing egg yolks that conform to § 160.180, with such precautions that the finished food is free of viable *Salmonella* microorganisms.

(b) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14462, Mar. 15, 1977, as amended at 58 FR 2884, Jan. 6, 1993]

PART 161—FISH AND SHELLFISH

Subpart A—General Provisions

Sec.

Subpart B—Requirements for Specific Standardized Fish and Shellfish

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14464, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 161 appear at 81 FR 49896, July 29, 2016.

Subpart A—General Provisions

§ 161.30 Declaration of quantity of contents on labels for canned oysters.

(a) For many years packers of canned oysters in the Gulf area of the United States have labeled their output with a declaration of the drained weight of oysters in the containers. Packers in other areas have marketed canned oysters with a declaration of the total weight of the contents of the container. Investigation reveals that under present-day practice consumers generally do not discard the liquid packing medium, but use it as a part of the food. Section 403(e)(2) of the Federal Food, Drug, and Cosmetic Act and the regulations thereunder require food in package form to bear an accurate label statement of the quantity of food in the container.

(b) It is concluded that compliance with the label declaration of quantity of contents requirement will be met by an accurate declaration of the total weight of the contents of the can. The requirements of § 161.145(c), establishing a standard of fill of container for canned oysters and specifying the statement of substandard fill for those canned oysters failing to meet that standard remain unaffected by this interpretation.

Subpart B—Requirements for Specific Standardized Fish and Shellfish

§ 161.130 Oysters.

(a) Oysters, raw oysters, shucked oysters, are the class of foods each of which is obtained by shucking shell oysters and preparing them in accordance with the procedure prescribed in paragraph (b) of this section. The name of each such food is the name specified in the applicable definition and standard of identity prescribed in §§ 161.131 to 161.140, inclusive.

(b) If water, or salt water containing less than 0.75 percent salt, is used in any vessel into which the oysters are shucked the combined volume of oysters and liquid when such oysters are emptied from such vessel is not less than four times the volume of such water or salt water. Any liquid accumulated with the oysters is removed. The oysters are washed, by blowing or otherwise, in water or salt water, or both. The total time that the oysters are in contact with water or salt water after leaving the shucker, including the time of washing, rinsing, and any other contact with water or salt water is not more than 30 minutes. In computing the time of contact with water or salt water, the length of time that oysters are in contact with water or salt water that is agitated by blowing or otherwise, shall be calculated at twice its actual length. Any period of time that oysters are in contact with salt water containing not less than 0.75 percent salt before contact with oysters, shall not be included in computing the time that the oysters are in contact with water or salt water. Before packing into the containers for shipment or other delivery for consumption the oysters are thoroughly drained and are packed without any added substance.

(c) For the purposes of this section:

(1) *Shell oysters* means live oysters of any of the species, *Ostrea virginica, Ostrea gigas, Ostrea lurida,* in the shell, which, after removal from their beds, have not been floated or otherwise held under conditions which result in the addition of water.

(2) *Thoroughly drained* means one of the following:

(i) The oysters are drained on a strainer or skimmer which has an area of not less than 300 square inches per gallon of oysters, drained, and has perforations of at least ¼ of an inch in diameter and not more than 1¼ inches apart, or perforations of equivalent areas and distribution. The oysters are distributed evenly over the draining surface of the skimmer and drained for not less than 5 minutes; or

(ii) The oysters are drained by any method other than that prescribed by paragraph (c)(2)(i) of this section whereby liquid from the oysters is removed so that when the oysters are tested within 15 minutes after packing by draining a representative gallon of oysters on a skimmer of the dimensions and in the manner described in paragraph (c)(2)(i) of this section for 2 minutes, not more than 5 percent of liquid by weight is removed by such draining.

§ 161.136 Olympia oysters.

Olympia oysters, raw Olympia oysters, shucked Olympia oysters, are of the species *Ostrea lurida* and conform to the definition and standard of identity prescribed for oysters in § 161.130.

§ 161.145 Canned oysters.

(a) *Identity.* (1) Canned oysters is the food prepared from one or any mixture of two or all of the forms of oysters specified in paragraph (a)(2) of this section, and a packing medium of water, or the watery liquid draining from oysters before or during processing, or a mixture of such liquid and water. The food may be seasoned with salt. It is sealed in containers and so processed by heat as to prevent spoilage.

(2) The forms of oysters referred to in paragraph (a)(1) of this section are prepared from oysters which have been removed from their shells and washed and which may be steamed while in the shell or steamed or blanched or both after removal therefrom, and are as follows:

(i) Whole oysters with such broken pieces of oysters as normally occur in removing oysters from their shells, washing, and packing.

(ii) Pieces of oysters obtained by segregating pieces of oysters broken in shucking, washing, or packing whole oysters.

(iii) Cut oysters obtained by cutting whole oysters.

(3)(i) When the form of oysters specified in paragraph (a)(2)(i) of this section is used, the name of the food is ''Oysters'' or ''Cove oysters'', if of the species *Ostrea virginica;* ''Oysters'' or ''Pacific oysters'', if of the species *Ostrea gigas;* ''Oysters'' or ''Olympia oysters'', if of the species *Ostrea lurida.*

(ii) When the form of oysters specified in paragraph (a)(2)(ii) of this section is used, the name of the food is ''Pieces of _____'', the blank being

filled in with the name ''Oysters'' or ''Cove oysters'', if of the species *Ostrea virginica;* ''Oysters'' or ''Pacific oysters'', if of the species *Ostrea gigas;* ''Oysters'' or ''Olympia oysters'', if of the species *Ostrea lurida*.

(iii) When the form of oysters specified in paragraph (a)(2)(iii) of this section is used, the name of the food is ''Cut _____, the blank being filled in with the name ''Oysters'' or ''Cove oysters'', if of the species *Ostrea virginica;* ''Oysters'' or ''Pacific oysters'', if of the species *Ostrea gigas;* ''Oysters'' or ''Olympia oysters'', if of the species *Ostrea lurida*.

(iv) In case a mixture of two or all such forms of oysters is used, the name is a combination of the names specified in this paragraph (a)(3) of the forms of oysters used, arranged in order of their predominance by weight.

(4) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container*. (1) The standard of fill of container for canned oysters is a fill such that the drained weight of oysters taken from each container is not less than 59 percent of the water capacity of the container.

(2) Water capacity of containers is determined by the general method provided in § 130.12(a) of this chapter.

(3) Drained weight is determined by the following method: Keep the unopened canned oyster container at a temperature of not less than 68° or more than 95 °Fahrenheit for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute its contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth under ''2.38 mm (No. 8)'' in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.

(4) If canned oysters fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter in the manner and form therein specified, followed by the statement, ''A can of this size should contain _____ oz. of oysters. This can contains only _____ oz.'', the blanks being filled in with the applicable figures.

[42 FR 14464, Mar. 15, 1977, as amended at 47 FR 11832, Mar. 19, 1982; 49 FR 10102, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2884, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 161.170 Canned Pacific salmon.

(a) *Identity*. (1) Canned Pacific salmon is the food prepared from one of the species of fish enumerated in paragraph (a)(2) of this section, prepared in one of the forms of pack specified in paragraph (a)(3) of this section, and to which may be added one or more of the optional ingredients specified in paragraph (a)(4) of this section. The food is packed in hermetically sealed containers and so processed by heat as to prevent spoilage and soften bones. The food is labeled in accordance with paragraph (a)(5) of this section.

(2)(i) The species of fish which may be used in this food are:

Oncorhynchus tshawytscha.	Chinook, king, spring.
Oncorhynchus nerka	Blueback, red, sockeye

Oncorhynchus kisutch	Coho, Cohoe, medium red, silver
Oncorhynchus gorbuscha	Pink
Oncorhynchus keta	Chum, keta
Oncorhynchus masou	Masou, cherry

(ii) For the purpose of paragraph (a)(5)(i) of this section, the common or usual name or names of each species of fish enumerated in paragraph (a)(2)(i) of this section is (are) the name(s) immediately following the scientific name of each species.

(3) The optional forms of canned Pacific salmon are processed from fish prepared by removing the head, gills, and tail, and the viscera, blood, fins, and damaged or discolored flesh to the greatest extent practicable in accordance with good manufacturing practice; and then washing. Canned Pacific salmon is prepared in one of the following forms of pack:

(i) ''Regular'' consists of sections or steaks which are cut transversely from the fish and filled vertically into the can. In preparation, segments of skin or large backbone may be removed. The sections or steaks are so packed that the cut surfaces approximately parallel the ends of the container. A small portion of salmon may be added if necessary to complete the fill of the container.

(ii) ''Skinless and backbone removed'' consists of the regular form of canned salmon set forth in paragraph (a)(3)(i) of this section from which the skin and vertebrae have been removed in accordance with good manufacturing practices.

(iii) ''Minced salmon'' consists of salmon which has been minced or ground.

(iv) ''Salmon tips or tidbits'' consists of small pieces of salmon.

(v) ''No salt added'' consists of canned salmon to which no salt has been added.

(4) One or more of the following optional ingredients may be added to the food:

(i) Salt.

(ii) Edible salmon oil comparable in color, viscosity, and flavor to the oil which would occur naturally in the species of salmon canned.

(5)(i) The name of the food is ''salmon'' together with the common or usual name or names of the species. At least one species name shall be printed in letters of the same style of type and not less in height than those used for the word ''salmon''.

(ii) Whenever the form of pack is that described in paragraph (a)(3) (ii), (iii), or (iv) of this section, the word or words describing the form of pack shall immediately precede or follow the name of the food without intervening written, printed, or graphic matter in the manner prescribed in §101.3(c) of this chapter; for example, ''red salmon'' as the name of the food followed by ''skinless and backbone removed''.

(iii) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container.* (1) The standard of fill of container for canned salmon is a fill including all the contents of the container and is not less than the minimum net weight specified for the corresponding can size in the following table:

I. Can size	II. Minimum net weight
603 × 405	1.814 kg (64 oz).
301 × 411	454 g (16 oz).
301 × 408	439 g (15½ oz).
401 × 211	439 g (15½ oz).
607 × 406 × 108	439 g (15½ oz).
301 × 308	340 g (12 oz).
307 × 200.25	220 g (7¾ oz).
513 × 307 × 103	220 g (7¾ oz).
307 × 113	191 g (6¾ oz).
301 × 106	106 g (3¾ oz).
407 × 213 × 015	106 g (3¾ oz).

If the can size in question is not listed, calculate the value for Column II as follows: From the list, select as the comparable can size, that one having the nearest water capacity of the can size in question, multiply the net weight listed in Column II by the water capacity of the can size in question, and divide by the water capacity of the comparable can size. Water capacities are determined by the general method provided in §130.12(a) of this chapter.

(2) Sampling and acceptance procedure: The sample size of the sample representing the lot will be selected in accordance with the sampling plan shown in paragraph (c)(2)(ii) of this section. A lot is to be considered acceptable when the average net weight of all the sample units is not less than the

minimum net weight stated in paragraph (c)(1) of this section for the corresponding can size.

(i) Definitions of terms to be used in the sampling plans in paragraph (c)(2)(ii) of this section are as follows:

(*a*) *Lot.* A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(*b*) *Lot size.* The number of primary containers or units in the lot.

(*c*) *Sample size* (*n*). The total number of sample units drawn for examination from a lot.

(*d*) *Sample unit.* A container, the entire contents of a container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for examination or testing as a single unit.

(ii) Sampling plans:

Lot size (primary containers)	Size of container [1] (*n*)
4,800 or less	13
4,801 to 24,000	21
24,001 to 48,000	29
48,001 to 84,000	48
84,001 to 144,000	84
144,001 to 240,000	126
Over 240,000	200

[1] Net weight equal to or less than 1 kg. (2.2 lb).

Lot size (primary containers)	Size of container [1] (*n*)
2,400 or less	13
2,401 to 15,000	21
15,001 to 24,000	29
24,001 to 42,000	48
42,001 to 72,000	84
72,001 to 120,000	126
Over 120,000	200

n-number of primary containers in sample.

[1] Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kgs (10 lb).

(3) If canned salmon falls below the standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14464, Mar. 15, 1977, as amended at 58 FR 2884, Jan. 6, 1993; 80 FR 41436, July 15, 2015]

§ 161.173 Canned wet pack shrimp in transparent or nontransparent containers.

(a) *Identity.* (1) Canned wet pack shrimp is the food consisting of the processed meat of peeled shrimp, free of heads and, to the extent practicable under good manufacturing practice, free of shells, legs, and antennae; in one or any combination of species enumerated in paragraph (a)(2) of this section; prepared in one of the styles specified in paragraph (a)(3) of this section, in sufficient water or other suitable aqueous packing medium to fill the interstices and permit proper processing in accordance with good manufacturing practice. Canned shrimp may contain one or more of the optional ingredients specified in paragraph (a)(4) of this section. It is packed in hermetically sealed transparent or nontransparent containers and so processed by heat as to prevent spoilage.

(2) The species of shrimp that may be used in the food are of the families: Penaeidae, Pandalidae, Crangonidae, and Palaemonidae.

(3) *Styles.* Canned shrimp is prepared in one of the following styles:

(i) Shrimp with readily visible dark vein (dorsal tract, back vein, or sand vein).

(ii) Deveined shrimp containing not less than 95 percent by weight of shrimp prepared by removing the dark vein from the first five segments by deliberate cutting action.

(iii) Shrimp, other than ''deveined'' as described in paragraph (a)(3)(ii) of this section, containing not less than 95 percent by weight of shrimp with no readily visible dark vein within the first five segments.

(iv) Broken shrimp, consisting of less than four segments and otherwise conforming to one of the styles described in paragraph (a)(3)(i), (ii), or (iii) of this section.

(4) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(i) Salt.

(ii) Lemon juice.

(iii) Organic acids.

(iv) Nutritive carbohydrate sweeteners.

(v) Spices or spice oils or spice extracts.

(vi) Flavorings.

(vii) Sodium bisulfite.

(viii) Calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate), complying with the provisions of § 172.120 of this chapter.

(5) *Labeling.* (i) The name of the food is ''shrimp'' or ''shrimps.'' The word ''prawns'' may appear on the label in parentheses immediately after the word ''shrimp'' or ''shrimps'' if the shrimp are of large or extra large size as designated in paragraph (a)(5)(iv) of this section.

(ii) When the food is of the style described in paragraph (a)(3)(ii) of this section, the words ''cleaned,'' ''cleaned (deveined),'' or ''deveined'' may be declared on the label.

(iii) When the food is of the style described in paragraph (a)(3)(iii) of this section, the words ''contain no dark veins'' or their equivalent may be declared on the label.

(iv) When the food is whole shrimp within a size range designated in table I as ''extra large,'' ''large,'' ''medium,'' or ''small'' and does not contain broken shrimp as defined in paragraph (a)(3)(iv) of this section in excess of the amount listed in table II for the applicable size, the appropriate size designation may be declared on the label.

TABLE I

Size	Number of shrimp per 28.4 g (1 oz) of drained product		Number of shrimp per 100 g (3.5 oz) of drained product	
	Other than deveined style	Deveined style	Other than deveined style	Deveined style
Extra large or jumbo	Less than 3.5	Less than 3.8	Less than 12.3	Less than 13.4.
Large	3.5 to 5.0 inclusive	3.8 to 5.4 inclusive	12.3 to 17.7 inclusive	13.4 to 19.1 inclusive.
Medium	More than 5.0 but not more than 9.0.	More than 5.4 but not more than 9.8.	More than 17.7 but not more than 31.8.	More than 19.1 but not more than 34.6.
Small	More than 9.0 but not more than 17.0.	More than 9.8 but not more than 18.4.	More than 31.8 but not more than 60.0.	More than 34.6 but not more than 65.3.
Tiny	More than 17.0	More than 18.4	More than 60.0	More than 65.3.

TABLE II

Size	Maximum percent by weight of broken shrimp [a]
Extra large or jumbo	5
Large	5
Medium	5
Small	10
Tiny	15

[a] Grams of broken shrimp per 100 g of cut-out weight as determined in § 161.173(c) of this section.

(v) When the food consists of tiny shrimp, as designated in table I in paragraph (a)(5)(iv) of this section and does not contain broken shrimp as defined in paragraph (a)(3)(iv) of this section in excess of 15 percent by weight, the name of the food on the label shall be accompanied by the word ''tiny'' in type size equal to that used in the name of the food.

(vi) When the food consists of tiny shrimp, as designated in table I in paragraph (a)(5)(iv) of this section and contains more than 15 percent by weight of broken shrimp as defined in paragraph (a)(3)(iv) of this section, the name of the food on the label shall be accompanied by the word ''broken'' or ''pieces'' rather than the word ''tiny,'' in type size equal to that used in the name of the food.

(vii) When the food consists wholly or in part of sizes other than tiny, as designated in table I in paragraph (a)(5)(iv) of this section and contains more than 10 percent by weight of broken shrimp as defined in paragraph (a)(3)(iv) of this section, the name of the food on the label shall be accompanied by the word ''broken'' or ''pieces'' in type size equal to that used in the name of the food.

(viii) The name of the food shall include a declaration of any flavoring that characterizes the food, as specified in § 101.22 of this chapter, and the term ''spiced'' if spice characterizes the food.

(ix) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(6) *Sampling and acceptance procedure.* A lot is to be considered acceptable when the number of defectives does not

code__of__federal__regulations/ibr__locations.html. Without shifting the material on the sieve, incline the sieve at an angle of approximately 17° to 20° to facilitate drainage. Allow the shrimp to drain for 2 minutes, measured from the moment the product is poured onto the sieve. Weigh the sieve and the drained shrimp. The weight so found, less the weight of the sieve, shall be considered to be the cut-out weight of the shrimp.

(2) Sampling and acceptance procedure: A container that falls below the requirement for minimum fill prescribed in paragraph (c)(1) of this section is considered a ''defective.'' Determine compliance with paragraph (c)(1) of this section as specified in paragraph (a)(6) of this section except that the sample unit shall be the entire contents of the container.

(3) If canned wet pack shrimp in transparent or nontransparent containers falls below the applicable standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill provided in § 130.14(b) of this chapter, in the manner and form therein specified.

[43 FR 19840, May 9, 1978; 43 FR 25423, June 13, 1978, as amended at 47 FR 11833, Mar. 19, 1982; 49 FR 10102, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2884, Jan. 6, 1994; 63 FR 14035, Mar. 24, 1998]

EFFECTIVE DATE NOTE: Paragraphs (a) and (c) of § 161.173 were stayed until further notice by a document published at 44 FR 50328, Aug. 28, 1979.

§ 161.175 Frozen raw breaded shrimp.

(a) Frozen raw breaded shrimp is the food prepared by coating one of the optional forms of shrimp specified in paragraph (c) of this section with safe and suitable batter and breading ingredients as provided in paragraph (d) of this section. The food is frozen.

(b) The food tests not less than 50 percent of shrimp material as determined by the method prescribed in paragraph (g) of this section, except that if the shrimp are composite units the method prescribed in paragraph (h) of this section is used.

(c) The term *shrimp* means the tail portion of properly prepared shrimp of commercial species. Except for composite units, each shrimp unit is individually coated. The optional forms of shrimp are:

(1) Fantail or butterfly: Prepared by splitting the shrimp; the shrimp are peeled, except that tail fins remain attached and the shell segment immediately adjacent to the tail fins may be left attached.

(2) Butterfly, tail off: Prepared by splitting the shrimp; tail fins and all shell segments are removed.

(3) Round: Round shrimp, not split; the shrimp are peeled, except that tail fins remain attached and the shell segment immediately adjacent to the tail fins may be left attached.

(4) Round, tail off: Round shrimp, not split; tail fins and all shell segments are removed.

(5) Pieces: Each unit consists of a piece or a part of a shrimp; tail fins and all shell segments are removed.

(6) Composite units: Each unit consists of two or more whole shrimp or pieces of shrimp, or both, formed and pressed into composite units prior to coating; tail fins and all shell segments are removed; large composite units, prior to coating, may be cut into smaller units.

(d) The batter and breading ingredients referred to in paragraph (a) of this section are the fluid constituents and the solid constituents of the coating around the shrimp. These ingredients consist of suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Batter and breading ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, artificial colors, and chemical preservatives, other than those provided for in this paragraph, are not suitable ingredients of frozen raw breaded shrimp. Chemical preservatives that are suitable are:

(1) Ascorbic acid, which may be used in a quantity sufficient to retard development of dark spots on the shrimp; and

(2) The antioxidant preservatives listed in subpart D of part 182 of this

speed to 120 r.p.m. Add shrimp and stir for 10 minutes. Stack the sieves, the ½-inch mesh over the No. 20, and pour the contents of the container onto them. Set the sieves under a faucet, preferably with spray attached, and rinse shrimp with no rubbing of flesh, being careful to keep all rinsings over the sieves and not having the stream of water hit the shrimp on the sieve directly. Lay the shrimp out singly on the sieve as rinsed. Inspect each shrimp and use the rubber-tipped rod and the spray to remove the breading material that may remain on any of them, being careful to avoid undue pressure or rubbing, and return each shrimp to the sieve. Remove the top sieve and drain on a slope for 2 minutes, then remove the shrimp to weighing pan. Rinse contents of the No. 20 sieve onto a flat pan and collect any particles other than breading (i.e., flesh and tail fins) and add to shrimp on balance pan and weigh.

(ii) Calculate percent shrimp material:

Percent shrimp material = (Weight of debreaded sample) / (Weight of sample) × 100 + 2

(h) The method for determining percentage of shrimp material for composite units, specified in paragraph (c)(6) of this section, is as follows:

(1) *Equipment needed.* (i) Water bath (for example a 3–liter to 4–liter beaker).

(ii) Balance accurate to 0.1 gram.

(iii) Clip tongs of wire, plastic, or glass.

(iv) Stop-watch or regular watch readable to a second.

(v) Paper towels.

(vi) Spatula, 4–inch blade with rounded tip.

(vii) Nut picker.

(viii) Thermometer (immersion type) accurate to ±2 °F.

(ix) Copper sulfate crystals ($CuSo_4 \cdot 5H_2O$).

(2) *Procedure.* (i) Weigh all composite units in the sample while they are still hard frozen.

(ii) Place each composite unit individually in a water bath that is maintained at 63 °F–86 °F, and allow to remain until the breading becomes soft and can easily be removed from the still frozen shrimp material (between 10 seconds to 80 seconds for composite units held in storage at 0 °F). If the composite units were prepared using batters that are difficult to remove after one dipping, redip them for up to 5 seconds after the initial debreading and remove residual batter materials.

NOTE: Several preliminary trials may be necessary to determine the exact dip time required for ''debreading'' the composite units in a sample. For these trials only, a saturated solution of copper sulfate (1 pound of copper sulfate in 2 liters of tap water) is necessary. The correct dip time is the minimum time of immersion in the copper sulfate solution required before the breading can easily be scraped off: *Provided*, That the ''debreaded'' units are still solidly frozen and only a slight trace of blue color is visible on the surface of the ''debreaded'' shrimp material.

(iii) Remove the unit from the bath; blot lightly with double thickness of paper toweling; and scrape off or pick out coating from the shrimp material with the spatula or nut picker.

(iv) Weigh all the ''debreaded'' shrimp material.

(v) Calculate the percentage of shrimp material in the sample, using the following formula:

Percent shrimp material = (Weight of debreaded shrimp sample) / Weight of sample × 100

(i) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14464, Mar. 15, 1977, as amended at 47 FR 11833, Mar. 19, 1982; 49 FR 10102, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2884, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 161.176 Frozen raw lightly breaded shrimp.

Frozen raw lightly breaded shrimp complies with the provisions of § 161.175, except that it contains not less than 65 percent of shrimp material, as determined by the method prescribed in § 161.175 (g) or (h), as appropriate, and that in the name prescribed the word ''lightly'' immediately precedes the words ''breaded shrimp''.

§ 161.190 Canned tuna.

(a) *Identity.* (1) Canned tuna is the food consisting of processed flesh of

fish of the species enumerated in paragraph (a)(2) of this section, prepared in one of the optional forms of pack specified in paragraph (a)(3) of this section, conforming to one of the color designations specified in paragraph (a)(4) of this section, in one of the optional packing media specified in paragraph (a)(5) of this section, and may contain one or more of the seasonings and flavorings specified in paragraph (a)(6) of this section. For the purpose of inhibiting the development of struvite crystals, sodium acid pyrophosphate may be added in a quantity not in excess of 0.5 percent by weight of the finished food. It is packed in hermetically sealed containers and so processed by heat as to prevent spoilage. It is labeled in accordance with the provisions of paragraph (a)(8) of this section.

(2) The fish included in the class known as tuna fish are:

Thunnus thynnus (Linnaeus, 1758)—Northern bluefin tuna
Thunnus maccoyii (Castelnau, 1872)—Southern bluefin tuna
Thunnus alalunga (Bonnaterre, 1788)—Albacore
Thunnus atlanticus (Lesson, 1830)—Blackfin tuna
Thunnus obesus (Lowe, 1839)—Bigeye tuna
Thunnus albacares (Bonnaterre, 1788)—Yellowfin tuna
Thunnus tonggol (Bleeker, 1851)—Longtail tuna
Katsuwonus pelamis (Linnaeus, 1758)—Skipjack tuna
Euthynnus alletteratus (Rafinesque, 1810)—Spotted tunny
Euthynnus lineatus Kishinouye, 1920—Black skipjack tuna
Euthynnus affinis (Cantor, 1849)—Kawakawa
Allothunnus fallai Serventy, 1948—Slender tuna
Auxis rochei (Risso, 1810)—Bullet tuna
Auxis thazard (Lacepede, 1800)—Frigate tuna

(3) The optional forms of processed tuna consist of loins and other striated muscular tissue of the fish. The loin is the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, viscera and from the nonstriated part of such muscle, which part (known anatomically as the median superficial muscle) is highly vascular in structure, dark in color because of retained blood, and granular in form. Canned tuna is prepared in one of the following forms of pack, the identity of which is determined in accordance with the methods prescribed in paragraph (c)(2) of this section.

(i) Solid or solid pack consists of loins freed from any surface tissue discolored by diffused hemolyzed blood, cut in transverse segments to which no free fragments are added. In containers of 1 pound or less of net contents, such segments are cut in lengths suitable for packing in one layer. In containers of more than 1 pound net contents, such segments may be cut in lengths suitable for packing in one or more layers of equal thickness. Segments are placed in the can with the planes of their transverse cut ends parallel to the ends of the can. A piece of a segment may be added if necessary to fill a container. The proportion of free flakes broken from loins in the canning operation shall not exceed 18 percent.

(ii) Chunk, chunks, chunk style consists of a mixture of pieces of tuna in which the original muscle structure is retained. The pieces may vary in size, but not less than 50 percent of the weight of the pressed contents of a container is retained on a ½-inch-mesh screen.

(iii) Flake or flakes consist of a mixture of pieces of tuna in which more than 50 percent of the weight of the pressed contents of the container will pass through a ½-inch-mesh screen, but in which the muscular structure of the flesh is retained.

(iv) Grated consists of a mixture of particles of tuna that have been reduced to uniform size, that will pass through a ½-inch-mesh screen, and in which the particles are discrete and do not comprise a paste.

(v) Any of the specified forms of pack of canned tuna may be smoked. Canned smoked tuna shall be labeled in accordance with the provisions of paragraph (a)(8)(v) of this section.

(4) Canned tuna, in any of the forms of pack specified in paragraph (a)(3) of this section, falls within one of the following color designations, measured by visual comparison with matte surface neutral reflectance standards corresponding to the specified Munsell units of value, determined in accordance with paragraph (a)(7) of this section.

(i) *White.* This color designation is limited to the species *Thunnus alalunga* (albacore), and is not darker than Munsell value 6.3.

(ii) *Light.* This color designation includes any tuna not darker than Munsell value 5.3.

(iii) *Dark.* This color designation includes all tuna darker than Munsell value 5.3.

(iv) *Blended.* This color designation may be applied only to tuna flakes specified in paragraph (a)(3)(iii) of this section, consisting of a mixture of tuna flakes of which not less than 20 percent by weight meet the color standard for either white tuna or light tuna, and the remainder of which fall within the color standard for dark tuna. The color designation for blended tuna is determined in accordance with paragraph (a)(7) of this section.

(5) Canned tuna is packed in one of the following optional packing media:

(i) Any edible vegetable oil other than olive oil, or any mixture of such oils not containing olive oil.

(ii) Olive oil.

(iii) Water.

(6) Canned tuna may be seasoned or flavored with one or more of the following:

(i) Salt.

(ii) Monosodium glutamate.

(iii) Hydrolyzed protein declared in accordance with the applicable provisions of § 101.22.

(iv) Spices or spice oils or spice extracts.

(v) Vegetable broth in an amount not in excess of 5 percent of the volume capacity of the container, such broth to consist of a minimum of 0.5 percent by weight of vegetable extractives and to be prepared from two or more of the following vegetables: Beans, cabbage, carrots, celery, garlic, onions, parsley, peas, potatoes, green bell peppers, red bell peppers, spinach, and tomatoes.

(vi) Garlic.

(vii) Lemon flavoring to be prepared from lemon oil and citric acid together with safe and suitable carriers for the lemon oil which are present at nonfunctional and insignificant levels in the finished canned food. When lemon flavoring is added, a safe and suitable solubilizing and dispersing ingredient may be added in a quantity not exceeding 0.005 percent by weight of the finished food. A substance used in accordance with this paragraph is deemed to be suitable if it is used in an amount no greater than necessary to achieve the intended flavor effect, and is deemed to be safe if it is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act), or if it is a food additive as so defined, it is used in conformity with regulations established pursuant to section 409 of the act.

(viii) Edible vegetable oil or partially hydrogenated vegetable oil, excluding olive oil, used alone or in combination in an amount not to exceed 5 percent of the volume capacity of the container, with or without any suitable form of emulsifying and suspending ingredients that has been affirmed as GRAS or approved as a food additive to aid in dispersion of the oil, as seasoning in canned tuna packed in water.

(7) For determination of the color designations specified in paragraph (a)(4) of this section, the following method shall be used: Recombine the separations of pressed cake resulting from the method prescribed in paragraph (c)(2) of this section. Pass the combined portions through a sieve fitted with woven-wire cloth of ¼-inch mesh complying with the specifications for such cloth set forth in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Mix the sieved material and place a sufficient quantity into a 307 × 113 size container (bearing a top seam and having a false bottom approximately ½-inch deep and painted flat black inside and outside) so that

PART 163—CACAO PRODUCTS

Subpart A—General Provisions

Subpart B—Requirements for Specific Standardized Cacao Products

AUTHORITY: 21 U.S.C. 321, 331, 341, 343, 348, 371, 379e.

SOURCE: 58 FR 29529, May 21, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 163.5 Methods of analysis.

Shell and cacao fat content in cacao products shall be determined by the following methods of analysis prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(a) Shell content—12th ed. (1975), methods 13.010–13.014, under the heading ''Shell in Cacao Nibs—Official Final Action,'' pp. 208–210.

(b) Fat content—15th ed. (1990), method 963.15, under the heading ''Fat in Cacao Products—Soxhlet Extraction Method—Final Action, 1973,'' pp. 770–771.

[58 FR 29529, May 21, 1993, as amended at 63 FR 14035, Mar. 24, 1998]

Subpart B—Requirements for Specific Standardized Cacao Products

§ 163.110 Cacao nibs.

(a) *Description.* (1) Cacao nibs is the food prepared by removing the shell from cured, cleaned, dried, and cracked cacao beans. The cacao shell content is not more than 1.75 percent by weight, calculated on an alkali free basis, as determined by the method prescribed in § 163.5(a).

(2) The cacao nibs, or the cacao beans from which they are prepared, may be processed by heating with one or more of the optional alkali ingredients specified in paragraph (b)(1) of this section.

(3) The cacao nibs, or the cacao beans from which they are prepared, as appropriate, may be further processed with one or more of the optional neutralizing agents specified in paragraph (b)(2) of this section.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, added as such, or in aqueous solution. For each 100 parts by weight of cacao nibs, used as such, or before shelling from the cacao beans, the total quantity of alkali ingredients used is not greater in neutralizing value (calculated from the respective combined weights of the alkali ingredients used) than the neutralizing value of 3 parts by weight of anhydrous potassium carbonate.

(2) Neutralizing agents. Phosphoric acid, citric acid, and *L*-tartaric acid, added as such, or in aqueous solution. For each 100 parts by weight of cacao nibs, used as such, or before shelling from the cacao beans, the total quantity of phosphoric acid used is not greater than 0.5 part by weight, expressed as P_2O_5. The total amount, singly or in combination, of citric acid

and *L*-tartaric acid is not greater than 1.0 part by weight.

(c) *Nomenclature.* The name of the food is ''cacao nibs'', ''cocoa nibs'', or ''cracked cocoa''. (1) When the cacao nibs, or the cacao beans from which they are prepared, are processed with alkali ingredients specified in paragraph (b)(1) of this section, the name of the food shall be accompanied by the statement ''Processed with alkali'' or ''Processed with _____'', the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When the cacao nibs, or the cacao beans from which they are prepared, are processed with neutralizing agents specified in paragraph (b)(2) of this section, the name of the food shall be accompanied by the statement ''Processed with neutralizing agent'' or ''Processed with _____'', the blank being filled in with the common or usual name of the specific neutralizing agent used in the food.

(3) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in paragraphs (c)(1) and (c)(2) of this section shall precede or follow the name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.111 Chocolate liquor.

(a) *Description.* (1) Chocolate liquor is the solid or semiplastic food prepared by finely grinding cacao nibs. The fat content of the food may be adjusted by adding one or more of the optional ingredients specified in paragraph (b)(1) of this section to the cacao nibs. Chocolate liquor contains not less than 50 percent nor more than 60 percent by weight of cacao fat as determined by the method prescribed in § 163.5(b).

(2) Optional alkali ingredients specified in paragraph (b)(2) of this section may be used as such in the preparation of chocolate liquor under the conditions and limitations specified in § 163.110(b)(1).

(3) Optional neutralizing agents specified in paragraph (b)(3) of this section may be used as such in the preparation of the chocolate liquor under the conditions and limitations specified in § 163.110(b)(2).

(4) Chocolate liquor may be spiced, flavored, or seasoned with one or more of the ingredients listed in paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Cacao fat and cocoas (breakfast cocoa, cocoa, or lowfat cocoa);

(2) Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, added as such, or in aqueous solution;

(3) Neutralizing agents. Phosphoric acid, citric acid, and *L*-tartaric acid, added as such, or in aqueous solution;

(4) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

(5) Butter or milkfat; or

(6) Salt.

(c) *Nomenclature.* The name of the food is ''chocolate liquor'', ''chocolate'', ''unsweetened chocolate'', ''bitter chocolate'', ''baking chocolate'', ''cooking chocolate'', ''chocolate coating'', or ''unsweetened chocolate coating''.

(1) When any optional alkali ingredient specified in paragraph (b)(2) of this section is used, including those used in the preparation of the cacao nibs and cocoas from which the chocolate liquor was prepared, the name of the food shall be accompanied by the statement ''Processed with alkali'' or ''Processed with _____'', the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When any optional neutralizing agent specified in paragraph (b)(3) of this section is used, including those used in the preparation of the cacao nibs and cocoas from which the chocolate liquor was prepared, the name of the food shall be accompanied by the

statement ''Processed with neutralizing agent'' or ''Processed with _____'', the blank being filled in with the common or usual name of the specific neutralizing ingredient used in the food.

(3) When one or more spices, flavorings, or seasonings specified in paragraphs (b)(4) and (b)(5) of this section are used in the chocolate liquor, the label shall bear an appropriate statement, e.g., ''Spice added'', ''Flavored with _____'', ''Seasoned with _____'', or ''With _____ added'', the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(4) When two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner that is appropriate, but not misleading.

(5) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing optional ingredients used, shall precede or follow the name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.112 Breakfast cocoa.

(a) *Description.* (1) Breakfast cocoa is the food prepared by pulverizing the material remaining after part of the cacao fat has been removed from ground cacao nibs. Breakfast cocoa contains not less than 22 percent by weight of cacao fat as determined by the method prescribed in § 163.5(b).

(2) Optional alkali ingredients specified in paragraph (b)(1) of this section may be used as such in the preparation of breakfast cocoa under the conditions and limitations specified in § 163.110(b)(1).

(3) Optional neutralizing agents specified in paragraph (b)(2) of this section may be used as such in the preparation of the breakfast cocoa under the conditions and limitations specified in § 163.110(b)(2).

(4) Breakfast cocoa may be spiced, flavored, or seasoned with one or more of the ingredients listed in paragraphs (b)(3) and (b)(4) of this section.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Alkali ingredients. Ammonium, potassium, or sodium bicarbonate, carbonate, or hydroxide, or magnesium carbonate or oxide, used as such, or in aqueous solution;

(2) Neutralizing agents. Phosphoric acid, citric acid and L-tartaric acid, used as such, or in aqueous solution;

(3) Spices, natural and artificial flavorings, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter; or

(4) Salt.

(c) *Nomenclature.* The name of the food is ''breakfast cocoa'', or ''high fat cocoa''.

(1) When any optional alkali ingredient specified in paragraph (b)(1) of this section is used, including those used in the preparation of the cacao nibs from which the breakfast cocoa was prepared, the name of the food shall be accompanied by the statement ''Processed with alkali'', or ''Processed with _____'', the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When any optional neutralizing agent specified in paragraph (b)(2) of this section is used, including those used in the preparation of the cacao nibs from which the breakfast cocoa was prepared, the name of the food shall be accompanied by the statement ''Processed with neutralizing agent'' or ''Processed with _____'', the blank being filled in with the common or usual name of the specific neutralizing agent used in the food.

(3) When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(3) of this section are used in the breakfast cocoa, the label shall bear an appropriate statement, e.g., ''Spice added'', ''Flavored with _____'', or ''With _____ added'', the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(4) When two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner that is appropriate, but not misleading.

(5) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this paragraph showing optional ingredients used shall precede or follow the name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.113 Cocoa.

(a) *Description.* Cocoa is the food that conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for breakfast cocoa in § 163.112, except that the cacao fat content is less than 22 percent, but not less than 10 percent by weight, as determined by the method prescribed in § 163.5(b).

(b) *Nomenclature.* The name of the food is ''cocoa'' or ''medium fat cocoa''.

§ 163.114 Lowfat cocoa.

(a) *Description.* Lowfat cocoa is the food that conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for breakfast cocoa in § 163.112, except that the cacao fat content is less than 10 percent by weight, as determined by the method prescribed in § 163.5(b).

(b) *Nomenclature.* The name of the food is ''lowfat cocoa''.

§ 163.117 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

(a) *Description.* Cocoa with dioctyl sodium sulfosuccinate for manufacturing is the food additive complying with the provisions prescribed in § 172.520 of this chapter. It conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, for breakfast cocoa in § 163.112, or for cocoa in § 163.113, or for lowfat cocoa in § 163.114, except that the food additive contains dioctyl sodium sulfosuccinate (complying with the requirements of § 172.810 of this chapter, including the limit of not more than 0.4 percent by weight of the finished food additive).

(b) *Nomenclature.* The name of the food additive is ''cocoa with dioctyl sodium sulfosuccinate for manufacturing'' to which is added any modifier of the word ''cocoa'' required by the definition and standard of identity to which the food additive otherwise conforms. When the food additive is used in a fabricated food, the phrase ''for manufacturing'' may be omitted from any declaration of ingredients required under § 101.4 of this chapter.

§ 163.123 Sweet chocolate.

(a) *Description.* (1) Sweet chocolate is the solid or semiplastic food prepared by intimately mixing and grinding chocolate liquor with one or more optional nutritive carbohydrate sweeteners, and may contain one or more of the other optional ingredients specified in paragraph (b) of this section.

(2) Sweet chocolate contains not less than 15 percent by weight of chocolate liquor complying with the requirements of § 163.111, as calculated by subtracting from the weight of the chocolate liquor used the weight of the cacao fat therein and the weights therein of any alkali, neutralizing, and seasoning ingredients, and multiplying the remainder by 2.2, dividing the result by the weight of the finished sweet chocolate, and multiplying the quotient by 100. The finished sweet chocolate contains less than 12 percent by weight of total milk solids based on those dairy ingredients specified in paragraph (b)(4) of this section, exclusive of any added sweetener or other dairy derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(3) Semisweet chocolate or bittersweet chocolate is sweet chocolate that contains not less than 35 percent by weight of chocolate liquor complying with the requirements of § 163.111 and calculated in the same manner as set forth in paragraph (a)(2) of this section.

(4) Cacao fat is determined by the method prescribed in § 163.5(b).

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Cacao fat;

(2) Nutritive carbohydrate sweeteners;

(3) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

(4) Dairy ingredients:

(i) Cream, milkfat, butter;

(ii) Milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk;

(iii) Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk;

(iv) Concentrated buttermilk, dried buttermilk; and

(v) Malted milk; or

(5) Emulsifying agents, used singly or in combination, the total amount of which does not exceed 1.0 percent by weight.

(c) *Nomenclature.* The name of the food is ''sweet chocolate'', ''sweet chocolate coating'', ''semisweet chocolate'', ''semisweet chocolate coating'', ''bittersweet chocolate'', or ''bittersweet chocolate coating'', as appropriate.

(1) When optional alkalizing ingredients are used in the preparation of the chocolate liquor or the cacao nibs from which the chocolate was prepared, the label shall bear the statement ''Processed with alkali'', or ''Processed with _____'', the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When optional neutralizing agents are used in the preparation of the chocolate liquor or the cacao nibs from which the chocolate was prepared, the label shall bear the statement ''Processed with neutralizing agents'', or ''Processed with _____'', the blank being filled in with the common or usual name of the specific neutralizing agent used in the food.

(3) When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(3) of this section are used in the breakfast cocoa, the label shall bear an appropriate statement, e.g., ''Spice added'', ''Flavored with _____'', or ''With _____ added'', the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(4) When two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner that is appropriate, but not misleading.

(5) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this paragraph showing optional ingredients used shall precede or follow such name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.124 White chocolate.

(a) *Description.* (1) White chocolate is the solid or semiplastic food prepared by intimately mixing and grinding cacao fat with one or more of the optional dairy ingredients specified in paragraph (b)(2) of this section and one or more optional nutritive carbohydrate sweeteners and may contain one or more of the other optional ingredients specified in paragraph (b) of this section. White chocolate shall be free of coloring material.

(2) White chocolate contains not less than 20 percent by weight of cacao fat as calculated by subtracting from the weight of the total fat the weight of the milkfat, dividing the result by the weight of the finished white chocolate, and multiplying the quotient by 100. The finished white chocolate contains not less than 3.5 percent by weight of milkfat and not less than 14 percent by weight of total milk solids, calculated by using only those dairy ingredients specified in paragraph (b)(2) of this section, and not more than 55 percent by weight nutritive carbohydrate sweetener.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Nutritive carbohydrate sweeteners;

(2) Dairy ingredients:

(i) Cream, milkfat, butter;

(ii) Milk, dry whole milk, concentrated milk, evaporated milk, sweetened condensed milk;

(iii) Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk;

(iv) Concentrated buttermilk, dried buttermilk; and

(v) Malted milk;

(3) Emulsifying agents, used singly or in combination, the total amount of which does not exceed 1.5 percent by weight;

(4) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

(5) Antioxidants; and

(6) Whey or whey products, the total amount of which does not exceed 5 percent by weight.

(c) *Nomenclature.* The name of the food is ''white chocolate'' or ''white chocolate coating.'' When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(4) of this section are used, the label shall bear an appropriate statement, e.g., ''Spice added'', ''Flavored with _____ '', or ''With _____ added'', the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[67 FR 62177, Oct. 4, 2002]

§ 163.130 Milk chocolate.

(a) *Description.* (1) Milk chocolate is the solid or semiplastic food prepared by intimately mixing and grinding chocolate liquor with one or more of the optional dairy ingredients and one or more optional nutritive carbohydrate sweeteners, and may contain one or more of the other optional ingredients specified in paragraph (b) of this section.

(2) Milk chocolate contains not less than 10 percent by weight of chocolate liquor complying with the requirements of § 163.111 as calculated by subtracting from the weight of the chocolate liquor used the weight of cacao fat therein and the weights of alkali, neutralizing and seasoning ingredients, multiplying the remainder by 2.2, dividing the result by the weight of the finished milk chocolate, and multiplying the quotient by 100. The finished milk chocolate contains not less than 3.39 percent by weight of milkfat and not less than 12 percent by weight of total milk solids based on those dairy ingredients specified in paragraph (b)(4) of this section, exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Optional ingredients.* The following safe and suitable ingredients may be used:

(1) Cacao fat;

(2) Nutritive carbohydrate sweeteners;

(3) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

(4) Dairy ingredients:

(i) Cream, milkfat, butter;

(ii) Milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk; and

(iii) Skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk; or

(5) Emulsifying agents, used singly or in combination, the total amount of which does not exceed 1.0 percent by weight.

(c) *Nomenclature.* The name of the food is ''milk chocolate'' or ''milk chocolate coating''.

(1) When optional alkali ingredients are used in the preparation of the chocolate liquor or the cacao nibs from which the milk chocolate was prepared, the label shall bear the statement ''Processed with alkali'', or ''Processed with _____'', the blank being filled in with the common or usual name of the specific alkali ingredient used in the food.

(2) When optional neutralizing agents are used in the preparation of the chocolate liquor or the cacao nibs from which the milk chocolate was prepared, the label shall bear the statement ''Processed with neutralizing agents'', or ''Processed with _____'', the blank being filled in with the common or usual name of the specific neutralizing agent used in the food.

(3) When one or more of the spices, flavorings, or seasonings specified in paragraph (b)(3) of this section are used in the breakfast cocoa, the label shall bear an appropriate statement, e.g., ''Spice added'', ''Flavored with _____'', or ''With _____ added'', the blank being filled in with the common or usual name of the spice, flavoring, or seasoning used, in accordance with § 101.22 of this chapter.

(4) When two or more of the statements set forth in this paragraph are required, such statements may be combined in a manner that is appropriate, but not misleading.

(5) Whenever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this paragraph showing optional ingredients used shall precede or follow such name without intervening printed or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

§ 163.135 Buttermilk chocolate.

(a) *Description.* Buttermilk chocolate is the food that conforms to the standard of identity, and is subject to the requirements for label declaration of ingredients for milk chocolate in § 163.130, except that:

(1) The optional dairy ingredients are limited to sweet cream buttermilk, concentrated sweet cream buttermilk, dried sweet cream buttermilk, and any combination of these; and

(2) The finished buttermilk chocolate contains less than 3.39 percent by weight of milkfat and not less than 12 percent by weight of sweet cream buttermilk solids based on those dairy ingredients specified in paragraph (a)(1) of this section, exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Nomenclature.* The name of the food is ''buttermilk chocolate'', ''buttermilk chocolate coating'', ''sweet buttermilk chocolate'', ''sweet buttermilk chocolate coating'', ''sweet cream buttermilk chocolate'', or ''sweet cream buttermilk chocolate coating''.

§ 163.140 Skim milk chocolate.

(a) *Description.* Skim milk chocolate is the food that conforms to the standard of identity, and is subject to the requirements for label declaration of ingredients for milk chocolate in § 163.130, except that:

(1) The optional dairy ingredients are limited to skim milk, evaporated skim milk, concentrated skim milk, sweetened condensed skim milk, nonfat dry milk, and any combination of these; and

(2) The finished skim milk chocolate contains less than 3.39 percent by weight of milkfat and not less than 12 percent by weight of skim milk solids based on those dairy ingredients specified in paragraph (a)(1) of this section, exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Nomenclature.* The name of the food is ''skim milk chocolate'', ''skim milk chocolate coating'', ''sweet skim milk chocolate'', or ''sweet skim milk chocolate coating''.

§ 163.145 Mixed dairy product chocolates.

(a) *Description.* Mixed dairy product chocolates are the foods that conform to the standard of identity, and are subject to the requirements for label declaration of ingredients for milk chocolate in § 163.130, except that:

(1) The optional dairy ingredients for each of the foods are mixtures of two or more of the following:

(i) Any dairy ingredients specified in § 163.130;

(ii) Any dairy ingredients specified in § 163.135;

(iii) Any dairy ingredients specified in § 163.140; or

(iv) Malted milk; and

(2) The finished mixed dairy product chocolates shall contain not less than 12 percent by weight of total milk solids derived from those dairy products referred to in paragraph (a)(1) of this section, exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy product, and may contain less than 3.39 percent by weight of milkfat. The quantity of each component used in any such mixture is such that no component contributes less than one third of the weight of the total milk solids contributed by that component which is used in the largest proportion.

(b) *Nomenclature.* The name of the food is ''chocolate'', or ''chocolate coating'', preceded by the designation of the type of milk ingredients used as prescribed in paragraph (a) of this section in order of predominance by weight, e.g., ''milk and skim milk chocolate''.

§ 163.150 Sweet cocoa and vegetable fat coating.

(a) *Description.* Sweet cocoa and vegetable fat coating is the food that conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for sweet chocolate in § 163.123, except that:

(1) In the preparation of the product, cocoa or a mixture of cocoa and chocolate liquor is used in such quantity that the finished food contains not less than 6.8 percent by weight of nonfat cacao solids, calculated on a moisture-free basis;

(2) One or more optional ingredients specified in paragraph (b) of this section are used; and

(3) The requirement in § 163.123(a)(2) limiting the total milk solids content to less than 12 percent by weight does not apply.

(b) *Optional ingredients.* (1) Breakfast cocoa, cocoa, lowfat cocoa;

(2) Chocolate liquor;

(3) Safe and suitable vegetable derived fats, oils, and stearins other than cacao fat. The fats, oils, and stearins may be hydrogenated;

(4) Safe and suitable dairy-derived ingredients; and

(5) Safe and suitable bulking agents, formulation aids, humectants, and texturizers.

(c) *Nomenclature.* The name of the food is ''sweet cocoa and vegetable fat coating''. Alternatively, the common or usual name of the vegetable derived fat ingredient may be used in the name of the food, e.g., ''sweet cocoa and _____ oil coating'', the blank being filled in with the common or usual name of the specific vegetable fat used.

§ 163.153 Sweet chocolate and vegetable fat coating.

(a) *Description.* Sweet chocolate and vegetable fat coating is the food that conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for sweet chocolate in § 163.123, except that one or more optional ingredients specified in paragraph (b) of this section are used. Compliance with the requirement in § 163.123(a)(2) limiting the total milk solids content to less than 12 percent by weight shall be calculated by including only those dairy ingredients referred to in § 163.123(b)(4), exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Optional ingredients.* (1) Safe and suitable vegetable derived fats, oils, and stearins other than cacao fat. The fats, oils, and stearins may be hydrogenated;

(2) Safe and suitable dairy-derived ingredients; and

(3) Safe and suitable bulking agents, formulation aids, humectants, and texturizers.

(c) *Nomenclature.* The name of the food is ''sweet chocolate and vegetable fat coating''. Alternatively, the common or usual name of the vegetable derived fat ingredient may be used in the name of the food, e.g., ''sweet chocolate and _____ oil coating'', the blank being filled in with the common or usual name of the specific vegetable fat used.

§ 163.155 Milk chocolate and vegetable fat coating.

(a) *Description.* Milk chocolate and vegetable fat coating is the food that

conforms to the standard of identity, and is subject to the requirements for label declaration of ingredients for milk chocolate in §163.130 or skim milk chocolate in §163.140, except that one or more optional ingredients specified in paragraph (b) of this section are used. Compliance with the requirement in §163.130(a)(2) that the product contains not less than 12 percent by weight of nonfat milk solids shall be calculated using only those dairy ingredients referred to in §163.130(b)(4), exclusive of any added sweetener or other dairy-derived ingredient that is added beyond that amount that is normally present in the specified dairy ingredient.

(b) *Optional ingredients.* (1) Safe and suitable vegetable derived oils, fats, and stearins other than cacao fat. The oils, fats, and stearins may be hydrogenated;

(2) Safe and suitable dairy-derived ingredients; and

(3) Safe and suitable bulking agents, formulation aids, humectants, and texturizers.

(c) *Nomenclature.* The name of the food is ''milk chocolate and vegetable fat coating'' or ''skim milk chocolate and vegetable fat coating'', as appropriate. Alternatively, the common or usual name of the vegetable derived fat ingredient may be used in the name of the food, e.g., ''milk chocolate and _____ oil coating'', the blank being filled in with the common or usual name of the specific vegetable fat used.

PART 164—TREE NUT AND PEANUT PRODUCTS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Tree Nut and Peanut Products

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14475, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Tree Nut and Peanut Products

§ 164.110 Mixed nuts.

(a) Mixed nuts is the food consisting of a mixture of four or more of the optional shelled tree nut ingredients, with or without one or more of the optional shelled peanut ingredients, of the kinds prescribed by paragraph (b) of this section; except that when 2 ounces or less of the food is packed in transparent containers, three or more of the optional tree nut ingredients shall be present. Each such kind of nut ingredient when used shall be present in a quantity not less than 2 percent and not more than 80 percent by weight of the finished food. For purposes of this section, each kind of tree nut and peanut is an optional ingredient that may be prepared by any suitable method in accordance with good manufacturing practice. The finished food may contain one or more of the optional nonnut ingredients provided for in paragraph (c) of this section.

(b) The optional shelled nut ingredients referred to in paragraph (a) of this section are:

(1) Almonds, black walnuts, Brazil nuts, cashews, English walnuts (alternatively ''walnuts''), filberts, pecans, and other suitable kinds of tree nuts.

(2) Peanuts of the Spanish, Valencia, Virginia, or similar varieties, or any combination of two or more such varieties.

(c) The optional nonnut ingredients referred to in paragraph (a) of this section consist of suitable substances that are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Nonnut ingredients that perform a useful function are regarded as suitable, except that color additives are not suitable ingredients of the food.

(d) The name of the food is ''mixed nuts''. If the percentage of a single tree

nut ingredient or the total peanut content by weight of the finished food exceeds 50 percent but not 60 percent, the statement ''contains up to 60% _____'' or ''contains 60% _____'' or ''60% _____'' shall immediately follow the name ''mixed nuts'' and shall appear on the same background, be of the same color or, in the case of multicolors, in the color showing distinct contrast with the background, and be in letters not less than one-half the height of the largest letter in the words ''mixed nuts''. The blank is to be filled in with the appropriate name of the predominant nut ingredient; for example, ''contains up to 60% pecans'' or ''contains up to 60% Spanish peanuts''. The numbers ''70'' or ''80'' shall be substituted for the number ''60'' when the percentage of the predominant nut ingredient exceeds 60 but not 70, or exceeds 70 but not 80, respectively. Compliance with the requirements for percentage of nut ingredients of this section and the fill of container requirements of §164.120(c) will be determined by the following procedure:

(1) Take at random from a lot, in the case of containers bearing a weight declaration of 16 ounces or less, at least 24 containers, and for containers bearing a weight declaration of more than 16 ounces, enough containers to provide a total quantity of at least 24 pounds of nuts.

(2) If compliance with §164.120(c) is to be determined, first follow the procedure set forth therein.

(3) Determine the percent by weight of each nut ingredient present in each container separately. Calculate the average percentage of each nut ingredient present. If the average percent found for each nut ingredient present is 2 percent or more and none of the individual nut ingredients exceeds 80 percent by weight of the finished food, the lot will be deemed to be in compliance with the percentage requirements of paragraph (a) of this section. If the average percent found for a single nut ingredient exceeds 50 percent by weight of the finished food and the average percent found is within the range indicated by the number declared on the label in accordance with this paragraph, the lot will be deemed to be in compliance with the labeling requirements of this paragraph.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

(1) If the Spanish variety of peanuts is used, it shall be declared as ''Spanish peanuts''. Other varieties of peanuts shall be declared as ''peanuts'', or alternatively ''_____ peanuts'', the blank being filled in with the varietal name of the peanuts used.

(2) If the peanut ingredient or ingredients as provided for in paragraph (b)(2) of this section are unblanched, the label shall show that fact by such statement as ''Peanuts unblanched'', ''Peanuts skins on'', or words of similar import, unless the vignette clearly depicts peanuts with skins on.

(f) The words and statements specified in paragraph (e) of this section showing the ingredients present shall be listed on the principal display panel or panels or any appropriate information panel without obscuring design, vignettes, or crowding. The declaration shall appear in conspicuous and easily legible letters of boldface print or type the size of which shall be not less than one-half of that required by part 101 of this chapter for the statement of net quantity of contents appearing on the label, but in no case less than one-sixteenth of an inch in height. The entire ingredient statement shall appear on at least one panel of the label. If the label bears any pictorial representation of the mixture of nuts, it shall depict the relative proportions of the nut ingredients of the food. If the label bears a pictorial representation of only one of each nut ingredient present, the nuts shall be depicted in the order of decreasing predominance by weight. A factual statement that the food does not contain a particular nut ingredient or ingredients may be shown on the label if the statement is not misleading and does not result in an insufficiency of label space for the proper declaration of information required by or under authority of the act to appear on the label.

[42 FR 14475, Mar. 15, 1977, as amended at 58 FR 2885, Jan. 6, 1993]

§ 164.120 Shelled nuts in rigid or semirigid containers.

(a)–(b) [Reserved]

(c) *Fill of container.* (1) The standard of fill for shelled nuts in rigid or semirigid containers is a fill such that the average volume of nuts, from the number of containers specified in § 164.110(d)(1), is not less than 85 percent of the container volume as determined by the method in paragraph (c)(2) of this section.

(2) The method for determining the percent of fill is as follows:

(i) For the shelled nuts in each container, determine the loose volume, the settled volume, and the average volume in cubic centimeters. For the purposes of this subparagraph, consider volume in milliliters to be numerically equal to volume in cubic centimeters. Open the container and pour the nuts loosely into a vertical graduated cylinder (do not tilt) of appropriate size fitted with a funnel which has been modified, if necessary, to provide a minimum opening of 1½-inch diameter. (If the loose volume of the nuts is less than 500 milliliters, use a 500–milliliter cylinder with an inside diameter of approximately 1⅞ inches; but if the loose volume is 500 milliliters or more, use a 1,000–milliliter cylinder with an inside diameter of approximately 2¼ inches.) Without shaking the cylinder, estimate the location of a horizontal plane representing the average height of the product, read the volume of the nuts, and record as the loose volume. Raise the cylinder 2 inches and allow it a free vertical drop onto a level, firm, but resilient surface (do not tamp) for a total of 5 times and observe the volume as above. Repeat in successive five-drop increments until the nuts have so settled that the volume decreases less than 2 percent in the last five-drop increment. Read the last volume in the manner described above and record as the settled volume. The arithmetical average of the loose volume and the settled volume equals the average volume of nuts.

(ii) Classify the container by shape and determine its volume in cubic centimeters according to one of the following methods as appropriate:

(*a*) For containers of irregular shape, including glass jars, follow the general method for water capacity of containers as prescribed in § 130.12(a) of this chapter and determine the container volume, considering the water capacity in grams to be numerically equivalent to volume in cubic centimeters, or the water capacity in ounces (avoirdupois) to be equivalent to 28.35 cubic centimeters per ounce.

(*b*) For box-shaped containers (that is, with opposite sides parallel), measure the inside height, width, and depth and calculate the volume as the product of these three dimensions. For such containers used to enclose vacuum packs and containing 4 ounces or less of the product, consider the height to be the inside height minus three-eighths inch.

(*c*) For cylindrical containers, calculate the container volume in cubic centimeters as the product of the height times the square of the diameter, both measured in inches, times 12.87; or as the product of the height times the square of the diameter, both measured in centimeters, times 0.7854. For containers that do not have indented ends, use the inside height and inside diameter as the dimensions. For metal cans with indented ends (that is, metal cans with ends attached by double seams), consider the height to be the outside height at the double seam minus three-eighths inch (0.953 centimeter) and the diameter to be the outside diameter at the double seam minus one-eighth inch (0.318 centimeter). For fiber-bodied containers with indented ends (that is, fiber-bodied cans with metal ends attached by double seams), consider the height to be the outside height at the double seam minus three-eighths inch (0.953 centimeter) and the diameter to be the outside diameter at the double seam minus three-sixteenths inch (0.476 centimeter).

(iii) Calculate the percent fill of the container as follows: Divide the average volume of nuts found according to paragraph (c)(2)(i) of this section by the appropriate container volume found according to paragraph (c)(2)(ii) of this section and multiply by 100. The result shall be considered to be the percent fill of the container.

(3) If shelled nuts fall below the standard of fill of container prescribed

in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein specified.

§ 164.150 Peanut butter.

(a) Peanut butter is the food prepared by grinding one of the shelled and roasted peanut ingredients provided for by paragraph (b) of this section, to which may be added safe and suitable seasoning and stabilizing ingredients provided for by paragraph (c) of this section, but such seasoning and stabilizing ingredients do not in the aggregate exceed 10 percent of the weight of the finished food. To the ground peanuts, cut or chopped, shelled, and roasted peanuts may be added. During processing, the oil content of the peanut ingredient may be adjusted by the addition or subtraction of peanut oil. The fat content of the finished food shall not exceed 55 percent when determined as prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 27.006(a) under ''Crude Fat—Official First Action, Direct Method,'' in paragraph (a), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(b) The peanut ingredients referred to in paragraph (a) of this section are:

(1) Blanched peanuts, in which the germ may or may not be included.

(2) Unblanched peanuts, including the skins and germ.

(c) The seasoning and stabilizing ingredients referred to in paragraph (a) of this section are suitable substances which are not food additives as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act), or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act. Seasoning and stabilizing ingredients that perform a useful function are regarded as suitable, except that artificial flavorings, artificial sweeteners, chemical preservatives, and color additives are not suitable ingredients in peanut butter. Oil products used as optional stabilizing ingredients shall be hydrogenated vegetable oils. For the purposes of this section, hydrogenated vegetable oil shall be considered to include partially hydrogenated vegetable oil.

(d) If peanut butter is prepared from unblanched peanuts as specified in paragraph (b)(2) of this section, the name shall show that fact by some such statement as ''prepared from unblanched peanuts (skins left on).'' Such statement shall appear prominently and conspicuously and shall be in type of the same style and not less than half of the point size of that used for the words ''peanut butter.'' This statement shall immediately precede or follow the words ''peanut butter,'' without intervening written, printed, or graphic matter.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14475, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 61 FR 9325, Mar. 8, 1996; 63 FR 14035, Mar. 24, 1998]

PART 165—BEVERAGES

Subpart A—General Provisions

Subpart B—Requirements for Specific Standardized Beverages

AUTHORITY: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

SOURCE: 60 FR 57124, Nov. 13, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 165.3 Definitions.

(a) A *lot* is:

(1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production.

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A *sample* consists of 10 subsamples (consumer units), one taken from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.

(c) An *analytical unit* is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

Subpart B—Requirements for Specific Standardized Beverages

§ 165.110 Bottled water.

(a) *Identity*—(1) *Description.* Bottled water is water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Fluoride may be optionally added within the limitations established in § 165.110(b)(4)(ii). Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labeling as ''water,'' ''carbonated water,'' ''disinfected water,'' ''filtered water,'' ''seltzer water,'' ''soda water,'' ''sparkling water,'' and ''tonic water.'' The processing and bottling of bottled water shall comply with applicable regulations in part 129 of this chapter.

(2) *Nomenclature.* The name of the food is ''bottled water,'' ''drinking water,'' or alternatively one or more of the following terms as appropriate:

(i) The name of water from a well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer is ''artesian water'' or ''artesian well water.'' Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer.

(ii) The name of water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure is ''ground water.'' Ground water must not be under the direct influence of surface water as defined in 40 CFR 141.2.

(iii) The name of water containing not less than 250 parts per million (ppm) total dissolved solids (TDS), coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be ''mineral water.'' Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.

(iv) The name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of ''purified water'' in the United States Pharmacopeia, 23d Revision, January 1, 1995, which is incorporated by reference in accordance with 5 U.S.C. 551(a) and 1 CFR part 51. (Copies may be obtained from the United States Pharmacopial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852 and may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*), may be ''purified water'' or ''demineralized water.'' Alternatively, the water may be called

and compounds known as oleomargarine or margarine; (2) all substances, mixtures, and compounds which have a consistency similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter''. Notwithstanding the difference between this definition and the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act, it was the clear intent of Congress that any article which is represented as or purports to be oleomargarine or margarine is misbranded if it fails to comply with the definition and standard of identity for oleomargarine or margarine even though it may meet the statutory definition.

(g) Section 407(a) states that ''Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this act as if it had been introduced in interstate commerce''.

(h) Section 407(b)(4) requires that each part of the contents of the package be ''contained in a wrapper which bears the word 'oleomargarine' or 'margarine' in type or lettering not smaller than 20-point type''. The Food and Drug Administration interprets this to mean that the height of the actual letters is no less than 20 points, or $^{20}/_{72}$ of 1 inch.

(i) The wrappers on the subdivisions of oleomargarine or margarine contained within the package sold at retail are labels within the meaning of section 201(k) and shall contain all of the label information required by sections 403 and 407 of the Federal Food, Drug, and Cosmetic Act, just as in the case of 1-pound cartons, except that wrappers on the subdivisions contained within the retail package shall be exempt from compliance with the requirements of section 403 (e)(1), (g)(2), (i)(2), and (k) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor and label declaration of ingredients when (1) the subdivisions are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale; (2) the wrappers on the subdivisions are labeled with the statement ''This Unit Not Labeled For Retail Sale'' in type size not less than one-sixteenth inch in height. The word ''Individual'' may be used in lieu of or immediately preceding the word ''Retail'' in the statement.

[42 FR 14477, Mar. 15, 1977, as amended at 46 FR 31005, June 12, 1981; 47 FR 32421, July 27, 1982]

Subpart B—Requirements for Specific Standardized Margarine

§ 166.110 Margarine.

(a) *Description.* Margarine (or oleomargarine) is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), section 16.206, ''Indirect Method,'' under the heading ''Fat (47)—Official Final Action,'' which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Margarine contains only safe and suitable ingredients, as defined in § 130.3(d) of this chapter. It is produced from one or more of the optional ingredients in paragraph (a)(1) of this section, and one or more of the optional ingredients in paragraph (a)(2) of this section, to which may be added one or more of the optional ingredients in paragraph (b) of this section. Margarine contains vitamin A as provided for in paragraph (a)(3) of this section.

(1) Edible fats and/or oils, or mixtures of these, whose origin is vegetable or rendered animal carcass fats, or any form of oil from a marine species that has been affirmed as GRAS or listed as a food additive for this use, any or all of which may have been subjected to an accepted process of physico-chemical modification. They

may contain small amounts of other lipids, such as phosphatides or unsaponifiable constituents, and of free fatty acids naturally present in the fat or oil.

(2) One or more of the following aqueous phase ingredients:

(i) Water and/or milk and/or milk products.

(ii) Suitable edible protein including, but not limited to, the liquid, condensed, or dry form of whey, whey modified by the reduction of lactose and/or minerals, nonlactose containing whey components, albumin, casein, caseinate, vegetable proteins, or soy protein isolate, in amounts not greater than reasonably required to accomplish the desired effect.

(iii) Any mixture of two or more of the articles named under paragraphs (a)(2) (i) and (ii) of this section.

(iv) The ingredients in paragraphs (a)(2) (i), (ii), and (iii) of this section shall be pasteurized and then may be subjected to the action of harmless bacterial starters. One or more of the articles designated in paragraphs (a)(2) (i), (ii), and (iii) of this section is intimately mixed with the edible fat and/or ingredients to form a solidified or liquid emulsion.

(3) Vitamin A in such quantity that the finished margarine contains not less than 15,000 international units per pound.

(b) *Optional ingredients.* (1) Vitamin D in such quantity that the finished oleomargarine contains not less than 1,500 international units of vitamin D per pound.

(2) Salt (sodium chloride); potassium chloride for dietary margarine or oleomargarine.

(3) Nutritive carbohydrate sweeteners.

(4) Emulsifiers.

(5) Preservatives including but not limited to the following within these maximum amounts in percent by weight of the finished food: Sorbic acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent; propyl, octyl, and dodecyl gallates, BHT, BHA, ascorbyl palmitate, ascorbyl stearate, all individually or in combination, 0.02 percent; stearyl citrate, 0.15 percent; isopropyl citrate mixture, 0.02 percent.

(6) Color additives. For the purpose of this subparagraph, provitamin A (beta-carotene) shall be deemed to be a color additive.

(7) Flavoring substances. If the flavoring ingredients impart to the food a flavor other than in semblance of butter, the characterizing flavor shall be declared as part of the name of the food in accordance with §101.22 of this chapter.

(8) Acidulants.

(9) Alkalizers.

(c) *Nomenclature.* The name of the food for which a definition and standard of identity are prescribed in this section is ''margarine'' or ''oleomargarine''.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. For the purposes of this section the use of the term ''milk'' unqualified means milk from cows. If any milk other than cow's milk is used in whole or in part, the animal source shall be identified in conjunction with the word milk in the ingredient statement. Colored margarine shall be subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act as amended.

[42 FR 14478, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 48 FR 13024, Mar. 29, 1983; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 58 FR 21649, Apr. 23, 1993; 59 FR 26939, May 25, 1994; 63 FR 14035, Mar. 24, 1998]

PART 168—SWEETENERS AND TABLE SIRUPS

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Sweeteners and Table Sirups

Sec.

AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

SOURCE: 42 FR 14479, Mar. 15, 1977, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Requirements for Specific Standardized Sweeteners and Table Sirups

§ 168.110 Dextrose anhydrous.

(a) Dextrose anhydrous is purified and crystallized D-glucose without water of crystallization and conforms to the specifications of § 168.111, except that the total solids content is not less than 98.0 percent m/m.

(b) The name of the food is ''Dextrose anhydrous'' or ''Anhydrous dextrose'' or alternatively, ''_____ sugar anhydrous'' or ''Anhydrous sugar'', with the blank to be filled with the name of the food source, for example, ''Corn sugar anhydrous''.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 168.111 Dextrose monohydrate.

(a) Dextrose monohydrate is purified and crystallized D-glucose containing one molecule of water of crystallization with each molecule of D-glucose.

(b) The food shall meet the following specifications:

(1) The total solids content is not less than 90.0 percent mass/mass (m/m), and the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 99.5 percent m/m calculated on a dry basis.

(2) The sulfated ash content is not more than 0.25 percent m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 20 mg/kg.

(c) The name of the food is ''Dextrose monohydrate'' or ''Dextrose'' or alternatively, ''_____ sugar monohydrate'' or ''_____ sugar'', with the blank to be filled with the name of the food source, for example, ''Corn sugar monohydrate'' or ''Corn sugar''.

(d) For purposes of this section, the methods of analysis to be used to determine if the food meets the specifications of paragraph (b) (1) and (2) of this section are the following sections in ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(1) Total solids content, 31.005.

(2) Reducing sugar content, section 31.220(a).

(3) Sulfated ash content, section 31.216.

(4) Sulfur dioxide content, sections 20.106–20.111.

[42 FR 14479, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 58 FR 2886, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 168.120 Glucose sirup.

(a) Glucose sirup is the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch.

(b) The food shall meet the following specifications:

(1) The total solids content is not less than 70.0 percent mass/mass (m/m), and the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 20.0 percent m/m calculated on a dry basis.

(2) The sulfated ash content is not more than 1.0 percent m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 40 mg/kg.

(c) The name of the food is ''Glucose sirup''. When the food is derived from a specific type of starch, the name may alternatively be ''_____ sirup'', the blank to be filled in with the name of the starch. For example, ''Corn sirup'', ''Wheat sirup'', ''Tapioca sirup''. When the starch is derived from sorghum grain, the alternative name of the food is ''Sorghum grain sirup''. The word ''sirup'' may also be spelled ''syrup''.

(d) For purposes of this section, the methods of analysis to be used to determine if the food meets the specifications of paragraph (b)(1) and (2) of this section are the following sections in

''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(1) Total solids content, sections 31.208–31.209.

(2) Reducing sugar content, section 31.220(a).

(3) Sulfated ash content, section 31.216.

(4) Sulfur dioxide content, sections 20.106–20.111.

[42 FR 14479, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

§ 168.121 Dried glucose sirup.

(a) Dried glucose sirup is glucose sirup from which the water has been partially removed and conforms to the specifications of § 168.120, except that:

(1) The total solids content is not less than 90.0 percent m/m when the reducing sugar content (dextrose equivalent), expressed as D-glucose, is not less than 88.0 percent m/m, calculated on a dry basis; or

(2) The total solids content is not less than 93.0 percent m/m when the reducing sugar content, (dextrose equivalent) expressed as D-glucose, is less than 88.0 percent m/m, calculated on a dry basis.

(b) The name of the food is ''Dried glucose sirup'' or ''Glucose sirup solids''. When the food is derived from a specific type of starch, the name may alternatively be ''Dried _____ sirup'' or ''_____ sirup solids'', the blank to be filled in with the name of the starch; for example, ''Dried corn sirup'', ''Corn sirup solids'', ''Dried wheat sirup'', ''Wheat sirup solids'', ''Dried tapioca sirup'', ''Tapioca sirup solids''. When the starch is derived from sorghum grain, the alternative name of the food is ''Dried sorghum grain sirup'' or ''Sorghum grain sirup solids''. The word ''sirup'' may also be spelled ''syrup''.

§ 168.122 Lactose.

(a) Lactose is the carbohydrate normally obtained from whey. It may be anhydrous or contain one molecule of water of crystallization or be a mixture of both forms.

(b) The food shall meet the following specifications:

(1) The lactose content is not less than 98.0 percent, mass over mass (m/m), calculated on a dry basis.

(2) The sulfated ash content is not more than 0.3 percent, m/m, calculated on a dry basis.

(3) The pH of a 10.0-percent m/m solution is not less than 4.5 nor more than 7.5.

(4) The loss on drying for 16 hours at 120 °C is not more than 6.0 percent, m/m.

(c) The name of the food is ''Lactose'' or, alternatively, ''Milk sugar''.

(d) The methods of analysis in paragraphs (d)(1), (d)(2), (d)(3), (d)(4), and (d)(5) of this section are to be used to determine whether the food meets the requirements of paragraphs (b)(1), (b)(2), (b)(3), and (b)(4) of this section. The methods are contained in ''Official Methods of Analysis of the Association of Official Analytical Chemists'', 14th Ed. (1984), including the 4th Supp. (1988), which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies of the material incorporated by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(1) Lactose content, sections 31.064 to 31.071, ''Purity of Lactose, Liquid Chromatographic Method,'' First Action, 14th Ed. (1984), pp. 583 and 584.

(2) Lactose content, sections 31.064 to 31.071, ''Purity of Lactose, Liquid Chromatographic Method,'' ''Changes in Official Methods of Analysis,'' 14th

Ed., 4th Supp. (1988), p. 212. This reference recognizes the change in status of the method from first action to final action.

(3) Sulfated ash content, section 31.014, ''Ash of Sugars and Sirups,'' Final Action, Sulfated Ash, 14th Ed. (1984), p. 575.

(4) pH, section 14.022, ''pH of Flour, Potentiometric Method,'' Final Action, except that a 10-percent m/m solution of lactose in water is used for the determination, 14th Ed. (1984), p. 252.

(5) Loss on drying at 120 °C, section 31.070, 14th Ed. (1984), p. 584.

[42 FR 14479, Mar. 15, 1977, as amended at 47 FR 11834, Mar. 19, 1982; 49 FR 10103, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 55 FR 8459, Mar. 8, 1990; 63 FR 14035, Mar. 24, 1998]

§ 168.130 Cane sirup.

(a) Cane sirup is the liquid food derived by concentration and heat treatment of the juice of sugarcane (*Saccharum officinarum* L.) or by solution in water of sugarcane concrete made from such juice. It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in cane sirup are:

(1) Salt.

(2) Preservatives.

(3) Defoaming agents.

(c) The name of the food is ''Cane sirup'' or ''Sugar cane sirup''. Alternatively, the word ''sirup'' may be spelled ''syrup''.

(d) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 168.140 Maple sirup.

(a) Maple sirup is the liquid food derived by concentration and heat treatment of the sap of the maple tree (*Acer*) or by solution in water of maple sugar (mapel concrete) made from such sap. It contains not less than 66 percent by weight of soluble solids derived solely from such sap. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in maple sirup are:

(1) Salt.

(2) Chemical preservatives.

(3) Defoaming agents.

(c) The name of the food is ''Maple sirup''. Alternatively, the word ''sirup'' may be spelled ''syrup''.

(d) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2896, Jan. 6, 1993]

§ 168.160 Sorghum sirup.

(a) Sorghum sirup is the liquid food derived by concentration and heat treatment of the juice of sorghum cane (sorgos) (*Sorghum vulgare*). It contains not less than 74 percent by weight of soluble solids derived solely from such juice. The concentration may be adjusted with or without added water. It may contain one or more of the optional ingredients provided for in paragraph (b) of this section. All ingredients from which the food is fabricated shall be safe and suitable.

(b) The optional ingredients that may be used in sorghum sirup are:

(1) Salt.

(2) Chemical preservatives.

(3) Defoaming agents.

(4) Enzymes.

(5) Anticrystallizing agents.

(6) Antisolidifying agents.

(c) The name of the food is ''Sorghum sirup'' or ''Sorghum''. Alternatively, the word ''sirup'' may be spelled ''syrup''.

(d) *Label declaration*. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 168.180 Table sirup.

(a) Table sirup is the liquid food consisting of one or more of the optional sweetening ingredients provided for in paragraph (b)(1) of this section. The food contains not less than 65 percent soluble sweetener solids by weight and is prepared with or without added water. It may contain one or more of the optional ingredients prescribed in paragraphs (b)(2) through (12) of this section. All ingredients from which the food is fabricated shall be safe and suitable. (Vitamins, minerals, and protein added for nutritional purposes and artificial sweeteners are not considered to be suitable ingredients for this food.)

(b) The optional ingredients that may be used in table sirup are:

(1) One or more of the nutritive carbohydrate sweeteners provided for in this paragraph (b)(1). When a sweetener provided for in paragraph (b)(1)(i) or (ii) of this section is used it shall constitute not less than 2 percent by weight of the finished food.

(i) The sirups identified by §§ 168.130, 168.140, and 168.160, except that the use of any such ingredient is so limited that the finished food does not meet the requirement prescribed for any sirup by § 168.130, § 168.140, or § 168.160.

(ii) Honey.

(iii) Other nutritive carbohydrate sweeteners.

(2) Butter, in a quantity not less than 2 percent by weight of the finished food.

(3) Edible fats and oils, except that, in products designated as ''buttered sirups'', butter as provided for in paragraph (b)(2) of this section is the only fat that may be used.

(4) Emulsifiers or stabilizers or both.

(5) Natural and artificial flavorings, either fruit or nonfruit, alone or in carriers.

(6) Color additives.

(7) Salt.

(8) Chemical preservatives.

(9) Viscosity adjusting agents.

(10) Acidifying, alkalizing, or buffering agents.

(11) Defoaming agents.

(12) Any other ingredient (e.g., shredded coconut, ground orange peel) that is not incompatible with other ingredients in the food.

(c) Except as provided for in this paragraph and in paragraphs (d) (2) and (3) of this section, the name of the food is ''Table sirup'', ''Sirup'', ''Pancake sirup'', ''Waffle sirup'', ''Pancake and waffle sirup'', or ''_____ sirup'', the blank being filled in with the word or words that designate the sweetening ingredient that characterizes the food, except ''maple'', ''cane'', or ''sorghum'' alone, such sirups being required to comply in all respects with §§ 168.130, 168.140, and 168.160, respectively, and in the case of more than one sweetening ingredient, in descending order of predominance by weight in the food. The type shall be of uniform style and size.

(1) When one of the sweeteners constitutes at least 80 percent of the total sweetener solids, the name of the food may be designated as the corresponding sirup, for example, ''Corn sirup'', provided that the name is immediately and conspicuously followed, without intervening written, printed, or graphic matter, by the statement ''with _____'' as part of the name, the blank being filled in with the name or names of each additional sweetening ingredient present, stated in a clear legible manner in letters of uniform style and size not less than one-half the height of, nor larger than, the letters used in the name of the principal sweetener.

(2) When butter is used, as provided for in paragraph (b)(2) of this section, the name of the food may be ''Buttered _____'', the blank being filled in with the name otherwise prescribed in this paragraph. The percentage by weight of butter present shall be declared as part of the name of the food as prescribed by part 102 of this chapter.

(3) Alternatively, the word ''sirup'' may be spelled ''syrup''.

(d)(1) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2) A statement (other than in the ingredient listing) or a vignette identifying a flavor may be included on the label only if such flavor contributes the primary recognizable flavor that characterizes the sirup. When maple, honey, or both maple and honey are

Subpart B—Requirements for Specific Standardized Food Dressings and Flavorings

§ 169.115 French dressing.

(a) *Description.* French dressing is the separable liquid food or the emulsified viscous fluid food prepared from vegetable oil(s) and one or both of the acidifying ingredients specified in paragraph (b) of this section. One or more of the ingredients specified in paragraph (c) of this section may also be used. The vegetable oil(s) used may contain an optional crystallization inhibitor as specified in paragraph (c)(11) of this section. All the ingredients from which the food is fabricated shall be safe and suitable. French dressing contains not less than 35 percent by weight of vegetable oil. French dressing may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen.

(b) *Acidifying ingredients.* (1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with an optional acidifying ingredient as specified in paragraph (c)(9) of this section. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice and/or lime juice in any appropriate form, which may be diluted with water.

(c) *Other optional ingredients.* The following optional ingredients may also be used:

(1) Salt.

(2) Nutritive carbohydrate sweeteners.

(3) Spices and/or natural flavorings.

(4) Monosodium glutamate.

(5) Tomato paste, tomato puree, catsup, sherry wine.

(6) Eggs and ingredients derived from eggs.

(7) Color additives that will impart the color traditionally expected.

(8) Stabilizers and thickeners to which calcium carbonate or sodium hexametaphosphate may be added. Dioctyl sodium sulfosuccinate may be added in accordance with §172.810 of this chapter.

(9) Citric and/or malic acid, in an amount not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid.

(10) Sequestrant(s), including but not limited to calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) and/or disodium EDTA (disodium ethylenediaminetetraacetate), may be used to preserve color and/or flavor.

(11) Crystallization inhibitors, including but not limited to oxystearin, lecithin, or polyglycerol esters of fatty acids.

(d) *Nomenclature.* The name of the food is ''French dressing''.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14481 Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 169.140 Mayonnaise.

(a) *Description.* Mayonnaise is the emulsified semisolid food prepared from vegetable oil(s), one or both of the acidifying ingredients specified in paragraph (b) of this section, and one or more of the egg yolk-containing ingredients specified in paragraph (c) of this section. One or more of the ingredients specified in paragraph (d) of this section may also be used. The vegetable oil(s) used may contain an optional crystallization inhibitor as specified in paragraph (d)(7) of this section. All the ingredients from which the food is fabricated shall be safe and suitable. Mayonnaise contains not less than 65 percent by weight of vegetable oil. Mayonnaise may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen.

(b) *Acidifying ingredients.* (1) Any vinegar or any vinegar diluted with water to an acidity, calculated as acetic acid, of not less than 2½ percent by weight, or any such vinegar or diluted vinegar mixed with an optional acidifying ingredient as specified in paragraph (d)(6) of this section. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice and/or lime juice in any appropriate form, which may be diluted with water to an acidity, calculated as citric acid, of not less than 2½ percent by weight.

(c) *Egg yolk-containing ingredients.* Liquid egg yolks, frozen egg yolks, dried egg yolks, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one or more of the foregoing ingredients listed in this paragraph with liquid egg white or frozen egg white.

(d) *Other optional ingredients.* The following optional ingredients may also be used:

(1) Salt.

(2) Nutritive carbohydrate sweeteners.

(3) Any spice (except saffron or turmeric) or natural flavoring, provided it does not impart to the mayonnaise a color simulating the color imparted by egg yolk.

(4) Monosodium glutamate.

(5) Sequestrant(s), including but not limited to calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) and/or disodium EDTA (disodium ethylenediaminetetraacetate), may be used to preserve color and/or flavor.

(6) Citric and/or malic acid in an amount not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar, calculated as acetic acid.

(7) Crystallization inhibitors, including but not limited to oxystearin, lecithin, or polyglycerol esters of fatty acids.

(e) *Nomenclature.* The name of the food is ''Mayonnaise''.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14481, Mar. 15, 1977, as amended at 57 FR 34246, Aug. 4, 1992; 58 FR 2886, Jan. 6, 1993]

§ 169.150 Salad dressing.

(a) *Description.* Salad dressing is the emulsified semisolid food prepared from vegetable oil(s), one or both of the acidifying ingredients specified in paragraph (b) of this section, one or more of the egg yolk-containing ingredients specified in paragraph (c) of this section, and a starchy paste prepared as specified in paragraph (e) of this section. One or more of the ingredients in paragraph (e) of this section may also be used. The vegetable oil(s) used may contain an optional crystallization inhibitor as specified in paragraph (e)(8) of this section. All the ingredients from which the food is fabricated shall be safe and suitable. Salad dressing contains not less than 30 percent by weight of vegetable oil and not less egg yolk-containing ingredient than is equivalent in egg yolk solids content to 4 percent by weight of liquid egg yolks. Salad dressing may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen.

(b) *Acidifying ingredients.* (1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with an optional acidifying ingredient as specified in paragraph (e)(6) of this section. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice and/or lime juice in any appropriate form, which may be diluted with water.

(c) *Egg yolk-containing ingredients.* Liquid egg yolks, frozen egg yolks, dried egg yolks, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one of more of the foregoing ingredients listed in this paragraph with liquid egg white or frozen egg white.

(d) *Starchy paste.* It may be prepared from a food starch, food starch-modified, tapioca flour, wheat flour, rye flour, or any two or more of these. Water may be added in the preparation of the paste.

(e) *Other optional ingredients.* The following optional ingredients may also be used:

(1) Salt.

(2) Nutritive carbohydrate sweeteners.

(3) Any spice (except saffron or turmeric) or natural flavoring, provided it does not impart to the salad dressing a color simulating the color imparted by egg yolk.

(4) Monosodium glutamate.

(5) Stabilizers and thickeners. Dioctyl sodium sulfosuccinate may be added in accordance with §172.810 of this chapter.

(6) Citric and/or malic acid may be used in an amount not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid.

(7) Sequestrant(s), including but not limited to calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) and/or disodium EDTA (disodium ethylenediaminetetraactetate), may be used to preserve color and/or flavor.

(8) Crystallization inhibitors, including but not limited to oxystearin, lecithin, or polyglycerol esters of fatty acids.

(f) *Nomenclature.* The name of the food is ''Salad dressing''.

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14481, Mar. 15, 1977, as amended at 42 FR 25325, May 17, 1977; 58 FR 2886, Jan. 6, 1993]

§ 169.175 Vanilla extract.

(a) Vanilla extract is the solution in aqueous ethyl alcohol of the sapid and odorous principles extractable from vanilla beans. In vanilla extract the content of ethyl alcohol is not less than 35 percent by volume and the content of vanilla constituent, as defined in §169.3(c), is not less than one unit per gallon. The vanilla constituent may be extracted directly from vanilla beans or it may be added in the form of concentrated vanilla extract or concentrated vanilla flavoring or vanilla flavoring concentrated to the semisolid form called vanilla oleo-resin. Vanilla extract may contain one or more of the following optional ingredients:

(1) Glycerin.

(2) Propylene glycol.

(3) Sugar (including invert sugar).

(4) Dextrose.

(5) Corn sirup (including dried corn sirup).

(b)(1) The specified name of the food is ''Vanilla extract'' or ''Extract of vanilla''.

(2) When the vanilla extract is made in whole or in part by dilution of vanilla oleoresin, concentrated vanilla extract, or concentrated vanilla flavoring, the label shall bear the statement ''Made from _____'' or ''Made in part from _____'', the blank being filled in with the name or names ''vanilla oleoresin'', ''concentrated vanilla extract'', or ''concentrated vanilla flavoring'', as appropriate. If the article contains two or more units of vanilla constituent, the name of the food shall include the designation ''__–fold'', the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (b)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 169.176 Concentrated vanilla extract.

(a) Concentrated vanilla extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by §169.175, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in §169.3(c). The content of ethyl alcohol is not less than 35 percent by volume.

(b) The specified name of the food is ''Concentrated vanilla extract __–fold'' or ''__–fold concentrated vanilla extract'', the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article. (For example, ''Concentrated vanilla extract 2–fold''.)

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 169.177 Vanilla flavoring.

(a) Vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label

statement of ingredients prescribed for vanilla extract by §169.175, except that its content of ethyl alcohol is less than 35 percent by volume.

(b) The specified name of the food is ''Vanilla flavoring''.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 169.178 Concentrated vanilla flavoring.

(a) Concentrated vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla flavoring by §169.177, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in §169.3(c).

(b) The specified name of the food is ''Concentrated vanilla flavoring __–fold'' or ''__–fold concentrated vanilla flavoring'', the blank being filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article. (For example, ''Concentrated vanilla flavoring 3–fold''.)

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

§ 169.179 Vanilla powder.

(a) Vanilla powder is a mixture of ground vanilla beans or vanilla oleoresin or both, with one or more of the following optional blending ingredients:

(1) Sugar.

(2) Dextrose.

(3) Lactose.

(4) Food starch (including food starch-modified as prescribed in §172.892 of this chapter).

(5) Dried corn sirup.

(6) Gum acacia.

Vanilla powder may contain one or any mixture of two or more of the anticaking ingredients specified in paragraph (b) of this section, but the total weight of any such ingredient or mixture is not more than 2 percent of the weight of the finished vanilla powder. Vanilla powder contains in each 8 pounds not less than one unit of vanilla constituent, as defined in §169.3(c).

(b) The anticaking ingredients referred to in paragraph (a) of this section are:

(1) Aluminum calcium silicate.

(2) Calcium silicate.

(3) Calcium stearate.

(4) Magnesium silicate.

(5) Tricalcium phosphate.

(c)(1) The specified name of the food is ''Vanilla powder __–fold'' or ''__–fold vanilla powder'', except that if sugar is the optional blending ingredient used, the word ''sugar'' may replace the word ''powder''. The blank in the name is filled in with the whole number (disregarding fractions) expressing the number of units of vanilla constituent per 8 pounds of the article. However, if the strength of the article is less than 2–fold, the term ''__–fold'' is omitted from the name.

(2) The label of vanilla powder shall bear the common names of any of the optional ingredients specified in paragraphs (a) and (b) of this section that are used, except that where the alternative name ''Vanilla sugar'' is used for designating the food it is not required that sugar be named as an optional ingredient.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (c)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

§ 169.180 Vanilla-vanillin extract.

(a) Vanilla-vanillin extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by §169.175, except that for each unit of vanilla constituent, as defined in §169.3(c), contained therein, the article also contains not more than 1 ounce of added vanillin.

(b) The specified name of the food is ''Vanilla-vanillin extract __–fold'' or ''__–fold vanilla-vanillin extract'', followed immediately by the statement ''contains vanillin, an artificial flavor (or flavoring)''. The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per gallon of the article. However, if the strength of the article is less than 2–fold, the term ''__–fold'' is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

§ 169.181 Vanilla-vanillin flavoring.

(a) Vanilla-vanillin flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla-vanillin extract by § 169.180, except that its content of ethyl alcohol is less than 35 percent by volume.

(b) The specified name of the food is ''Vanilla-vanillin flavoring __–fold'' or ''__–fold vanilla-vanillin flavoring'', followed immediately by the statement ''contains vanillin, an artificial flavor (or flavoring)''. The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per gallon of the article. However, if the strength of the article is less than 2–fold, the term ''__–fold'' is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

§ 169.182 Vanilla-vanillin powder.

(a) Vanilla-vanillin powder conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla powder by § 169.179, except that for each unit of vanilla constituent as defined in § 169.3(c) contained therein, the article also contains not more than 1 ounce of added vanillin.

(b) The specified name of the food is ''Vanilla-vanillin powder __–fold'' or ''__–fold vanilla-vanillin powder'', followed immediately by the statement ''contains vanillin, an artificial flavor (or flavoring)''. If sugar is the optional blending ingredient used, the word ''sugar'' may replace the word ''powder'' in the name. The blank in the name is filled in with the whole number (disregarding fractions) expressing the sum of the number of units of vanilla constituent plus the number of ounces of added vanillin per 8 pounds of the article. However, if the strength of the article is less than 2–fold the term ''__–fold'' is omitted from the name.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2887, Jan. 6, 1993]

II Toxic Substance Regulation

PART 1 Chemical Contaminants in Food

Chemical Contaminants in Food

Part of how the FDA oversees the safety of the U.S. food supply (domestic and imports) is by monitoring chemical contaminants in food and assessing the potential exposure and risk posed by these chemicals. The different types of chemical contaminants include **environmental contaminants** (such as industrial chemicals called dioxins), **process contaminants** (/food/chemical-contaminants-food/process-contaminants-food) that form while cooking or heating food (such as acrylamide), and **chemical contaminants used for economically motivated adulteration** (such as melamine). Some contaminants can have more than one source.

Environmental Contaminants

- Benzene (/food/chemical-contaminants/benzene)
- Dioxins and PCBs (/food/chemical-contaminants/dioxins-pcbs)
- Perchlorate (/food/chemical-contaminants/perchlorate)
- Per- and Polyfluoroalkyl Substances (PFAS) (/food/chemicals/and-polyfluoroalkyl-substances-pfas)
- Radionuclides (/food/chemical-contaminants-food/radionuclides-domestic-and-imported-foods)

Process Contaminants (/food/chemical-contaminants-food/process-contaminants-food)

- 3-Monochloropropane-1,2-diol (MCPD) Esters and Glycidyl Esters (GE) (/food/chemicals/3-monochloropropane-12-diol-mcpd-esters-and-glycidyl-esters)
- 4-Methylimidazole (4-MEI) (/food/food-additives-petitions/questions-answers-about-4-mei)
- Acrylamide (/food/chemical-contaminants/acrylamide)
- Ethyl Carbamate (/food/chemical-contaminants/ethyl-carbamate-urethane)

- Furan (/food/chemical-contaminants/furan)

Chemical Contaminants Used for Economically Motivated Adulteration

- Melamine (/food/chemical-contaminants/melamine)

For information on toxic elements such as arsenic or lead, please go to our Metals and Your Food (/food/chemical-contaminants-metals-pesticides-food/metals-and-your-food) page.

A. Environmental Contaminants

1. Benzene

- Skip -

(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

2. Dioxins and PCBs

COMPLIANCE POLICY GUIDE (CPG)

CPG Sec 565.200 Red Meat Adulterated with PCBs

NOVEMBER 1987

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/cpg-sec-565200-red-meat-adulterated-pcbs)
Office of Regulatory Affairs

BACKGROUND:

In the Federal Register of June 29, 1979, (44 FR 38330) FDA published a final regulation reducing the tolerance for polychlorinated biphenyls (PCB's) in poultry from 5 parts per million (ppm) to 3 ppm (fat basis). This tolerance for poultry has been informally applied to red meat for regulatory purposes by the U.S. Department of Agriculture, Food Safety and *Inspection* Service *(FSIS)*.

In response to a request from the *FSIS* to formally establish a tolerance for PCB's in red meat animals, the Food and Drug Administration (FDA) has determined that although the frequency with which PCB residues occur in red meat may not be sufficient to require a tolerance, an action level should be established.

FDA has no reason to expect that red meat animals (cattle, swine, goats, sheep and horses) consuming feed contaminated with PCB's at or below current tolerance levels will accumulate residues in their fat above 3 ppm. An action level of 3 ppm PCB's in the fat of red meat animals should not result in increases in current dietary exposures to PCB's, therefore FDA considers a 3 ppm level for red meat sufficient to protect the public health.

POLICY:

For purposes of advising State agencies and for enforcement by *FSIS*, the FDA has established an action level of 3 ppm PCB residues in red meat on a fat basis.

Material between asterisks is new or revised

Reissued: 10/1/80
Revised: 11/10/87
Revised: 08/24/18

Food Use May Result in Lead Poisoning,'' and ''Not for Food Use—Food Consumed from this Vessel May be Harmful,'' and

(ii) A conspicuous and legible permanent statement of the message selected from paragraph (b)(1)(i) of this section molded or fired onto the exterior surface of the base or, when the ceramicware is not fired after decoration, permanently painted onto the exterior surface of the base. This permanent statement shall be in letters at least 3.2 millimeters (0.125 inch) in height, except that if insufficient space exists for the permanent statement in letters of such height, the statement shall be in the largest letters that will allow it to fit on the base of the piece, provided that the letters are at least 1.6 millimeters (0.062 inch) in height; or

(2) A hole is bored through the potential food-contact surface.

(c) In addition to steps required under paragraphs (b)(1) and (b)(2) of this section, the following optional information may be provided on the ware:

(1) A further explanatory statement concerning the decorative nature of the piece, such as ''Decorative'' or ''For Decorative Purposes Only,'' may be used; however, such additional statement shall be placed after the required statement.

(2) A symbol may be used to advise that a piece of ornamental or decorative ceramicware is not to be used with food, as illustrated below.

The circle of the above symbol should be at least 2.54 centimeters (1 inch) in diameter. The symbol may be used on the temporary label or applied to the base of the piece in the same manner as the permanent statement.

[59 FR 1641, Jan. 12, 1994]

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

§ 109.30 Tolerances for polychlorinated biphenyls (PCB's).

(a) Polychlorinated biphenyls (PCB's) are toxic, industrial chemicals. Because of their widespread, uncontrolled industrial applications, PCB's have become a persistent and ubiquitous contaminant in the environment. As a result, certain foods and animal feeds, principally those of animal and marine origin, contain PCB's as unavoidable, environmental contaminants. PCB's are transmitted to the food portion (meat, milk, and eggs) of food-producing animals ingesting PCB-contaminated animal feed. In addition, a significant percentage of paper food-packaging materials contain PCB's which may migrate to the packaged food. The source of PCB's in paper food-packaging materials is primarily of certain types of carbonless copy paper (containing 3 to 5 percent PCB's) in waste paper stocks used for manufacturing recycled paper. Therefore, temporary tolerances for residues of PCB's as unavoidable environmental or industrial contaminants are established for a sufficient period of time following the effective date of this paragraph to permit the elimination of such contaminants at the earliest practicable time. For the purposes of this paragraph, the term ''polychlorinated biphenyls (PCB's)'' is applicable to mixtures of chlorinated biphenyl compounds, irrespective of which mixture of PCB's is present as the residue. The temporary tolerances for residues of PCB's are as follows:

(1) 1.5 parts per million in milk (fat basis).

(2) 1.5 parts per million in manufactured dairy products (fat basis).

(3) 3 parts per million in poultry (fat basis).

(4) 0.3 parts per million in eggs.

(5) 0.2 parts per million in finished animal feed for food-producing animals (except the following finished animal feeds: feed concentrates, feed supplements, and feed premixes).

(6) 2 parts per million in animal feed components of animal origin, including

fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food producing animals.

(7) 2 parts per million in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones.

(8) 0.2 parts per million in infant and junior foods.

(9) 10 parts per million in paper food-packaging material intended for or used with human food, finished animal feed and any components intended for animal feeds. The tolerance shall not apply to paper food-packaging material separated from the food therein by a functional barrier which is impermeable to migration of PCB's.

(b) A compilation entitled ''Analytical Methodology for Polychlorinated Biphenyls, June 1979'' for determining compliance with the tolerances established in this section is available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(c) A barrier is functional for purposes of paragraph (a)(9) of this section if the barrier limits migration of PCB's from the packaging material to food to a level not exceeding the migration which occurs under the same test conditions from packaging material containing 10 parts per million PCB without the use of a barrier. A class of barrier material is functional for purposes of paragraph (a)(9) of this section if a representative barrier of the class limits migration of PCB's from the packaging material to food to a level not exceeding the migration which occurs under the same test conditions from packaging material containing 10 parts per million PCB without the use of a barrier. Migration levels shall be determined for purpose of this paragraph solely by use of testing conditions described in ''Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983'', which is incorporated by reference. Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* A class of barrier material shall be deemed functional only if the definition of the class and the designation of one or more representative barriers has been approved by the Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration. In the event that the Director, Center for Food Safety and Applied Nutrition, does not approve a proposal made to the Center regarding the definition of a class of barrier material or the designation of representative barriers, the Director shall advise the person making the proposal of the reasons for the Center's disapproval within 90 days of receipt of the proposal. All proposals for definition of classes and determinations of the Food and Drug Administration regarding such proposals shall be on file with the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(d) Any person who asserts that a barrier or class of barriers is functional shall submit the results of tests conducted to determine the functionality of the barrier or class of barriers to Center for Food Safety and Applied Nutrition (HFS–308), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. All barriers or classes of barriers shall be tested with the four solid food receptors specified in ''Test Procedures for Determination of PCB Permeability of Food Packaging, Inner-Wraps, September 1976, revised May 1983'', which is incorporated by reference. The availability of this reference is given in paragraph (c) of this section. The test results as to each barrier shall be accompanied by (1) a description of the barrier's composition adequate to enable identification; and (2) a specific definition of the barrier by relevant technical characteristics. The Center for Food Safety and Applied Nutrition shall review submitted test results promptly. Within 60 days of the receipt of test results, the Director,

3. Perchlorate

- Skip -

(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

4. Per- and Poly uoroalkyl Substances (PFAS)

- Skip -

(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

5. Radionuclides

Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods

[Docket No. 2003D-0558]

Prepared July 2004
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Plant and Dairy Foods and Beverages

Related CPG: CPG Sec. 555.880 Guidance Levels for Radionuclides in Domestic and Imported Foods (/media/72014/download) November 19, 2020

Table of Contents

I. Introduction ~ III. FDA's Guidance Levels for Radionuclide Activity Concentrations in Food Established in 1998

- skip -

IV. FDA s 1998 Guidance Levels for Radionuclide Activity Concentration in Food Adopted in the CPG

The guidance levels for radionuclide activity concentration in food in the CPG are referred to in the 1998 document as "Derived Intervention Levels" or DILs. DILs are used by scientists internationally to describe the radionuclide activity concentrations at which introduction of protective measures should be considered. The term DILs as used in the CPG replaces the term LOCs used in CPG 7119.14 and allows for consistency in scientific terminology between the CPG and the internationally accepted scientific term. Efforts by international organizations to develop DILs have been extensive. Derivations have been based on consensus values for the intervention levels of dose, called PAGs by FDA, and have been used to establish guidance levels for radionuclides in foods within individual countries and in international trade. In general, food with concentrations below the DILs is permitted to move in international trade without restriction. Food with concentrations at or above the DILs is not normally permitted into international trade.(4)

By definition, a DIL corresponds to the radionuclide activity concentration in food present throughout the relevant period of time that, in the absence of any intervention, could lead to an individual receiving a radiation dose equal to the PAG. The equation given below is the formula that the agency used for calculating recommended DILs.

DILs (Bq/kg) = [PAG (mSv)] / [f x FI (kg) x DC (mSv/Bq)]

Where:

DC = Dose Coefficient; the radiation dose received per unit of radionuclide activity ingested (mSv/Bq)

f = Fraction of the food intake assumed to be contaminated

FI = Food Intake; the quantity of food consumed in an appropriate period of time (kg)

Guidance levels or LOCs contained in CPG 7119.14 addressed only I-131, Cs-134 and Cs-137 because these radionuclides were known at that time to be the principal radionuclides that contribute to radiation dose by ingestion following a nuclear reactor accident. Information gained following the Chernobyl accident determined that Ru-103 and Ru-106 could also contribute to radiation dose and, therefore, these radionuclides were included in the 1998 FDA document. In addition, other radionuclides were included in the 1998 FDA document to address other radiological emergencies where there is a possibility of accidental radioactive contamination of food. This approach provides the flexibility necessary to respond to special circumstances that may be unique to a particular accident. The types of accidents and the principle radionuclides for which DILs were developed are:

- Nuclear reactors (I-131; Cs-134 + Cs-137; Ru-103 + Ru-106)
- Nuclear fuel processing plants (St-90; Cs-137; Pu-238 + Pu-239 + Am-241)
- Nuclear waste storage facilities (Sr-90; Cs-137; Pu-238 + Pu-239 + Am-241)

- Nuclear weapons (i.e., dispersal of nuclear weapon material without nuclear detonation) (Pu-239), and
- Radioisotope thermoelectric generators and radioisotope heater units used in space vehicles (Pu-238).

The DILs are for radionuclides expected to deliver the major portion of the radiation dose from ingestion during the first year following an accidental episode of radiological food contamination. If there is concern that food will continue to be significantly contaminated beyond the first year, the long-term circumstances need to be evaluated to determine whether the recommended DILs would be appropriate or if other guidance is more applicable.

Detailed information on derivation of DILs is presented in the appendix. The DILs are based upon calculations for nine radionuclides expected to be the predominant contributors to radiation dose through ingestion (Sr-90, I-131, Cs-134, Cs-137, Ru-103, Ru-106, Pu-238, Pu-239, and Am-241). For each radionuclide, DILs were calculated for six age groups using PAGs, dose coefficients relevant to each radionuclide and age group, and dietary intakes relevant to each age group. The age groups include 3 months, 1 year, 5 years, 10 years, 15 years and adult (>17 years). The dose coefficients were adopted by FDA from the International Commission on Radiological Protection Publication 56 (ICRP 1989). The dietary intakes were derived from a 1984 EPA report which presented average daily food intake by age and gender (EPA 1984a, EPA 1984b).

The nine radionuclides listed above comprise five radionuclide groups, each having common characteristics. The five groups are: Strontium-90; Iodine-131; Cesium-134 + Cesium-137; Ruthenium-103 + Ruthenium-106; and Plutonium-238 + Plutonium-239 + Americium-241. An accident could involve more than one of the five groups. A single DIL for each radionuclide group was chosen based on the most limiting PAG and age group for the radionuclide group (i.e., the most limiting PAG and age group result in the lowest DIL). These five DILs are the ones incorporated into the new CPG.

The calculations underlying the DILs are based on the entire diet for each age group, not for individual foods or food groups. Unlike the previous LOCs that assumed 100 percent radionuclide contamination of the diet, DILs assume ten percent radionuclide contamination of the diet which is then multiplied by a factor of three. Use of ten percent of the dietary intake as the portion contaminated is consistent with recommendations made by a group of experts to the Commission of the European Communities (CEC 1986b) and by the Nuclear Energy Agency (NEA) of the Organization for Economic Cooperation and Development (NEA 1989). FDA applied an additional factor of three to account for limited sub-populations that might be more dependent on specific food supplies. Therefore, a value of thirty percent is the fraction of food intake that FDA presumed to be contaminated. For infants, (i.e., the 3-months and 1-year age groups) DILs were calculated assuming 100 percent radionuclide contamination of the infant diet.

With one exception (LOCs for I-131 in non-infant food), guidance levels or DILs for radionuclides established in the 1998 FDA document that FDA has adopted in the CPG are higher than guidance levels or LOCs for those same radionuclides contained in the CPG 7119.14. In deriving guidance levels or DILs contained in the 1998 FDA document, FDA employed updated international consensus values for intervention levels of dose (called PAGs by FDA) as well as updated dose coefficients and food intake estimates. In addition, information gained by FDA and others following the Chernobyl accident determined that the amount of food affected by an accident would be significantly lower than the level originally estimated. For this reason, DILs contained in the 1998 FDA document assume thirty percent of the dietary intake would be contaminated after a nuclear accident, compared to the 100 percent assumption of contamination employed in deriving LOCs. FDA's decision to reduce the assumption for dietary intake contamination from 100 percent to thirty percent is the main reason that the guidance levels established in the 1998 FDA document and adopted in the CPG are higher than the guidance levels contained in CPG 7119.14.

The 1998 FDA document established guidance levels only for food accidentally contaminated with radionuclides in domestic interstate commerce. In the CPG, FDA has adopted those same guidance levels for food either accidentally or intentionally contaminated with radionuclides, regardless of whether that food is in domestic interstate commerce or offered for import. FDA has taken this action because radionuclides that could be implicated in an event involving the accidental contamination of food could also be implicated in an event involving the intentional contamination of food. The radionuclides addressed in the 1998 FDA document are widely used and available. Furthermore, an incident resulting in release of radionuclides from one of the nuclear facilities addressed in the 1998 FDA document would likely result in the release of the same radionuclides regardless of whether the cause of the release was accidental or intentional. FDA has therefore concluded that the assumptions used in establishing the DILs in the 1998 FDA document and adopted in the CPG are appropriate for both accidental as well as intentional radionuclide contamination of food.

The DILs established in the 1998 FDA document and contained in the CPG for food offered for import and food in domestic interstate commerce are given in Table 2.

Table 1
Levels of concern (LOCS) for radionuclide activity concentration in imported food from CPG sec. 560.750 Radionuclides in Imported Foods -- Levels of Concern (CPG 7119.14) which have been superceded by derived intervention levels (DILs).[a]

	LOCs (Bq/kg)	
Radionuclide Group	**A. Infant Food**	**B. Other Food**
Iodine-131	55	300
Cesium-134 + Cesium-137	370	370

[a]For consistency with current recommendations, LOCs in this table are expressed in Bq/kg. In CPG 7119.14, LOCs were expressed in pCi/kg.

Table 2

Derived intervention levels (DILS) in the new CPG for food in domestic commerce and food offered for import[a,b]. These values, which are included in CPG sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14), supercede levels of concern (LOCS) in CPG sec. 560.750 Radionuclides in Imported Foods -- Levels of Concern (CPG 7119.14).

Radionuclide Group	DIL (Bq/kg)
Strontium-90	160
Iodine-131	170
Cesium-134 + Cesium-137	1200
Plutonium-238 + Plutonium-239 + Americium-241	2
Ruthenium-103 + Ruthenium-106[c]	$(C_3 / 6800) + (C_6 / 450) <>$

[a]The DIL for each radionuclide group is applied independently. Each DIL applies to the sum of the concentrations of the radionuclides in the group at the time of measurement.

[b]Applicable to foods as prepared for consumption. For dried or concentrated products such as powdered milk or concentrated juices, adjust by a factor appropriate to reconstitution, and assume the reconstitution water is not contaminated. For spices, which are consumed in very small quantities, use a dilution factor of 10.

[c]Due to the large differences in DILs for Ruthenium-103 and Ruthenium-106, the individual concentrations of Ruthenium-103 and Ruthenium-106 are divided by their respective DILs and then summed. The sum must be less than one. C_3 and C_6 are the concentrations, at the time of measurement, for Ruthenium-103 and Ruthenium-106, respectively.

V. Appendix -- Derivation of Recommended Derived Intervention Levels

- skip -

VI. Reference

- skip -

B. Process Contaminants

1. 3-Monochloropropane-1,2-diol (MCPD) Esters and Glycidyl Esters (GE)

-Skip -

(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

2. 4-Methylimidazole (4-MEI

- Skip -

(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

3. Acrylamide

- Skip -

(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

4. Ethyl Carbamate

- Skip -

(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

5. Furan

- Skip -

(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

C. Chemical Contaminants Used for Economically Motivated Adulteration

1. Melamine

- Skip -

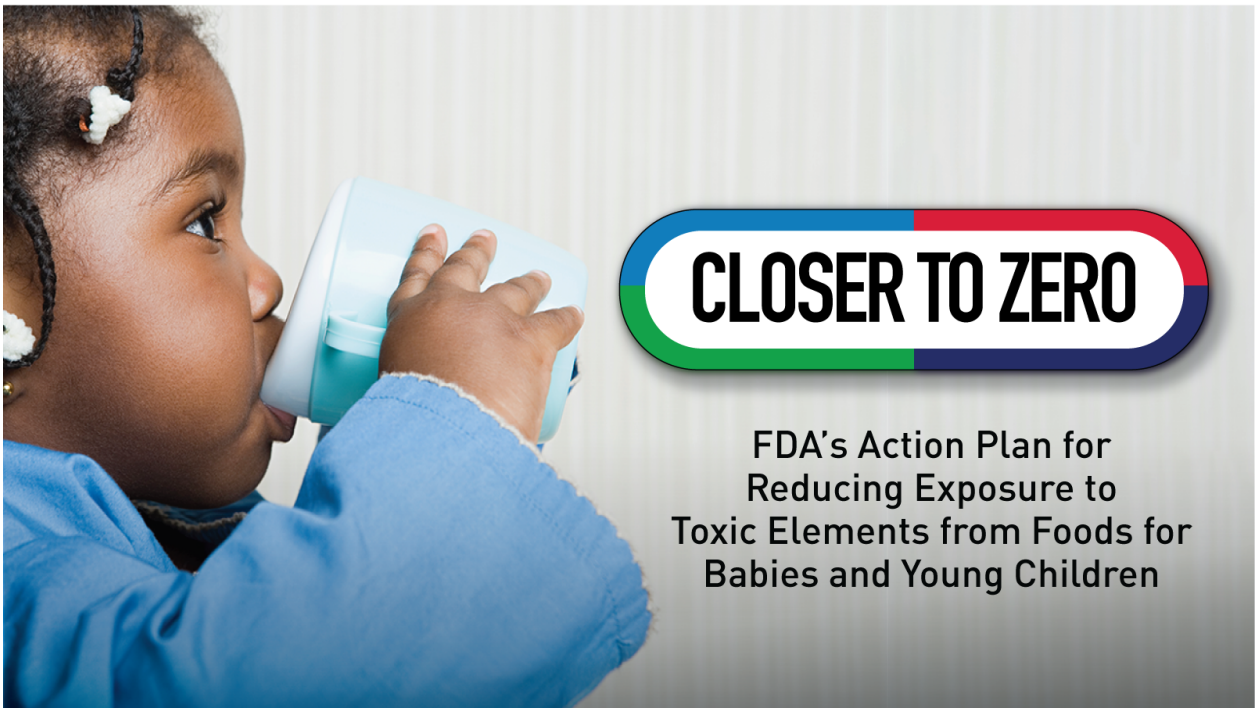
(There is no content to set standards related to processed food. It mainly defines terms and presents the response direction of the US government)

PART 2

Metals and Your Food

Metals and Your Food

Spotlight



(/food/metals-and-your-food/closer-zero-action-plan-baby-foods)

The U.S. Food and Drug Administration's (FDA) plan, *Closer to Zero* (/food/metals-and-your-food/closer-zero-action-plan-baby-foods), identifies actions the agency will take to reduce exposure to toxic elements from foods eaten by babies and young children —to as low as possible. Learn more about FDA's Action Plan (/food/metals-and-your-food/closer-zero-action-plan-baby-foods).

Metals, like other naturally occurring elements, enter our food supply through our air, water and soil. The levels found in food depend on many factors, including:

- the levels of these elements in the air, water and soil used to grow the crops, which vary depending on factors such as natural geographical differences and past or current contamination,
- the type of the food crop and how much "uptake" there is of specific elements from the environment, and
- industrial, manufacturing, and agricultural processes.

The Key to a Well-Balanced Diet is Eating a Variety of Healthy Foods (/media/146439/download)

In addition, some metals that are beneficial to health, such as iron, are intentionally added to certain foods, including breakfast cereals and infant formulas, to enhance their dietary benefits.

The properties of specific metals, the amount of intake, and a person's age and developmental stage are all key factors that help determine how a metal affects individual health. Understanding the risk that harmful metals pose in our food supply is complicated by the fact that exposure to metals comes from many different foods. Combining all of the foods we eat, even low levels of harmful metals from individual food sources, can sometimes add up to a level of concern.

To help protect the safety of the food supply, the FDA monitors, tests, and sets standards for metals in foods, animal feed (/animal-veterinary/biological-chemical-and-physical-contaminants-animal-food/chemical-hazards#Metals) and in cosmetics (/cosmetics/cosmetic-products-ingredients/potential-contaminants-cosmetics). When the level of metals is determined to be unsafe, the FDA uses its authority to take action on a case-by-case basis.

For information on health risks, FDA regulations and guidance to industry, FDA monitoring and testing, and consumer resources please visit the arsenic (/food/metals-and-your-food/arsenic-food-and-dietary-supplements), lead (/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) and mercury (/food/metals-and-your-food/mercury-and-methylmercury) webpages, and *Closer to Zero (/food/metals-and-your-food/closer-zero-action-plan-baby-foods)*, our action plan to address toxic elements in foods eaten by babies and young children.

A. Arsenic

Inorganic Arsenic in Rice Cereals for Infants: Action Level Guidance for Industry

Additional copies are available from:
Office of Food Safety, HFS-300
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-1700
http://www.fda.gov/FoodGuidances

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www/regulations.gov. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-1099 listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

August 2020

Table of Contents

Inorganic Arsenic in Rice Cereals for Infants: Action Level[1] Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance provides information to manufacturers on the action level[2] for inorganic arsenic in rice cereals for infants (hereafter referred to as infant rice cereals) that is intended to help protect public health by reducing infants' dietary exposure to inorganic arsenic and is achievable by industry with the use of current good manufacturing practices. This guidance applies to all types of infant rice cereals.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Division of Plant Products and Beverages, Office of Food Safety, in the Center for Food Safety and Applied Nutrition at the Food and Drug Administration.

[2] Under 21 CFR 109.4, when certain conditions are met, FDA may establish an action level for an added poisonous or deleterious substance to define a level of contamination at which a food may be regarded as adulterated, within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In this context, "added" does not mean added by the manufacturer, but rather resulting from the hand of man; for example, from previous pesticide use (*see United States vs. Anderson Seafood, Inc.* 622 F.2d 157 (5th Cir. 1980)). These action levels serve as guidance to FDA field staff and industry. We will establish an action level, as opposed to a tolerance or regulatory limit (which must be established by rulemaking (21 CFR 109.4)), when technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future (21 CFR 109.6(d)). Consistent with 21 CFR 109.6, we will consider action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case.

II. Background

Arsenic is an element that occurs in the environment from both natural and manmade sources, including erosion of arsenic-containing rocks, volcanic eruptions, contamination from mining and smelting ores, and previous or current use of arsenic-containing pesticides (Ref. 1).[3] Arsenic is found in both inorganic and organic forms (together referred to as total arsenic), and inorganic arsenic is generally considered more toxic than organic arsenic (Ref. 5).[4] Consumption of inorganic arsenic has been associated with cancer, skin lesions, cardiovascular disease and diabetes in humans (Refs. 5-6). A report by the National Research Council (NRC) (Ref. 6) also listed adverse pregnancy outcomes and neurodevelopmental toxicity as adverse health effects of concern for exposure to inorganic arsenic. The Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) (Ref. 5), which includes participation by FDA scientists, concluded that food can be a major contributor to inorganic arsenic exposure, and the European Food Safety Authority (EFSA) (Ref. 7) concluded that dietary exposure to inorganic arsenic should be reduced.

These findings support our initiatives to assess and reduce exposure to inorganic arsenic in food. For example, in July 2013, we announced the availability of a draft quantitative assessment of lifetime risk of certain cancers associated with exposure to inorganic arsenic in apple juice (Ref. 8) and a draft guidance for industry with an action level for inorganic arsenic in apple juice (78 FR 42086). We also conducted surveys in 2013, 2016, and 2018 of arsenic in other foods (Refs. 9-11), focusing primarily on rice and rice products, and released consumer advice on consumption of rice and rice products, available online at https://www.fda.gov/consumers/consumer-updates/consumers-seven-things-pregnant-women-and-parents-need-know-about-arsenic-rice-and-rice-cereal. On April 6, 2016, FDA published in the *Federal Register* (81 FR 19976) a notice of availability for a draft guidance for industry entitled "Inorganic Arsenic in Rice Cereals for Infants: Action Level," a supporting document entitled "Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants," and a risk assessment report entitled "Arsenic in Rice and Rice Products Risk Assessment: Report." This guidance finalizes the approach presented in the April 2016 draft guidance.

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[3] Generally, it is not possible for FDA to identify the specific source of any arsenic that may be found in a particular type of food, including infant rice cereal. Therefore, for purposes of this guidance, FDA is not distinguishing the presence of arsenic that may be due to prior pesticide use, such that the residues are pesticide chemical residues subject to a tolerance or tolerance exemption by the Environmental Protection Agency (EPA) under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), or other environmental contamination. Our understanding from EPA information is that currently arsenical pesticide use in the United States is limited to the organic arsenicals monosodium methanearsonate (MSMA) for use on sod farms, golf courses, highway rights-of-way, and to control weeds in cotton fields (Ref. 2) and 10,10'-Oxybisphenoxarsine (OBPA) to prevent microorganism growth in plastics and as a material preservative in adhesives and coatings (Ref. 3), and to chromated arsenicals for use by certified pesticide applicators using specialized high-pressure equipment in wood treatment facilities (Ref. 4).

[4] Organic in this sentence refers to arsenic molecules that contain carbon. Inorganic arsenic molecules do not contain carbon. Use of the term "organic" here does not refer to organically grown food.

III. Discussion

Exposure to Inorganic Arsenic in Rice and Rice Products

Because it is in the environment, inorganic arsenic is found in some foods. Rice and rice-based food products have higher levels of inorganic arsenic than do other foods tested by FDA, and given their widespread consumption, are a major food source of inorganic arsenic (Ref. 12). Rice also tends to have higher arsenic concentrations than other cereal crops (such as wheat and barley), because of its ability to take up arsenic from soil and water and because it is typically grown under flooded conditions, which increases the potential for arsenic uptake (Ref. 12). Evidence from FDA's Total Diet Study (Ref. 13) – an ongoing survey and analysis of the average American diet – revealed that total arsenic levels, although varying, tend to be higher in rice and rice products than in other foods. Our follow-up sampling also revealed significant levels of inorganic arsenic in rice and rice products, including rice cereals for infants (Refs. 9-11). Rice is commonly served to infants, primarily in the form of infant rice cereal (Ref. 12), which is the most commonly consumed infant instant cereal in the U.S.[5] Rice and rice products are a greater potential source of dietary inorganic arsenic exposure for infants and children than for adults, because the dietary patterns of infants and children are often less varied than those of adults, and because infants and children consume more food relative to their body weight than do adults (Ref. 15). Therefore, elevated levels of inorganic arsenic in foods that infants eat, such as rice cereals, may represent a significant source of exposure for infants (Ref. 12). In addition, infants and children may be particularly susceptible to adverse neurodevelopmental effects of exposure to inorganic arsenic (Refs. 6, 12). We think that it is possible to reduce dietary exposure to inorganic arsenic from infant rice cereals through industry's use of current good manufacturing practices, in particular selection of sources of rice or rice-derived ingredients with lower inorganic arsenic levels and testing these incoming rice and rice-derived ingredients. Using rice with lower levels of inorganic arsenic will result in lower levels of inorganic arsenic in the infant rice cereal because the main ingredient (rice) will have lower levels of inorganic arsenic. Therefore, we are issuing this guidance on an action level for inorganic arsenic in rice cereal for infants.

Risk Assessment and Achievability

To facilitate development of an action level for inorganic arsenic in rice cereal for infants, we conducted a risk assessment on arsenic in rice and rice products (Ref. 12). The risk assessment includes a qualitative component that addresses the risk of certain non-cancer adverse health effects to infants, to young children, and during pregnancy from dietary exposure to inorganic arsenic in rice and rice products. The risk assessment also includes a quantitative component that provides estimates of exposure to inorganic arsenic from rice and rice products and estimates of lifetime cancer risk from this exposure. Finally, the risk assessment estimates potential reductions in inorganic arsenic exposure and cancer risk from possible mitigation actions, including limiting the maximum level of inorganic arsenic in infant rice cereals.

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[5] Based on data from the U.S. National Health and Nutrition Examination Survey (NHANES), What We Eat In America (WWEIA), for the years 2003-2010 (Ref. 14), the mean per capita daily intake of dry instant infant cereals (not containing fruit) for the first year of life is as follows: rice, 4.8 g/d; oatmeal 2.8 g/d; barley, 0.1 g/d; and mixed grains, 0.8 g/d.

The qualitative component of the risk assessment concluded that exposure to inorganic arsenic during pregnancy, infancy, and early childhood may increase the risk of neurodevelopmental toxicity and/or adverse pregnancy outcomes. The quantitative component of the risk assessment found that exposure to inorganic arsenic in rice and rice products may increase lung and bladder cancer cases in later life, whether exposure occurs only during infancy (through infant rice cereals) or throughout life. The quantitative assessment also showed that establishing an action level will reduce inorganic arsenic exposure and risk (Ref. 16). More information can be found in the Arsenic in Rice and Rice Products Risk Assessment Report (Ref. 12) and the Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants (Ref. 16).

To assess achievability, or manufacturers' ability to achieve hypothetical maximum limits on inorganic arsenic in infant rice cereals, we used results of surveys from three data sets of rice cereals to determine the percentage of samples of infant rice cereals that would fall below each of the hypothetical maximum limits.[6] More information on achievability and arsenic data can be found in the Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants (Ref. 16). FDA used the information in the supporting document and risk assessment document to identify an action level for inorganic arsenic in infant rice cereals.

IV. Action Level

Because of the potential for human health risks associated with exposure to inorganic arsenic, human exposure to inorganic arsenic in rice cereal for infants should not exceed levels achievable with the use of current good manufacturing practices, in particular selective sourcing of rice or rice-derived ingredients with lower levels of inorganic arsenic and testing these incoming rice and rice-derived ingredients. The action level for inorganic arsenic in infant rice cereals that FDA considers achievable with the use of such practices is 100 microgram per kilogram (µg/kg), or 100 parts per billion (ppb) (see Ref. 16). FDA has made the determination that this level is achievable based on sampling and testing results. Based upon our risk assessment and achievability assessment, we consider that this reduction in inorganic arsenic in rice cereal will lead to a predicted quantifiable reduction in the lifetime risk of certain cancers associated with exposure to inorganic arsenic, as well as an unquantifiable reduction in the risk of certain non-cancer adverse health outcomes reviewed in the risk assessment, including neurodevelopmental effects in infants. This guidance applies to all types of infant rice cereals (e.g., white-rice, brown-rice, organically grown, and conventionally grown). Though not binding, the action level for inorganic arsenic in infant rice cereals is intended to encourage manufacturers to reduce levels of inorganic arsenic in their products, thus reducing the possible risk for infants fed rice cereal.

V. Conclusion

For the reasons discussed above, we have concluded that a level of 100 µg/kg or 100 ppb inorganic arsenic in infant rice cereals is achievable under current good manufacturing practices, based on evaluation of recent FDA data on inorganic arsenic levels in infant rice cereals. We intend to analyze samples of infant rice cereals for total arsenic, and to speciate samples

[6] The method used by FDA for analyzing inorganic arsenic in rice is posted on the FDA website at https://www.fda.gov/media/95197/download.

containing more than 100 µg/kg or 100 ppb total arsenic to determine inorganic arsenic levels. We intend to consider the action level of 100 µg/kg or 100 ppb inorganic arsenic as an important source of information for determining whether infant rice cereal is adulterated within the meaning of section 402(a)(1) of the FD&C Act (21 U.S.C. 342(a)(1)). FDA considers on a case-by-case basis whether a food that contains a contaminant is adulterated. When considering whether to bring an enforcement action in a particular case, we will consider whether the inorganic arsenic causes a particular infant rice cereal to be adulterated under section 402(a)(1) of the FD&C Act.

VI. References

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Contains Nonbinding Recommendations
Draft-Not for Implementation

Guidance for Industry
Arsenic in Apple Juice: Action Level

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

July 2013

Table of Contents

Contains Nonbinding Recommendations

Draft-Not for Implementation

Guidance for Industry[1]

Arsenic in Apple Juice: Action Level

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This draft guidance document provides information to manufacturers on the action level for inorganic arsenic in apple juice that FDA considers protective of human health and achievable with the use of good manufacturing practices.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Arsenic is an element that occurs in the environment from both natural and anthropogenic sources including erosion of arsenic-containing rocks, volcanic eruptions, contamination from mining and smelting ores, and previous or current use of arsenic-containing pesticides (Ref. 1).[2] Arsenic is found in both inorganic and organic forms (together referred to as total arsenic), and inorganic arsenic is generally considered more toxic than organic arsenic (Ref. 2). Consumption of inorganic arsenic has been associated with cancer, skin lesions, developmental effects, cardiovascular disease, neurotoxicity, and diabetes in humans (Ref. 2). In recent assessments, the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert

[1] This guidance has been prepared by the Division of Plant and Dairy Food Safety, Office of Food Safety, in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] Generally, it is not possible for FDA to identify the source of arsenic in food, including apple juice, when found. Therefore, for purposes of this guidance FDA is not distinguishing the presence of arsenic that may be due to prior pesticide use, such that the residues are pesticide chemical residues subject to a tolerance or tolerance exemption by EPA under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a)), or other environmental contamination.

Committee on Food Additives (JECFA) (Ref. 2), which includes participation by U.S. FDA scientists, concluded that food can be a major contributor to inorganic arsenic exposure, and the European Food Safety Authority (EFSA) (Ref. 3) concluded that dietary exposure to inorganic arsenic should be reduced. These findings suggest a need to reduce exposure to inorganic arsenic from food.

Occurrence in Apple Juice

Apple juice is one source of exposure to arsenic from food. Apple juice is a greater potential source of dietary inorganic arsenic exposure for children than for adults, because children's dietary patterns are often less varied than those of adults, and they consume more apple juice relative to their body weight than do adults (Ref. 4). FDA has conducted routine surveillance for arsenic in apple juice for many years through its Total Diet Study (Ref. 5) and Toxic Elements in Food and Foodware, and Radionuclides in Food Program (Ref. 6), and through monitoring of imports and targeted domestic assignments. Total arsenic levels in apple juice samples have routinely been below 10 parts per billion (ppb); for example, more than 95 percent of total arsenic levels in a set of 94 apple juice samples collected at retail as part of a fiscal year 2011 assignment were below 10 ppb (Ref. 7). The remaining four samples in that assignment with total arsenic levels above 10 ppb had inorganic arsenic levels below 10 ppb. However, FDA has identified apple juice samples with inorganic arsenic levels above 10 ppb in previous years (Ref. 8). FDA considers that it is possible to further reduce public exposure to inorganic arsenic from apple juice in general, and specifically from apple juice that currently may contain inorganic arsenic at levels above 10 ppb. Therefore, FDA is issuing draft guidance on an action level for inorganic arsenic in apple juice.

Possible sources of inorganic arsenic in apple juice include processing aids, prior use of arsenic-based pesticides on land currently used for apple orchards, current use of arsenic-based pesticides in other countries, naturally high levels of arsenic in soil or water, and atmospheric deposition from industrial activities. It may be possible in some cases for manufacturers who have found inorganic arsenic in sources of apples or apple juice concentrate to reduce or limit inorganic arsenic in apple juice by choosing sources of apples or apple juice concentrate with lower inorganic arsenic levels or no detectable inorganic arsenic.

Another potential source of inorganic arsenic in apple juice is water used by manufacturers to dilute concentrate to prepare ready-to-drink juice. It may be possible in some cases for manufacturers who have found arsenic in water used to dilute concentrate to reduce or limit levels of inorganic arsenic in ready-to-drink apple juice by examining and controlling arsenic levels in water used for dilution of juice concentrate.

Risk Assessment, Level of Concern, and Achievability

In 2008, FDA established a level of concern (Ref. 9) of 23 ppb for inorganic arsenic in single-strength (ready to drink) apple juice as part of a hazard assessment. This level of concern focused on non-cancer endpoints and average consumption of apple juice with higher levels of arsenic for a limited (not lifetime) period of time.

In 2011, FDA initiated a new quantitative risk assessment for inorganic arsenic in apple juice for cancer endpoints and based on chronic and lifetime exposure. The new risk assessment models

health effects based on average inorganic arsenic levels in apple juice when several hypothetical maximum limits for inorganic arsenic are in place. More information can be found in the risk assessment document, "A Quantitative Assessment of Inorganic Arsenic in Apple Juice" (Ref. 10).

To assess achievability, or manufacturers' ability to achieve the proposed limits on inorganic arsenic, FDA used survey results to determine the percentage of apple juice samples in the market that would fall at or below each of the hypothetical maximum limits. More information on achievability and arsenic data can be found in the "Supporting Document for Action Level for Arsenic in Apple Juice" (Ref. 11). FDA has used the information in the supporting document and risk assessment document to identify a new action level for inorganic arsenic in apple juice.

III. Action Level

Because of the potential for human health risks associated with exposure to inorganic arsenic, human exposure to inorganic arsenic should not exceed levels achievable with the use of good manufacturing practices. The action level for inorganic arsenic in single-strength (ready to drink) apple juice that FDA considers achievable with the use of good manufacturing practices is 10 micrograms/kilogram (µg/kg) or 10 ppb. FDA considers the action level for inorganic arsenic in apple juice to be protective of public health. The action level can reduce human exposure to inorganic arsenic that may be found in apple juice.

FDA intends to take the following sampling and enforcement approach to arsenic in apple juice. FDA intends to initially analyze apple juice samples for total arsenic. FDA intends to speciate samples containing more than 10 µg/kg or 10 ppb total arsenic to determine inorganic arsenic levels. Consistent with 21 CFR 109.6, FDA intends to consider the action level of 10 µg/kg or 10 ppb inorganic arsenic, in addition to other factors, when considering whether to bring enforcement action in a particular case.

IV. References

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B. Lead

Lead in Food, Foodwares, and Dietary Supplements

Bottled Water

The FDA, through its regulatory authority under the Federal Food, Drug, and Cosmetic Act (/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act), limits levels of lead (as well as other contaminants) in bottled water (https://www.ecfr.gov/cgi-bin/text-idx?SID=0c417253f5a12d9cc7d0d83a94655ab7&mc=true&node=pt21.2.129&rgn=div5) by establishing allowable levels in the quality standard for bottled water (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=165.110). For lead, this level is set at 5 ppb. This level is below the 15 ppb allowed by the U.S. Environmental Protection Agency for lead in public drinking water, as the tap water standard takes into account lead that can leach from pipes.

Action Levels for Lead in Juice: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2019-D-5609 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

April 2022

Table of Contents

Action Levels for Lead in Juice: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. Introduction

FDA is committed to reducing lead in food to the extent feasible. FDA's *Closer to Zero* action plan is a science-based, iterative approach to decreasing toxic elements (such as lead) in foods over time, including by setting action levels. This guidance provides information to industry on the action levels for lead in juice. The action levels for lead in juice in this document would, if finalized, replace the current level of 50 parts per billion (ppb) described in the Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance (Juice HACCP Guidance), First Edition (Ref. 1). FDA considers the action levels described in this guidance to be achievable by industry (or you) when measures are taken to minimize the presence of lead.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. Background

Juice[2] can become contaminated with lead through sources such as produce used to make juice (Ref. 1) and old lead-containing equipment, such as old lead-soldered machinery (Ref. 2). Lead is toxic to humans and can affect people of any age or health status. Lead is especially harmful to vulnerable populations, including infants, young children, pregnant women and their fetuses, and others with chronic health conditions. Even low lead exposure can harm children's health

[1] This guidance has been prepared by the Office of Food Safety, Division of Plant Products and Beverages in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] As stated in 21 CFR 120.1(a), "juice" means "the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree."

and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects (Ref. 3). Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time (Ref. 4). FDA has taken actions to address lead in juice, a food commonly consumed by young children.

In 1993, we established an emergency action level of 80 ppb and above for lead in juice packed in lead soldered cans as a measure to limit the presence of lead in juice while we undertook rulemaking to revoke the prior sanctions for lead soldered cans and ultimately prohibit their use for packing food (58 FR 17233).[3]

In 1999, the Joint World Health Organization (WHO)/Food and Agriculture Organization (FAO) Expert Committee on Food Additives (JECFA) released a toxicological assessment for lead which maintained the provisional tolerable weekly intake (PTWI) for lead of 25 micrograms per kilogram body weight (μg/kg bw) but noted that foods with high levels of lead remain in commerce. In 2001, the Codex Alimentarius Commission (Codex), an international food standards organization, established a maximum level (ML) of 50 ppb for lead in ready-to-drink fruit juices, including fruit nectars, that are in international trade. FDA concurred with the Codex ML and adopted 50 ppb as the recommended level not to be exceeded for lead in juice in the Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance (Juice HACCP Guidance), First Edition (FDA, 2004).

In 2011, JECFA reassessed the safety of lead and withdrew the PTWI for lead. JECFA further concluded that "it was not possible to establish a new PTWI [for lead] that would be considered to be health protective" (Ref. 5). JECFA concluded that in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and, if appropriate, to identify methods for reducing dietary exposure that are commensurate with the level of risk reduction (Ref. 5).

In 2012, Codex initiated work to reevaluate the previously established MLs for lead in multiple commodities in the Codex General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (Codex Stan 193-1995) (Ref. 6), prioritizing review of MLs for foods (such as juice) that are highly consumed by children.

This work, led by the U.S., as a member of Codex, resulted in the reduction of the lead ML for fruit juices in general from 50 ppb to 30 ppb and for grape juice from 50 ppb to 40 ppb. The ML for fruit juices made from berries and other small fruits was retained at 50 ppb. This analysis was based on the achievability of lower MLs following review of international data on lead in fruit juices.

Because no safe level of lead exposure has been identified for children's health, in 2018, FDA developed interim reference levels (IRLs) for dietary lead to replace FDA provisional tolerable total daily intakes (PTTDIs) (Ref. 4) which had been developed in the early 1990's. FDA used

[3] In the *Federal Register* of June 27, 1995 (60 FR 33106), we issued a final rule to prohibit the use of lead solders in the construction of food cans. The rule is codified at 21 CFR 189.240.

the Centers for Disease Control and Prevention (CDC) reference value of 5 µg/deciliter (dL) blood lead[4] level, the level at which public health interventions should be initiated for children, and dietary conversion factors calculated by the Environmental Protection Agency to derive IRLs of 3 µg/day for children and 12.5 µg/day for women of child-bearing age (WOCBA), respectively. The IRL for WOCBA is protective against possible fetal lead exposure in women who are not yet aware that they are pregnant (Ref. 4).

In 2021, FDA initiated the *Closer to Zero* action plan that identifies actions we will take to reduce exposure to toxic elements, including lead, from foods eaten by babies and young children (Ref. 7). The plan outlines an iterative approach for achieving continual improvements over time, reducing children's exposure to lead and other toxic elements from food through activities such as setting action levels. FDA will identify IRLs for certain toxic elements as appropriate and may use the IRLs to help inform the development of action levels. The plan commits to consulting with stakeholders, including on the achievability of reducing toxic element levels, and notes the importance of minimizing the potential for unintended consequences on the availability of nutritious foods for children.

In response to the 2011 JECFA conclusion, the Codex adoption of lower MLs for fruit juices based on achievability, as well as FDA's development of IRLs and the *Closer to Zero* plan, FDA reevaluated the 50 ppb lead level recommended in the current Juice HACCP Guidance (Ref. 1). Given that no safe level of lead exposure from food has been identified by JECFA (Ref. 5), FDA's reevaluation has focused on review of U.S. data to determine if lower levels of lead in juice were achievable and if lower levels would reduce lead exposures in vulnerable populations.

III. Action levels

Based on our review of lead levels in juice samples that were collected by FDA after the 50 ppb level for juice was established in 2004, in consideration of the IRL for lead of 3 µg/day for children, and in accordance with 21 CFR 109.6, we are establishing an action level for lead of 10 ppb for apple juice on a single-strength (ready-to-drink) basis and an action level for lead of 20 ppb for other single-strength juice types, including juice blends that contain apple juice (Ref. 8). The lower action level for apple juice is based on the fact that apple juice is the most commonly consumed juice type by young children in the U.S. For apple juice, an action level of 10 ppb is estimated to reduce dietary exposure to lead for children by 46% at the 90th percentile consumption level (see Ref. 8). For other fruit and vegetable juice types, an action level of 20 ppb is estimated to reduce dietary exposure to lead for children by 19% at the 90th percentile consumption level. Though not binding, these action levels are intended to encourage manufacturers to maintain lead levels in juices below the action levels, thus reducing risks associated with dietary lead exposures. The establishment of these action levels for lead in juice is consistent with FDA's longstanding policy of reducing consumers' lead exposure. Therefore, it is important that HACCP controls are considered to minimize the presence of this contaminant. The action is focused on juice, a product consumed frequently by infants and children, who are more sensitive than adults to the neurodevelopmental effects of lead exposure. The action levels

[4] The reference value of 5 µg/deciliter (dL) blood lead was updated in 2021 by the CDC. Additional information is available at: https://www.cdc.gov/media/releases/2021/p1028-blood-lead.html.

differ from international levels established by Codex, as the action levels reflect data from samples in the U.S. (from both import and domestic products in the marketplace), while Codex levels are based on international data.

Consistent with 21 CFR 109.4, these action levels define the levels of lead contamination that may cause the juice products described in this guidance to be regarded as adulterated. We intend to consider these action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case. When this draft guidance is finalized, we intend to update the Juice HACCP Guidance (Ref. 1) to reflect the new action levels.

FDA recommends that the juice industry continue to work to lower the lead concentrations in juices to the extent possible under current good manufacturing practices. As part of our *Closer to Zero* plan, we intend to further engage with stakeholders on proposed action levels, including the achievability of such levels, and the feasibility of further reducing the presence of lead in food. After action levels are finalized, we plan to monitor the levels of lead in food and children's exposure to lead from food to assess whether to adjust the action levels for lead in juice.

IV. References

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Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children

Guidance for Industry: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy (/food/guidance-documents-regulatory-information-topic/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children)

November 2006

[Docket No. 2005D-0481]

Table of Contents

I. Introduction

The purpose of this document is to further present the background and rationale for FDA's recommended maximum lead level in candy likely to be consumed frequently by small children. The 0.1 parts per million (ppm) recommended maximum lead level in candy described herein is included as a part of the 2006 updated FDA guidance on lead in candy entitled "Lead in Candy Likely To Be Frequently Consumed by Small Children: Recommended Maximum Level and Enforcement Policy (/food/guidance-documents-regulatory-information-topic/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children)." FDA considers the recommended maximum lead level to be achievable and to be protective of public heath.

II. Overview of FDA Activities Addressing Lead in Food

Lead is a naturally occurring element whose toxicity in humans has been documented throughout history.

Lead is widely present in our environment due to its natural occurrence and human activities that have introduced it into the general environment such as the use of leaded gasoline. Because lead may be present in environments where food crops are grown and animals used for food are raised, various foods may contain unavoidable but small amounts of lead that do not pose a significant risk to human health.

However, foods may become contaminated with lead if they are grown, stored or processed under conditions that could introduce larger amounts of lead into the food, such as when a root crop is grown in soil that has been contaminated from the past use of leaded pesticides on that acreage. Under such conditions, the resulting contamination of the food may pose a health risk to consumers.

FDA first recognized the need to control potential lead exposure from food in the 1930s. The earliest actions of the agency focused on limiting the potential for lead to become a component of food as a consequence of intentional uses of lead containing substances in agriculture and food processing, e.g., lead-based pesticides and lead containing solder in food cans. (Ref. 1)

During the 1970s and 1980s studies were published documenting adverse effects of lead in children at lower blood lead levels than had been previously established. In 1979, FDA stated that it intended to expand its programs to monitor and reduce lead levels in the food supply with the objective of reducing consumer's lead exposure to the lowest level that can be practicably obtained. (Ref. 2)

The goal of limiting lead contamination of food was facilitated by the development and implementation of the use of welded (non-soldered) food cans during the 1980s. This development and the concurrent prohibition of the use of lead containing gasoline in the U.S.

are largely responsible for dramatic decreases in measured lead levels in the U.S. diet beginning in the 1980s. (Ref. 3)

FDA's past and current activities intended to reduce or limit lead levels in food have addressed pesticides, lead glazed ceramic ware and other house wares, bottled water, wine, food cans, food additives, candy and candy wrappers.

III. FDA Actions Addressing Lead in Candy and Candy Wrappers

Candy products were not known to be a significant food source of lead until 1994, when California authorities found that an imported candy product from Mexico was contaminated with lead that had migrated into the candy from lead-based ink used in the candy's packaging. The package was poorly designed such that its inner coating did not maintain its structural integrity, allowing lead-based ink in the outer package layer to migrate into the candy.

Subsequently, FDA began testing other candy products with lead-based printing inks on their packaging to determine whether lead from the ink was migrating into the candy. In its testing, FDA discovered that, apart from any consideration of the wrapper as source of the lead, some imported candy products from Mexico contained higher lead levels than were typically found in domestic candy products. As discussed below, FDA determined that the higher lead levels were largely associated with certain ingredients used in these imported candy products.

Prompted by these findings, in 1995 FDA issued a letter entitled "Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers (/food/guidance-documents-regulatory-information-topic/guidance-industry-letter-manufacturers-importers-and-distributors-imported-candy-and-candy-wrappers)," (the 1995 letter), addressing its concerns about lead in candy derived from both candy wrappers and candy ingredients.

Concerning lead in candy derived from sources other than the wrapper, e.g., lead from candy ingredients, FDA advised manufacturers, importers, and distributors of imported candy, that where frequent consumption of candy products by small children could be anticipated, the agency would consider taking regulatory action against candy with lead levels that exceeded 0.5 parts per million (ppm). The 0.5 ppm guideline was, at that time, equivalent to the Food Chemicals Codex (FCC) specification for lead in sucrose (sugar), the main ingredient in many candy products.[1]

Many candy products contain sugar or chocolate as principal ingredients. Sugar (sucrose) is made by a process, i.e., re-crystallization, which when carried out under good manufacturing practices, typically results in low parts per billion (ppb) (1 ppb is equivalent to 0.001 ppm) or undetectable lead levels in the final product. Consequently, FDA typically finds low parts per

billion or undetectable levels of lead in sugar-based candies it analyzes in its monitoring activities. While the manufacture of chocolate does not involve a re-crystallization process, most finished milk chocolate products contain lead levels well below 0.1 ppm.

Many Mexican-style[2] candy products can contain significant amounts of chili powder (hereafter, chili). At the time we issued the 1995 letter, we were aware that candy products with ingredients, such as chili, may contain more lead than sugar-based candies because chili is a minimally refined ingredient which would not be expected to contain lead levels as low as those in highly refined ingredients like sugar.

Since the issuance of the 1995 letter, however, we have found several candy and related products, i.e., "powdered snack mix" products (described below) containing chili to be contaminated with levels of lead that suggest that good manufacturing practices are not being employed in the manufacture of the chili ingredient, resulting in significant contamination of the chili ingredient and finished candy products with lead.

These findings of elevated levels of lead in candy and powdered snack mix products and our belief that such lead contamination is avoidable led FDA to issue a letter to the industry[†] on March 25, 2004 (the 2004 letter) in which FDA announced that it intended to lower the 0.5 ppm guideline for considering enforcement action against candy products containing lead and likely to be consumed frequently by small children.

Concurrent with this document, FDA has issued a guidance document entitled "Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy (/food/guidance-documents-regulatory-information-topic/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children)." This guidance document announces a recommended maximum level for lead in candy likely to be consumed frequently by small children of 0.1 ppm. The guidance states FDAs commitment to take enforcement action against candy containing lead at levels that may pose a health risk. The guidance also rescinds the .5 ppm guideline for considering enforcement action because that level is no longer regarded as consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can practically be obtained.

IV. Lead Levels Found in Candy

a. Sugar-Based Candy

As noted above, FDA typically finds undetectable or low parts per billion levels of lead in most sugar-based candies it analyzes. For example, during the period late-1991 through 2002, FDA collected and analyzed 40 samples of suckers (lollipops of various flavors) as components of market baskets in its Total Diet Study (TDS) program.[3] Of the 40 sucker samples analyzed, FDA did not detect lead in 33 samples, and detected lead at levels too low to reliably quantify (referred to as a "trace" levels) in 7 samples. Based on all 40 results, the mean (average) estimated lead level was 4 ppb, with a standard deviation of 9 ppb and a maximum estimated trace value of 38 ppb. For granulated white sugar samples collected in

the TDS during the same period, FDA did not detect lead in 39 of 40 samples it analyzed, and found a trace level of 18 ppb in the remaining sample. These results are what we would expect to find in sugar and sugar-based foods, consistent with the current FCC specification for lead in sucrose (sugar) of 0.1 ppm (100 ppb) because food ingredients typically are manufactured to contain average levels of contaminants that are well below the applicable limit to ensure that lots of the ingredient containing lead at the high end of the production range will still be below the applicable limit. Accordingly, FDA believes that sugar-based candy products can be made with lead levels below 0.1 ppm.

b. Chocolate Candy

FDA's TDS data on milk chocolate candy during the period mid-1991 through 2002 indicate that the mean lead level in 40 samples of milk chocolate candy bars was 0.025 ppm, the standard deviation was 0.018 ppm, and the maximum lead level found was 0.110 ppm. Data provided to FDA by the chocolate industry in 2005 (Ref. 4) indicate that the mean lead level in 137 milk chocolate samples (consisting of 7 products) was 0.028 ppm, the standard deviation was 0.022 ppm, and the maximum lead level found was 0.222 ppm. The industry data showed one additional sample with a lead level slightly greater than 0.1 ppm; all other lead levels in products tested were below 0.1 ppm.

The chocolate industry data indicate that the mean lead level in 226 dark chocolate samples (consisting of 9 products) was 0.048 ppm, the standard deviation was 0.029 ppm, and the maximum lead level found was 0.275 ppm. Several dark chocolate samples had lead levels exceeding 0.1 ppm, and more dark chocolate than milk chocolate samples had lead levels approaching 0.1 ppm. Dark chocolate samples tended to have higher lead levels than milk chocolate samples because chocolate liquor is the principal source of lead in chocolate products, and dark chocolate products contain higher amounts of chocolate liquor than milk chocolate products.

We believe that if milk chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed 0.1 ppm lead. With respect to dark chocolate, we expect lead levels to be higher than lead levels in milk chocolate due to the higher chocolate liquor content of dark chocolate. However, we believe that the consumption of dark chocolate products by children is limited. Results of the United States Department of Agriculture's (USDA's) 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (CFSII) indicate that less than 1% of the children under age 6 surveyed consumed dark chocolate. We believe that, if dark chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed 0.1 ppm.

c. Mexican-Style Candy[4]

i. With Chili as an Ingredient

As noted above, we have found elevated levels of lead in Mexican-style candy products that contain chili. For example, from October 2000 to February 2004, we analyzed 132 candy products from Mexico, including powdered snack mix products for lead as part

of our imported foods monitoring activity (Ref. 5). Fifty-two of these products had no detectable lead, while 51 had detectable levels of lead that did not exceed 0.150 ppm. Eleven products had lead levels in the 0.151-0.250 ppm range while eighteen had lead levels greater than 0.250 ppm. Among the latter group, 10 of the 18 products contained chili, and based upon visual observation, we believe that some contained significant amounts of chili.[5]

When monitoring for lead levels in its TDS, FDA typically finds that fresh peppers contain lead at non-detectable levels or trace levels. During the mid-1991 through 2002 period, FDA analyzed 40 samples of raw green peppers in its TDS and did not detect lead in 37 samples, while it detected trace levels of lead in 3 samples with a maximum estimated level of 14 ppb. Although FDA currently has only limited data on chili peppers, because chili peppers are similar in physical characteristics to green peppers, we believe that freshly grown raw chili peppers are not likely to be inherently contaminated with lead. Industry has, however, reported to FDA that chili can become contaminated with lead when soil deposits (which contain some level of lead) that accumulate on peppers from their growing and handling in open fields, are not removed by a washing step prior to grinding the dried peppers into chili powder. (Ref. 6). The lead introduced by the deposited soil is further concentrated by the drying of the peppers.[6]

Information reported to FDA by the industry indicates a broad range of lead levels in finished chili available in Mexico, and that higher levels of lead are present in chili from unwashed peppers (Ref. 6). Chili made from washed peppers averaged 0.241 ppm lead (range 0.023 to 1.14 ppm) while chili made from unwashed chili peppers averaged 0.938 ppm lead (range 0.049 to 2.21 ppm). These data suggest that Mexican-style candy manufacturers could significantly reduce lead levels in their candy products by ensuring that their chili ingredients are sourced from suppliers that effectively wash the peppers before they are ground. Consequently, even for high-chili-content candy and powdered snack mix products, we believe that candy with appropriately sourced ingredients will not exceed 0.1 ppm lead.[7]

ii. **Salt-Based Powdered Snack Products**

Included in the 7 Mexican-style candy products tested by FDA that contained over 0.5 ppm lead were 3 powdered snack mix products that did not contain chili, but contained salt as their primary ingredient. Industry has reported to FDA that Mexican salt-based snack products can contain more than 50% salt (Ref. 6), and FDA has encountered powdered snack mix products consisting of only salt, citric acid and flavoring (the latter two ingredients are refined ingredients that are not likely to contain significant amounts of lead). The finding of elevated levels of lead in such products suggests that salt is a source of lead contamination in some imported powdered snack mix products. Since salt available for use as a food ingredient in Mexico is reported to contain lead ranges of 0.01-0.08 ppm for marine salt and 0.1-1.5 ppm for mined salt (Ref. 6) we believe that salt at the high end of the range for mined salt was used in formulating

some powdered snack mix products resulting in the food containing avoidable lead contamination. We believe that if manufacturers source salt to minimize lead levels, finished, high-salt- content powdered snack mix products will not exceed 0.1 ppm lead.

iii. **Tamarind Pulp**

Tamarind pulp is a popular ingredient in many Mexican-style candy products. Industry information submitted to FDA states that tamarind pulp may be present at levels not exceeding 5% in sugar-based Mexican candies. (Ref. 6) Although FDA has encountered some tamarind candy products packed in poorly made lead glazed bowls from which very high levels of lead leached into the candy,[8] the industry information for 22 samples of tamarind pulp from Mexico showed an average lead concentration of 0.014 ppm, with a standard deviation of 0.005 ppm, and a range of 0.006 to 0.028 ppm. These data suggest that tamarind as an ingredient can be produced under good manufacturing practices such that it is not likely to be a significant source of elevated lead levels in Mexican-style candies.

d. Other Candy Ingredients and Other Types of Candy

FDA reviewed data on lead levels in other common candy ingredients and other types of candy. For example, peanuts are a common candy ingredient. During the period mid-1991 through 2002, FDA collected and analyzed 40 samples of dry roasted peanuts as components of market baskets in its TDS. FDA did not detect lead in 39 of the 40 samples. FDA detected a trace amount of lead, estimated at 17 ppb, in the remaining sample.

Other types of nuts are used as candy ingredients. For mixed nuts collected in the TDS during the period mid-1991 through 2002, FDA did not detect lead in 33 of 40 samples it analyzed. FDA detected trace levels of lead in 6 of the 40 samples with a mean lead level of 4 ppb, and detected 90 ppb lead in the remaining sample.

Raisins are used as candy ingredients. During the period mid-1991 through 2002, FDA collected and analyzed 40 samples of raisins as components of market baskets in its TDS. FDA did not detect lead in 20 of the 40 raisin samples. The other 20 samples contained trace levels, with a mean lead level of 9 ppb, and a maximum estimated value of 31 ppb.

FDA also considered data for caramel candy, a candy typically made from sugar, butter, cream, and sometimes other ingredients such as syrup and flour. During the period mid-1991 through 2002, FDA collected and analyzed 40 samples of caramel candy as components of market baskets in its TDS. FDA did not detect lead in 36 of the 40 caramel candy samples. FDA detected trace levels of lead in the other 4 samples, with a mean lead level of 2 ppb, and a maximum value of 30 ppb.

Having considered data on common candy ingredients and other types of candy (besides sugar-based, chocolate and Mexican-style candy) FDA is not aware of any reason, e.g., ingredient considerations, why other types of candy cannot achieve lead levels of 0.1 ppm or

less as we similarly found for sugar-based, chocolate and Mexican-style candies. Accordingly FDA believes that other types of candy besides sugar-based, chocolate and Mexican-style candies can also achieve lead levels of 0.1 ppm or less.

V. Health Protection Considerations

- Skip -

VI. References

- Skip -

C. Mercury and Methylmercury

Mercury Levels in Commercial Fish and Shellfish (1990-2012)

Mercury and Methylmercury Main Page (/food/metals/mercury-and-methylmercury)

See also Mercury Concentrations in Fish: FDA Monitoring Program (/food/metals/mercury-concentrations-fish-fda-monitoring-program-1990-2010)

The table is sorted by MERCURY CONCENTRATION MEAN (PPM) from fish with lowest levels of mercury to highest levels of mercury. You may also sort the table by SPECIES in alphabetical order.

SPECIES	MERCURY CONCENTRATION MEAN (PPM)	MERCURY CONCENTRATION MEDIAN (PPM)	MERCURY CONCENTRATION STDEV (PPM)	MERCURY CONCENTRATION MIN (PPM)	MERCURY CONCENTRATION MAX (PPM)	NO. OF SAMPLES	SOURCE OF DATA
SCALLOP	0.003	ND	0.007	ND	0.033	39	FDA 1991-2009
CLAM	0.009	0.002	0.011	ND	0.028	15	FDA 1991-2010
SHRIMP	0.009	0.001	0.013	ND	0.05	40	FDA 1991-2009
OYSTER	0.012	ND	0.035	ND	0.25	61	FDA 1991-2009
SARDINE	0.013	0.010	0.015	ND	0.083	90	FDA 2002-2010
TILAPIA	0.013	0.004	0.023	ND	0.084	32	FDA 1991-2008
SALMON (CANNED)	0.014	0.010	0.021	ND	0.086	19	FDA 1993-2009
ANCHOVIES	0.016	0.011	0.015	ND	0.049	15	FDA 2007-2009
SALMON (FRESH/FROZEN)	0.022	0.015	0.034	ND	0.19	94	FDA 1991-2009
CATFISH	0.024	0.005	0.056	ND	0.314	59	FDA 1991-2010
SQUID	0.024	0.017	0.023	ND	0.07	36	FDA 2005-2009

SPECIES	MERCURY CONCENTRATION MEAN (PPM)	MERCURY CONCENTRATION MEDIAN (PPM)	MERCURY CONCENTRATION STDEV (PPM)	MERCURY CONCENTRATION MIN (PPM)	MERCURY CONCENTRATION MAX (PPM)	NO. OF SAMPLES	SOURCE OF DATA
POLLOCK	0.031	0.003	0.089	ND	0.78	95	FDA 1991-2008
CRAWFISH	0.033	0.035	0.012	ND	0.051	46	FDA 1991-2007
SHAD	0.038	0.033	0.045	ND	0.186	15	FDA 2007-2011
MACKEREL ATLANTIC (N.Atlantic)	0.05	N/A	N/A	0.02	0.16	80	NMFS REPORT 1978
MULLET	0.050	0.014	0.078	ND	0.27	20	FDA 1991-2008
WHITING	0.051	0.052	0.030	ND	0.096	13	FDA 1991-2008
HADDOCK (Atlantic)	0.055	0.049	0.033	ND	0.197	50	FDA 1991-2009
FLATFISH [2]	0.056	0.05	0.045	ND	0.218	71	FDA 1991-2009
BUTTERFISH	0.058	N/A	N/A	ND	0.36	89	NMFS REPORT 1978
CRAB [1]	0.065	0.05	0.096	ND	0.61	93	FDA 1991-2009
CROAKER ATLANTIC (Atlantic)	0.069	0.06	0.049	ND	0.193	90	FDA 2002-2011
TROUT (FRESHWATER)	0.071	0.025	0.141	ND	0.678	35	FDA 1991-2008
HERRING	0.078	0.042	0.128	ND	0.56	27	FDA 2005-2012
HAKE	0.079	0.067	0.064	ND	0.378	49	FDA 1994-2009
JACKSMELT	0.081	0.05	0.103	0.011	0.5	23	FDA 1997-2007

SPECIES	MERCURY CONCENTRATION MEAN (PPM)	MERCURY CONCENTRATION MEDIAN (PPM)	MERCURY CONCENTRATION STDEV (PPM)	MERCURY CONCENTRATION MIN (PPM)	MERCURY CONCENTRATION MAX (PPM)	NO. OF SAMPLES	SOURCE OF DATA
MACKEREL CHUB (Pacific)	0.088	N/A	N/A	0.03	0.19	30	NMFS REPORT 1978
WHITEFISH	0.089	0.067	0.084	ND	0.317	37	FDA 1991-2008
SHEEPSHEAD	0.090	0.08	0.050	ND	0.17	8	FDA 1992-2007
LOBSTER (Spiny)	0.093	0.062	0.097	ND	0.27	13	FDA 1991-2005
PICKEREL	0.095	0.091	0.100	ND	0.31	16	FDA 1991-2007
LOBSTER (NORTHERN / AMERICAN)	0.107	0.086	0.076	ND	0.23	9	FDA 2005-2007
CARP	0.110	0.134	0.237	ND	0.271	14	FDA 1992-2007
COD	0.111	0.066	0.152	ND	0.989	115	FDA 1991-2010
PERCH OCEAN	0.121	0.102	0.125	ND	0.578	31	FDA 1991-2010
TUNA (CANNED, LIGHT)	0.126	0.077	0.134	ND	0.889	545	FDA 1991-2010
BUFFALOFISH	0.137	0.12	0.094	0.032	0.43	17	FDA 1992-2008
SKATE	0.137	N/A	N/A	0.04	0.36	56	NMFS REPORT 1978
TILEFISH (Atlantic)	0.144	0.099	0.122	0.042	0.533	32	FDA 1994-2004
TUNA (FRESH/FROZEN, SKIPJACK)	0.144	0.15	0.119	0.022	0.26	3	FDA 1993-2007
PERCH (Freshwater)	0.150	0.146	0.112	ND	0.325	19	FDA 1991-2007

SPECIES	MERCURY CONCENTRATION MEAN (PPM)	MERCURY CONCENTRATION MEDIAN (PPM)	MERCURY CONCENTRATION STDEV (PPM)	MERCURY CONCENTRATION MIN (PPM)	MERCURY CONCENTRATION MAX (PPM)	NO. OF SAMPLES	SOURCE OF DATA
MONKFISH	0.161	0.139	0.095	ND	0.289	11	FDA 1994-2007
LOBSTER (Species Unknown)	0.166	0.143	0.099	ND	0.451	71	FDA 1991-2008
SNAPPER	0.166	0.113	0.244	ND	1.366	67	FDA 1991-2007
BASS (SALTWATER, BLACK, STRIPED, ROCKFISH) [3]	0.167	0.094	0.194	ND	0.96	101	FDA 1991-2010
MAHI MAHI	0.178	0.18	0.103	ND	0.45	29	FDA 1991-2005
MACKEREL SPANISH (S. Atlantic)	0.182	N/A	N/A	0.05	0.73	43	NMFS REPORT 1978
SCORPIONFISH	0.233	0.181	0.139	0.098	0.456	6	FDA 2006-2007
WEAKFISH (SEA TROUT)	0.235	0.157	0.216	ND	0.744	46	FDA 1991-2005
HALIBUT	0.241	0.188	0.225	ND	1.52	101	FDA 1992-2009
CROAKER WHITE (Pacific)	0.287	0.28	0.069	0.18	0.41	15	FDA 1997
TUNA (CANNED, ALBACORE)	0.350	0.338	0.128	ND	0.853	451	FDA 1991-2009
BASS CHILEAN	0.354	0.303	0.299	ND	2.18	74	FDA 1994-2010
TUNA (FRESH/FROZEN, YELLOWFIN)	0.354	0.311	0.231	ND	1.478	231	FDA 1993-2010
TUNA (FRESH/FROZEN, ALBACORE)	0.358	0.36	0.138	ND	0.82	43	FDA 1992-2008
SABLEFISH	0.361	0.265	0.241	0.09	1.052	26	FDA 2004-2009

SPECIES	MERCURY CONCENTRATION MEAN (PPM)	MERCURY CONCENTRATION MEDIAN (PPM)	MERCURY CONCENTRATION STDEV (PPM)	MERCURY CONCENTRATION MIN (PPM)	MERCURY CONCENTRATION MAX (PPM)	NO. OF SAMPLES	SOURCE OF DATA
BLUEFISH	0.368	0.305	0.221	0.089	1.452	94	FDA 1991-2009
TUNA (FRESH/FROZEN, ALL)	0.386	0.34	0.265	ND	1.816	420	FDA 1991-2010
TUNA (FRESH/FROZEN, Species Unknown)	0.410	0.334	0.308	ND	1.3	122	FDA 1991-2010
GROUPER (ALL SPECIES)	0.448	0.399	0.278	0.006	1.205	53	FDA 1991-2005
MACKEREL SPANISH (Gulf of Mexico)	0.454	N/A	N/A	0.07	1.56	66	NMFS REPORT 1978
MARLIN	0.485	0.39	0.237	0.1	0.92	16	FDA 1992-1996
ORANGE ROUGHY	0.571	0.562	0.183	0.265	1.12	81	FDA 1991-2009
TUNA (FRESH/FROZEN, BIGEYE)	0.689	0.56	0.341	0.128	1.816	21	FDA 1993-2005
MACKEREL KING	0.73	N/A	N/A	0.23	1.67	213	GULF OF MEXICO REPORT 2000
SHARK	0.979	0.811	0.626	ND	4.54	356	FDA 1991-2007
SWORDFISH	0.995	0.87	0.539	ND	3.22	636	FDA 1990-2010
TILEFISH (Gulf of Mexico)	1.123	N/A	N/A	0.65	3.73	60	NMFS REPORT 1978

Source of data: FDA 1990-2012, "National Marine Fisheries Service Survey of Trace Elements in the Fishery Resource" Report 1978, "The Occurrence of Mercury in the Fishery Resources of the Gulf of Mexico" Report 2000

ND-mercury concentration below detection level (Level of Detection (LOD)=0.01ppm)
N/A-data not available

[†]The following species have been removed from the tables:

- Bass (freshwater) – not commercial

‡Standard deviation data generated from data 1990 to 2012.

[1]Includes: Blue, King, Snow
[2]Includes: Flounder, Plaice, Sole
[3]Includes: Sea bass (black, Striped), Rockfish

NOTE: On February 8, 2006, technical changes were made to the data that was posted on January 19, 2006. The changes corrected data or more properly characterized the species of fish or shellfish sampled. On October 6, 2014, technical changes were made to allow viewers to review the list in order of mercury levels and in alphabetical order by fish species.

Mercury Concentrations in Fish: FDA Monitoring Program (/food/metals/mercury-concentrations-fish-fda-monitoring-program-1990-2010)

COMPLIANCE POLICY GUIDE (CPG)

CPG Sec. 540.600 Fish, Shellfish, Crustaceans and other Aquatic Animals - Fresh, Frozen or Processed - Methyl Mercury

FEBRUARY 2007

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/cpg-sec-540600-fish-shellfish-crustaceans-and-other-aquatic-animals-fresh-frozen-or-processed-methyl)
Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs

REGULATORY ACTION GUIDANCE:

The following represents criteria for recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

Methyl mercury expressed as mercury in excess of 1 ppm (edible portion only).

NOTE: Recommendations for legal action must clearly indicate the exact portion of the food used for analysis. The portion used for analysis must be prepared by the appropriate procedure outlined in Volume I of the Pesticide Analytical Manual, Sections 141.12 and 141.22.

Material between asterisks is new or revised.

Issued: 11/6/84
Revised: 3/95, 5/2005
Updated: 2/16/2007

CPG Sec. 578.400 Treated Grain Seed - Mercury Residue

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

The wheat contains an average of 10 or more pink kernels per 500 grams, and the mercury residue on the pink kernels exceeds one part per million.

SPECIMEN CHARGE:

Article adulterated when introduced into and while in interstate commerce, within meaning of 21 U.S.C. 342(a)(2)(B), in that it is a raw agricultural commodity and contains a pesticide chemical, namely, a mercurial compound, which is unsafe within meaning of 21 U.S.C. 346a(a), since no tolerance and no exemption from the requirement of a tolerance for such pesticide chemical on wheat has been prescribed by regulations promulgated pursuant to 21 U.S.C. 346a(b).

Issued: 10/1/80

PART 3 Natural Toxins in Food

Natural Toxins in Food

Natural toxins are chemicals produced by living things like plants, fungi, bacteria, algae, and animals. While these toxins don't hurt the organisms that produce them, consuming food with natural toxins can sometimes be harmful. When suitable preventive measures are not in place, these toxins can enter the food supply, primarily appearing in fruits, mushrooms, and legumes. They also can be in products that contain these foods as ingredients, such as plant-based beverages.

The FDA monitors domestic and imported foods to help prevent and reduce the chances of people being exposed to these toxins. The FDA has issued regulations to help growers and food producers put hazard controls in place and has developed guidance recommending maximum toxin levels for growers and food producers to follow.

Vegetables, Fruits, Plants and other Foods That Can Contain Toxins

Fish and Shellfish Toxins

Much like with plants, fish and shellfish can contain toxins. When people eat these fish and shellfish, these natural toxins can cause health problems. For more information, please go to our Seafood (/food/resources-you-food/seafood) page.

Natural toxins are often produced in plants as a defense against predators, insects, or infestation. Below are some examples of vegetables, fruits, plants, and other foods that can sometimes contain a natural toxin.

Please note that these foods can be safe to eat when properly grown, harvested, and/or prepared. This is not a complete list of all the natural toxins that can occur in food.

- **Ackee fruit (*Hypoglycin A* (/food/natural-toxins-food/hypoglycin-and-ackee-fruit))**: Hypoglycin A is a heat stable toxin found in high levels in the rinds and seeds of ackee, a tropical fruit that features prominently in Jamaican cuisine. Reactions to hypoglycin A can range from no symptoms, to vomiting, to coma and death. Properly harvested (/food/natural-toxins-food/hypoglycin-and-ackee-fruit) and prepared ackee will have low levels of hypoglycin and is safe to eat.

- **Blue-green algae (*Microcystins* (/food/natural-toxins-food/blue-green-algae-products-and-microcystins))**: Produced by *Microcystis* and other types of blue-green algae (BGA), microcystins are natural toxins that can cause gastrointestinal distress and potentially damage your liver over time. *Microcystis* cells can contaminate other BGA used in foods, such as wild-harvested *Aphanizomenon flos-aquae* (AFA). Properly harvested (/food/natural-toxins-food/blue-green-algae-products-and-microcystins) BGA is safe to eat and is used in some dietary supplements and food products.
- **Honey (*Grayanotoxins*)**: Bees collect nectar from flowers in order to create honey. If those flowers have a natural toxin, that toxin may end up in the honey from that beehive. One example is grayanotoxins, which plants such as rhododendrons and mountain laurel naturally produce. Eating honey with a high amount of this toxin can lead to "mad honey" poisoning, with symptoms such as nausea, vomiting, or dizziness. This type of poisoning is rare.
- **Beans (*Phytohaemagglutinin*)**: Phytohaemagglutinin (PHA) is a lectin found in raw or undercooked beans. Lectins are proteins that bind to carbohydrates and some plants produce them as a natural defense mechanism. In canned and properly cooked kidney beans, the low levels of PHA won't affect you. But at high levels in raw beans, PHA can lead to nausea, severe vomiting, and diarrhea. Soaking the beans for a minimum of 5 hours and then boiling them in fresh water for at least 30 minutes will remove and destroy this toxin.
- **Mushrooms (*Mushroom toxins*)**: It's well known that some mushrooms are toxic. Depending on the type of mushroom you eat, you could experience milder reactions like nausea or diarrhea. More severe reactions include coma and death.
- **Stone fruit, such as peaches or apricots (*Amygdalin*)**: Amygdalin, also called laetrile, is a natural chemical found in the seeds of apricots, bitter almonds, apples, peaches, and plums. The chemical is not found in the fruit itself and accidentally eating a seed or pit will not harm you. However, consuming a large amount of the seeds or pits can be problematic because enzymes in your intestines can turn amygdalin into cyanide and cause cyanide poisoning.

A. Mycotioxins

Mycotoxins in Foods

Mold or fungus can infect some foods with mycotoxins while the crop is growing or is being stored. Only certain molds and fungi produce mycotoxins that can make you sick if you eat them. Mycotoxins (/food/natural-toxins-food/mycotoxins) associated with human food include aflatoxins, patulin, fumonisin, ochratoxin A, and deoxynivalenol.

Index

1. Aflatoxin

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Compliance Policy Guide
Sec. 555.400 Aflatoxins in Human Food: Guidance for FDA Staff

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-0721 listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, contact the Center for Food Safety and Applied Nutrition (CFSAN), Office of Compliance at CFSANCompliancePolicy@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
and
Office of Regulatory Affairs

[June 2021]

Contains Nonbinding Recommendations

Table of Contents

Contains Nonbinding Recommendations

Compliance Policy Guide Sec. 555.400 Aflatoxins in Human Food: Guidance for FDA Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

*I. Introduction

The purpose of this document is to provide guidance for FDA staff on aflatoxins in human food. We revised this document to update the format and to include revisions for clarity, references to other aflatoxin Compliance Policy Guides (CPGs), and a reference to the Memorandum of Understanding between the Agricultural Marketing Service (AMS) of the United States Department of Agriculture (USDA) and FDA.

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II. Background

Aflatoxins (B1, B2, G1, and G2) are toxic metabolites produced by the molds *Aspergillus flavus, Aspergillus nomius,* and *Aspergillus parasiticus*. Toxicological manifestations of aflatoxins include teratogenicity, mutagenicity, and carcinogenicity in susceptible animal species. Consumption of food with high levels of aflatoxins is associated with liver cancer in humans. Aflatoxins may occur in food as a result of mold growth in susceptible raw agricultural commodities. The growth of molds that produce aflatoxins is influenced by environmental factors such as temperature, humidity, and extent of rainfall during the pre-harvesting, harvesting, or post-harvesting periods. Foods most susceptible to molds that produce aflatoxins include: peanuts, corn, some tree nuts including Brazil nuts and pistachios, and some small

grains such as rice. Because aflatoxins are known carcinogens to humans, the presence of aflatoxins in foods should be reduced to the lowest levels attainable using modern agricultural and processing techniques.

III. Policy

Aflatoxins are poisonous or deleterious substances, which may render a food injurious to health. FDA may consider human food containing total aflatoxins greater than 20 micrograms per kilogram (mcg/kg) or parts per billion (ppb) to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1)).

IV. Regulatory Action Guidance

The following represents the criteria for submitting a recommendation for seizure or a recommendation that the article is subject to import refusal to CFSAN, Office of Compliance, Division of Enforcement (HFS-605), for aflatoxins in human food, except Brazil nuts, peanuts and peanut products, and pistachio nuts:

- Both original and check analyses show total aflatoxins (i.e., aflatoxins B1, B2, G1, G2) greater than 20 ppb, and
- Identity of any aflatoxin present (i.e., aflatoxins B1, B2, G1, G2) is confirmed.

Divisions should include a detention without physical examination (DWPE) request, if applicable, in the recommendation that the article is subject to import refusal.

CFSAN will evaluate such requests and recommendations on a case-by-case basis, based on the information specific to each regulatory package.

See the following CPGs for guidance on aflatoxins in Brazil nuts, peanuts and peanut products, and pistachio nuts:

- CPG Sec. 570.200 Aflatoxins in Brazil Nuts
- CPG Sec. 570.375 Aflatoxins in Peanuts and Peanut Products
- CPG Sec. 570.500 Aflatoxins in Pistachio Nuts

Coordination with USDA/AMS

See the Memorandum of Understanding (MOU-225-19-031) between USDA/AMS and FDA for information regarding working arrangements for sampling and analyzing raw peanuts, Brazil nuts, and pistachio nuts for aflatoxins.

V. Specimen Charges

Domestic Seizure

The article of food was adulterated when introduced into, and while in interstate commerce, and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.*

Material between asterisks is new or revised

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Compliance Policy Guide
Sec. 570.200 Aflatoxins in Brazil Nuts: Guidance for FDA Staff

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-0721 listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, contact the Center for Food Safety and Applied Nutrition (CFSAN), Office of Compliance at CFSANCompliancePolicy@fda.hhs.gov.

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Center for Food Safety and Applied Nutrition
and
Office of Regulatory Affairs

June 2021

Contains Nonbinding Recommendations

Table of Contents

Contains Nonbinding Recommendations

Compliance Policy Guide Sec. 570.200 Aflatoxins in Brazil Nuts: Guidance for FDA Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

*I. Introduction

The purpose of this document is to provide guidance for FDA staff on aflatoxins in Brazil nuts. We revised this document to update the format and to include revisions for clarity, references to other aflatoxin Compliance Policy Guides (CPGs), and a reference to the Memorandum of Understanding between the Agricultural Marketing Service (AMS) of the United States Department of Agriculture (USDA) and FDA.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is suggested or recommended, but not required.

II. Background

Aflatoxins (B1, B2, G1, and G2) are toxic metabolites produced by the molds *Aspergillus flavus, Aspergillus nomius,* and *Aspergillus parasiticus*. Toxicological manifestations of aflatoxins include teratogenicity, mutagenicity, and carcinogenicity in susceptible animal species. Consumption of food with high levels of aflatoxins is associated with liver cancer in humans. Aflatoxins may occur in food as a result of mold growth in susceptible raw agricultural commodities. The growth of molds that produce aflatoxins is influenced by environmental factors such as temperature, humidity, and extent of rainfall during the pre-harvesting, harvesting, or post-harvesting periods. Foods most susceptible to molds that produce aflatoxins include: peanuts, corn, some tree nuts including Brazil nuts and pistachios, and some small

grains such as rice. Because aflatoxins are known carcinogens to humans, the presence of aflatoxins in foods should be reduced to the lowest levels attainable using modern agricultural and processing techniques.

III. Policy

Aflatoxins are poisonous or deleterious substances, which may render a food injurious to health. FDA may consider Brazil nuts containing total aflatoxins greater than 20 micrograms per kilogram (mcg/kg) or parts per billion (ppb) to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1)).

IV. Regulatory Action Guidance

The following represents the criteria for submitting a recommendation for seizure or a recommendation that the article is subject to import refusal to CFSAN, Office of Compliance, Division of Enforcement (HFS-605), for aflatoxins in Brazil nuts:

- Both original and check analyses show total aflatoxins (i.e., aflatoxins B1, B2, G1, G2) greater than 20 ppb, and
- Identity of any aflatoxin present (i.e., aflatoxins B1, B2, G1, G2) is confirmed.

Divisions should include a detention without physical examination (DWPE) request, if applicable, in the recommendation that the article is subject to import refusal.

CFSAN will evaluate such requests and recommendations on a case-by-case basis, based on the information specific to each regulatory package.

See the following CPGs for guidance on aflatoxins in human food, peanuts and peanut products, and pistachio nuts:

- CPG Sec. 555.400 Aflatoxins in Human Food
- CPG Sec. 570.375 Aflatoxins in Peanuts and Peanut Products
- CPG Sec. 570.500 Aflatoxins in Pistachio Nuts

Coordination with USDA/AMS

See the Memorandum of Understanding (MOU-225-19-031) between USDA/AMS and FDA for information regarding working arrangements for sampling and analyzing raw peanuts, Brazil nuts, and pistachio nuts for aflatoxins.

V. Specimen Charges

Domestic Seizure

The article of food was adulterated when introduced into, and while in interstate commerce, and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.*

Material between asterisks is new or revised

Issued: 08/1/83
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Compliance Policy Guide
Sec. 570.375 Aflatoxins in Peanuts and Peanut Products:
Guidance for FDA Staff

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-0721 listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, contact the Center for Food Safety and Applied Nutrition (CFSAN), Office of Compliance at CFSANCompliancePolicy@fda.hhs.gov.

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Center for Food Safety and Applied Nutrition
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Office of Regulatory Affairs

June 2021

Contains Nonbinding Recommendations

Table of Contents

Contains Nonbinding Recommendations

Compliance Policy Guide Sec. 570.375 Aflatoxins in Peanuts and Peanut Products: Guidance for FDA Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

*I. Introduction

The purpose of this document is to provide guidance for FDA staff on aflatoxins in peanuts and peanut products. We revised this document to update the format and to include revisions for clarity, references to other aflatoxin Compliance Policy Guides (CPGs), and a reference to the Memorandum of Understanding between the Agricultural Marketing Service (AMS) of the United States Department of Agriculture (USDA) and FDA.

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II. Background

Aflatoxins (B1, B2, G1, and G2) are toxic metabolites produced by the molds *Aspergillus flavus, Aspergillus nomius,* and *Aspergillus parasiticus*. Toxicological manifestations of aflatoxins include teratogenicity, mutagenicity, and carcinogenicity in susceptible animal species. Consumption of food with high levels of aflatoxins is associated with liver cancer in humans. Aflatoxins may occur in food as a result of mold growth in susceptible raw agricultural commodities. The growth of molds that produce aflatoxins is influenced by environmental factors such as temperature, humidity, and extent of rainfall during the pre-harvesting,

harvesting, or post-harvesting periods. Foods most susceptible to molds that produce aflatoxins include: peanuts, corn, some tree nuts including Brazil nuts and pistachios, and some small grains such as rice. Because aflatoxins are known carcinogens to humans, the presence of aflatoxins in foods should be reduced to the lowest levels attainable using modern agricultural and processing techniques.

III. Policy

Aflatoxins are poisonous or deleterious substances, which may render a food injurious to health. FDA may consider peanuts and peanut products containing total aflatoxins greater than 20 micrograms per kilogram (mcg/kg) or parts per billion (ppb), except raw peanuts that will be further processed to remove moldy and otherwise defective nuts, to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1)).

IV. Regulatory Action Guidance

The following represents the criteria for submitting a recommendation for seizure or a recommendation that the article is subject to import refusal to CFSAN, Office of Compliance, Division of Enforcement (HFS-605), for aflatoxins in processed peanuts and peanut products:

- Both original and check analyses show total aflatoxins (i.e., aflatoxins B1, B2, G1, G2) greater than 20 ppb, and
- Identity of any aflatoxin present (i.e., aflatoxins B1, B2, G1, G2) is confirmed.

The following represents the criteria for submitting a recommendation for seizure or a recommendation that the article is subject to import refusal to CFSAN, Office of Compliance, Division of Enforcement (HFS-605), for aflatoxins in raw peanuts:

- USDA's certificate of analysis of the raw peanuts indicates total aflatoxins of greater than 20 ppb, and
- The raw peanuts are being shipped to or are at a processor that does not have facilities and procedures that will remove moldy or otherwise defective nuts.

Divisions should include a detention without physical examination (DWPE) request, if applicable, in the recommendation that the article is subject to import refusal.

CFSAN will evaluate such requests and recommendations on a case-by-case basis, based on the information specific to each regulatory package.

See the following CPGs for guidance on aflatoxins in human food, Brazil nuts, and pistachio nuts:

- CPG Sec. 555.400 Aflatoxins in Human Food

- CPG Sec. 570.200 Aflatoxins in Brazil Nuts
- CPG Sec. 570.500 Aflatoxins in Pistachio Nuts

Coordination with USDA/AMS

See the Memorandum of Understanding (MOU-225-19-031) between USDA/AMS and FDA for information regarding working arrangements for sampling and analyzing raw peanuts, Brazil nuts, and pistachio nuts for aflatoxins.

V. Specimen Charges

Domestic Seizure

The article of food was adulterated when introduced into, and while in interstate commerce, and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.*

Material between asterisks is new or revised

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Contains Nonbinding Recommendations

Compliance Policy Guide
Sec. 570.500 Aflatoxins in Pistachio Nuts: Guidance for FDA Staff

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Center for Food Safety and Applied Nutrition
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Office of Regulatory Affairs

June 2021

Contains Nonbinding Recommendations

Table of Contents

Contains Nonbinding Recommendations

Compliance Policy Guide Sec. 570.500 Aflatoxins in Pistachio Nuts: Guidance for FDA Staff

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*I. Introduction

The purpose of this document is to provide guidance for FDA staff on aflatoxins in pistachio nuts. We revised this document to update the format and to include revisions for clarity, references to other aflatoxin Compliance Policy Guides (CPGs), and a reference to the Memorandum of Understanding between the Agricultural Marketing Service (AMS) of the United States Department of Agriculture (USDA) and FDA.

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II. Background

Aflatoxins (B1, B2, G1, and G2) are toxic metabolites produced by the molds *Aspergillus flavus, Aspergillus nomius,* and *Aspergillus parasiticus*. Toxicological manifestations of aflatoxins include teratogenicity, mutagenicity, and carcinogenicity in susceptible animal species. Consumption of food with high levels of aflatoxins is associated with liver cancer in humans. Aflatoxins may occur in food as a result of mold growth in susceptible raw agricultural commodities. The growth of molds that produce aflatoxins is influenced by environmental factors such as temperature, humidity, and extent of rainfall during the pre-harvesting, harvesting, or post-harvesting periods. Foods most susceptible to molds that produce aflatoxins include: peanuts, corn, some tree nuts including Brazil nuts and pistachios, and some small

grains such as rice. Because aflatoxins are known carcinogens to humans, the presence of aflatoxins in foods should be reduced to the lowest levels attainable using modern agricultural and processing techniques.

III. Policy

Aflatoxins are poisonous or deleterious substances, which may render a food injurious to health. FDA may consider pistachio nuts containing aflatoxins greater than 20 micrograms per kilogram (mcg/kg) or parts per billion (ppb) to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1)).

IV. Regulatory Action Guidance

The following represents the criteria for submitting a recommendation for seizure or a recommendation that the article is subject to import refusal to CFSAN, Office of Compliance, Division of Enforcement (HFS-605), for aflatoxins in pistachio nuts.

- Both original and check analyses show total aflatoxins (i.e., aflatoxins B1, B2, G1, G2) greater than 20 ppb, and
- Identity of any aflatoxin present (i.e., aflatoxins B1, B2, G1, G2) is confirmed.

Divisions should include a detention without physical examination (DWPE) request, if applicable, in the recommendation that the article is subject to import refusal.

CFSAN will evaluate such requests and recommendations on a case-by-case basis, based on the information specific to each regulatory package.

See the following CPGs for guidance on aflatoxins in human food, peanuts and peanut products, and Brazil nuts:

- CPG Sec. 555.400 Aflatoxins in Human Food
- CPG Sec. 570.375 Aflatoxins in Peanuts and Peanut Products
- CPG Sec. 570.200 Aflatoxins in Brazil Nuts

Coordination with USDA/AMS

See the Memorandum of Understanding (MOU-225-19-031) between USDA/AMS and FDA for information regarding working arrangements for sampling and analyzing raw peanuts, Brazil nuts, and pistachio nuts for aflatoxins.

V. Specimen Charges

Domestic Seizure

The article of food was adulterated when introduced into, and while in interstate commerce, and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, namely aflatoxins, which may render it injurious to health.*

Material between asterisks is new or revised

Issued: 10/1/82
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COMPLIANCE POLICY GUIDE (CPG)

CPG Sec 527.400 Whole Milk, Lowfat Milk, Skim Milk - Aflatoxin M1

NOVEMBER 2005

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/cpg-sec-527400-whole-milk-lowfat-milk-skim-milk-aflatoxin-m1)
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition

BACKGROUND:

Aflatoxins are a group of chemically related toxins produced as natural by-products during the growth of certain common molds. The aflatoxins are designated as B1, B2, G1, and G2. These compounds are demonstrated liver toxins and liver carcinogens. Aflatoxin B1 is considered the most potent of this group. They are potential contaminants of several commodities including corn. If a particular corn crop is stressed, for example, by drought or insect attack it is susceptible to mold growth and aflatoxin contamination.

A metabolite of aflatoxin B1 that is produced during normal biological processes of animals ingesting the toxin is chemically similar to B1 and has been designated as aflatoxin M1. The aflatoxin M1, though less potent than B1, has been shown to cause liver cancer in certain animals. Because the M1 metabolite may occur in the milk of dairy cattle ingesting feed contaminated with aflatoxin B1, exposure of these animals to aflatoxin contaminated feed should be minimized.

As a result of adverse weather conditions, insect damage and possibly other undetermined factors, the 1977 corn crop grown in the southeastern United States was severely affected by growth of aflatoxin producing molds. The Agency conducted surveys in the southeastern states to determine the incidence of aflatoxin M1 contamination of fluid milk products. The results of these surveys showed that aflatoxin contamination of milk in at least four southeastern states was a potentially serious public health hazard. The Commissioner therefore established a 0.5 parts per billion (ppb) action guideline for aflatoxin contamination of fluid milk products in 1977.

The Agency routinely monitors milk and milk products for aflatoxin contamination. It has generally been observed that the incidence and levels of aflatoxin M1 contamination varies with the extent of aflatoxin contamination of the corn crop for a particular year.

REGULATORY ACTION GUIDANCE:

The following represents criteria that should be considered when deciding whether to recommend legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

The original and check analysis show that the sample contains greater than 0.5 ppb aflatoxin M1 and the identity of aflatoxin M1 is confirmed by the chemical derivative test.

METHODOLOGY:

Samples of fluid milk products collected for aflatoxin M1 analysis shall consist of not less than 10 pounds composited from not less than 10 units or portions of units randomly selected from a given lot. In the case of bulk units, the composite 10 pound sample may be drawn directly from bulk fluid storage after adequate mixing of the contents and flushing of the sampling valve.

Prior to analysis, the total sample shall be mixed in a manner to provide analytical samples that are representative of the composite. Duplicate aliquots of the well mixed sample shall be analyzed by one of the methods for aflatoxin M1 in dairy products described in AOAC Official Methods of Analysis (1990) 15th edition, sections 974.17, 980.21 and 986.16. Confirmation of the aflatoxin identity shall be by the method described in section 980.21.

Material between asterisks is new or revised.

Issued: 10/1/80
Revised: 3/95, 8/96, 5/05
Updated: 11/29/05

2. Deoxynivalenol

GUIDANCE DOCUMENT

Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed

JULY 2010

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-advisory-levels-deoxynivalenol-don-finished-wheat-products-human)
Center for Veterinary Medicine
Center for Food Safety and Applied Nutrition

This document supersedes "Letter to State Agricultural Directors, State Feed Control Officials, and Food, Feed, and Grain Trade Organizations" issued on September 16, 1993

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

Deoxynivalenol (DON), commonly called vomitoxin, is produced by several molds of the genus *Fusarium*, especially F. *graminearum*, which causes pink scab disease in wheat. It is not possible to completely avoid the presence of DON in wheat. DON is sometimes found in wheat grown under normal weather conditions, however, the fungus thrives in cool, wet conditions. When DON occurs in wheat, the levels are reduced by the processing of wheat into wheat products like flour, but processing does not totally eliminate DON.

The matter of DON in wheat was the subject of an FDA advisory issued in 1982. At that time, the agency noted the levels of DON in wheat and wheat products that it believed would not present a public health hazard. However, because only limited toxicological data on DON

were available at that time, FDA stated that it was difficult to estimate the potential public health hazard posed by DON.

In 1993, FDA received numerous reports indicating that a significant portion of the hard red spring wheat crop from the upper Midwest states may contain high levels of DON due to the cool, wet conditions that occurred in the Midwest in the spring and summer of 1993. The agency reviewed additional data on DON that had become available since 1982. These data included reports of outbreaks of DON-associated acute gastrointestinal illness in humans in China in 1984/85 and in India in 1987. Although uncertainties existed concerning the precise role played by DON in these outbreaks, the data provided a clearer picture of the factors associated with human exposure to DON contaminated wheat.

On September 16, 1993, FDA issued a letter to State Agricultural Directors, State Feed Control Officials, and Food, Feed, and Grain Trade Organizations stating that, based upon the available data and information, FDA could now state with more confidence the levels of DON in wheat and wheat derived products that would not appear to present a public health hazard. Thus, FDA updated its advisory levels for DON in finished wheat products for human consumption. Advisory levels were also updated for grain and grain by-products used for animal feed. The letter stated that the updated advisory levels for DON were in response to the conditions experienced in the Midwest in 1993. This letter was subsequently incorporated into a final guidance that FDA placed on its guidance page website for ease of accessibility.

In response to a May 14, 2010 letter to Dr. Bernadette Dunham, Director, Center for Veterinary Medicine (CVM), from the National Grain and Feed Association and American Feed Industry Association, CVM conducted a review of the recent scientific literature and has determined that the 1993 advisory levels for DON in grains and grain by products destined for cattle can be revised. Recent studies demonstrate that higher levels of DON in feed for cattle would not appear to present an animal or public health hazard.

The advisory levels for DON are as follows:

1. 1 ppm DON on finished wheat products, e.g. flour, bran, and germ, that may potentially be consumed by humans. FDA is not stating an advisory level for wheat intended for milling because normal manufacturing practices and additional technology available to millers can substantially reduce DON levels in the finished wheat product from those found in the original raw wheat. Because there is significant variability in manufacturing processes, an advisory level for raw wheat is not practical.
2. 10 ppm DON on grains and grain by-products (on an 88% dry matter basis) and 30 ppm in distillers grains, brewers grains, and gluten feeds and gluten meals derived from grains (on an 88% dry matter basis) destined for ruminating beef and feedlot cattle older than 4 months and ruminating dairy cattle older than 4 months, with the added recommendations that the total ration[2] for ruminating beef and feedlot cattle older than 4 months not exceed 10 ppm DON, and the total ration for ruminating dairy

cattle older than 4 months not exceed 5 ppm DON. For chickens, 10 ppm DON on grains and grain by-products with the added recommendation that these ingredients not exceed 50% of the diet of chickens.

3. 5 ppm DON on grains and grain by-products destined for swine with the added recommendation that these ingredients not exceed 20% of their diet.
4. 5 ppm DON on grains and grain by-products destined for all other animals with the added recommendation that these ingredients not exceed 40% of their diet.

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1. This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition and the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the Food and Drug Administration (FDA).

2. The total ration includes grains, all grain by-products including distillers and brewers grains, hay, silage, and roughage.

Related Information

- Chemical, Metals, Natural Toxins & Pesticides Guidance Documents & Regulations (/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations)
- Resources for Human and Animal Food Producers Affected by Flooding (/about-fda/office-human-and-animal-food-operations/resources-human-and-animal-food-producers-affected-flooding)

Submit Comments

Submit comments on this guidance document electronically via docket ID: FDA-2013-S-0610 (https://www.regulations.gov/docket/FDA-2013-S-0610) - Specific Electronic Submissions Intended For FDA's Dockets Management Staff (i.e., Citizen Petitions, Draft Proposed Guidance Documents, Variances, and other administrative record submissions)

If unable to submit comments online, please mail written comments to:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

All comments should be identified with the title of the guidance.

3. Fumonisins

GUIDANCE DOCUMENT

Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds

NOVEMBER 2001

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/guidance-industry-fumonisin-levels-human-foods-and-animal-feeds)
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

For questions regarding this guidance document, contact Henry Kim, Center for Food Safety and Applied Nutrition (CFSAN), (202) 260-0631, for human food issues or Randall Lovell, Center for Veterinary Medicine (CVM), 301-827-0176, for animal feed issues.

This guidance document has been prepared by the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine at the Food and Drug Administration. This guidance represents the Agency's current thinking on the control of fumonisins in human foods and animal feeds as a prudent public health measure. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

The purpose of this guidance is to identify recommended maximum fumonisin levels that FDA considers adequate to protect human and animal health and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices. FDA considers this guidance to be a prudent public health measure during the development of a better understanding of the human health risk associated with fumonisins and the development of a long-term risk management policy and program by the agency for the control of fumonisins in human foods and animal feeds.

BACKGROUND

Fumonisins are environmental toxins produced by the molds *Fusarium moniliforme (F. verticillioides)*, *F. proliferatum*, and other *Fusarium* species that grow on agricultural commodities in the field or during storage. These mycotoxins have been found as contaminants worldwide, mainly in corn. More than ten types of fumonisins have been isolated and characterized. Of these, fumonisin B_1 (FB_1), fumonisin B_2 (FB_2), and fumonisin B_3 (FB_3) are the major fumonisins produced in nature. The most prevalent of these mycotoxins in contaminated corn is FB_1, which is believed to be the most toxic (1, 2).

Occurrence in Raw Corn

The extent of contamination of raw corn with fumonisins varies with geographic location, agronomic and storage practices, and the vulnerability of the plants to fungal invasion during all phases of growth, storage, and processing. The levels of fumonisins in raw corn are also influenced by environmental factors such as temperature, humidity, and rainfall during pre-harvest and harvest periods (3). High levels of fumonisins are associated with hot and dry weather, followed by periods of high humidity. High levels of fumonisins may also occur in raw corn that has been damaged by insects (4, 5). Further, fumonisin levels in raw corn can increase under improper storage conditions. For example, optimal growth of fumonisin-producing molds that lead to increased levels of fumonisins in raw corn can occur when the moisture content of harvested raw corn during storage is 18-23 percent (5).

Occurrence in Processed Corn Products

The levels of fumonisins in processed corn products for human consumption vary depending on the milling and manufacturing processes that raw corn undergoes. Discussion of the various milling and manufacturing processes of raw corn and their effects on fumonisin levels in various processed corn products can be found in CFSAN's "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption."

Animal and Human Health Effects

Fumonisins are associated with a variety of adverse health effects in livestock and experimental animals. Currently, there is no direct evidence that fumonisins cause adverse health effects in humans because available studies demonstrate only inconclusive associations between fumonisins and human cancer. The available toxicological information on the adverse health effects of fumonisins in animals can be found in CFSAN's "Background Paper in Support of Fumonsin Levels in Corn and Corn Products Intended for Human Consumption" and in CVM's "Background Paper in Support of Fumonisin Levels in Animal Feed." The available epidemiological information on the association between fumonisins and human disease can be found in CFSAN's "Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption."

FDA STRATEGY

As part of a long-term strategy for the control of fumonisins in the U.S. food and feed supply, FDA will participate in national and international scientific workshops to gather information that may be used in further assessment of the potential risk to animals and humans from exposure to fumonisins. For example, a Fumonisin Risk Assessment Workshop, sponsored by FDA, the Joint Institute for Food Safety and Applied Nutrition, the World Health Organization, and the United States Department of Agriculture, was held January 10-12, 2000 at College Park, MD to discuss the elements of risk assessment for fumonisins. FDA intends to use information from this and other sources as the scientific basis for developing a long-term risk management policy and program for the control of fumonisins in the U.S. food and feed supply.

GUIDANCE LEVELS

Based on the wealth of available information on the adverse animal health effects associated with fumonisins, human health risks associated with exposure to fumonisins are possible. Therefore, human exposure to such natural toxins should not exceed levels achievable with the use of good agricultural and good manufacturing practices.

The recommended maximum levels for fumonisins in human foods and in animal feeds that FDA considers achievable with the use of good agricultural and good manufacturing practices are presented below. FDA believes that controlling fumonisins to these recommended levels can reduce exposure to fumonisins that may be found in corn products intended for human and animal consumption.

Human Foods

Product	**Total Fumonisins (FB_1+FB_2+FB_3)**
Degermed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of < 2.25%,="" dry="" weight="">	2 parts per million (ppm)
Whole or partially degermed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of ≥ 2.25 %, dry weight basis)	4 ppm
Dry milled corn bran	4 ppm
Cleaned corn intended for masa production	4 ppm
Cleaned corn intended for popcorn	3 ppm

Animal Feeds

Corn and corn by-products intended for:	**Total Fumonisins (FB_1+FB_2+FB_3)**
Equids and rabbits	5 ppm (no more than 20% of diet)**
Swine and catfish	20 ppm (no more than 50% of diet)**
Breeding ruminants, breeding poultry and breeding mink*	30 ppm (no more than 50% of diet)**

Corn and corn by-products intended for:	Total Fumonisins (FB_1+FB_2+FB_3)
Ruminants ≥ 3 months old being raised for slaughter and mink being raised for pelt production	60 ppm (no more than 50% of diet)**
Poultry being raised for slaughter	100 ppm (no more than 50% of diet)**
All other species or classes of livestock and pet animals	10 ppm (no more than 50% of diet)**
*Includes lactating dairy cattle and hens laying eggs for human consumption **Dry weight basis	

REFERENCES

1. Thiel, P.G., Marasas, W.F.O., Sydenham, E.W., Shephard, G.S. and Gelderblom, W.C.A. The implications of naturally occurring levels of fumonisins in corn for human and animal health. Mycopathologia 117:3-9, 1992.
2. Musser, S.M. and Plattner, R.D. Fumonisin composition in cultures of *Fusarium moniliforme, Fusarium proliferatum,* and *Fusarium nygami*. J. Agric. Food Chem. 45:1169-1173, 1997.
3. Shelby, R.A., White, D.G., and Bauske, E.M. Differential fumonisin production in maize hybrids. Plant Dis. 78:582-584, 1994.
4. Miller, J.D. Factors affecting the occurrence of fumonisin in corn. Abstract of Papers (p.21)-International Conference on the toxicology of Fumonisin, June 28-30, 1999, Arlington, VA.
5. Bacon, C.W. and Nelson, P.E. Fumonisin production in corn by toxigenic strains of *Fusarium moniliforme* and *Fusarium proliferatum*. J. Food Prot. 57(6):514-521, 1994.

November 9, 2001: Background Paper in Support of Fumonisin Levels in Corn and Corn Products Intended for Human Consumption (https://wayback.archive-it.org/7993/20170404222936/https:/www.fda.gov/Food/FoodborneIllnessContaminants/NaturalToxins/ucm212899.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

November 9, 2001: Background Paper in Support of Fumonisin Levels in Animal Feed (https://wayback.archive-it.org/7993/20161022111510/http:/www.fda.gov/Food/FoodborneIllnessContaminants/NaturalToxins/ucm212900.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Related Information

- Chemical, Metals, Natural Toxins & Pesticides Guidance Documents & Regulations (/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations)
- Resources for Human and Animal Food Producers Affected by Flooding (/about-fda/office-human-and-animal-food-operations/resources-human-and-animal-food-producers-affected-flooding)

4. Patulin

COMPLIANCE POLICY GUIDE (CPG)

CPG Sec 510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin

NOVEMBER 2005

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/cpg-sec-510150-apple-juice-apple-juice-concentrates-and-apple-juice-products-adulteration-patulin)
Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs

This guidance document represents the Agency's current thinking on its enforcement process concerning the adulteration of apple juice, apple juice concentrates, and apple juice products with patulin. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

INTRODUCTION

This compliance guidance document is an update to the Compliance Policy Guides Manual (August 2000 edition). It is a new CPG and will be included in the next printing of the Compliance Policy Guides Manual. It is intended for FDA personnel and is available electronically to the public.

BACKGROUND:

Patulin is a toxic substance produced by molds that may grow on apples. In the past, patulin has been found to occur at high levels in some apple juice products offered for sale in or import into the U.S.

REGULATORY ACTION GUIDANCE:

The following criteria should be considered in deciding whether to recommend legal action or whether to recommend detention of imports to CFSAN/Office of *Compliance/Division of Enforcement* (HFS-605):

The sample is analyzed in accordance with applicable methods of the current Official Methods of Analysis of the Association of Official Analytical Chemists1, and its supplements, and both of the following conditions are met:

and

1. Original and check analysis show patulin at or above 50 micrograms per kilogram (50 parts per billion) as determined on single strength apple juice, reconstituted single strength apple juice (if the food is an apple juice concentrate), or the single strength apple juice component of the food (if the food contains apple juice as an ingredient); (For the purpose of this guidance, single strength juice is 100 percent juice that is unconcentrated (see 21 CFR 101.30(h)).)
2. Identity of patulin is confirmed by gas chromatography/mass spectrometry.

SPECIMEN CHARGE:

For domestic goods:

The article (apple juice, apple juice concentrate, or apple juice product) was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within the meaning of 21 U.S.C. 342 (a)(1), in that it bears or contains an added poisonous or deleterious substance, patulin, which may render the article of food injurious to health.

For imported goods:

The article (apple juice, apple juice concentrate, or apple juice product) is subject to refusal of admission pursuant to 21 U.S.C. 381 (a)(3) in that it appears to bear or contain an added poisonous or deleterious substance, patulin, which may render the article injurious to health (adulteration under 21 U.S.C. 342 (a)(1)).

[1]At the time of this issuance, the current method can be found in the Seventeenth Edition, section 995.10 - Patulin in apple juice, liquid chromatographic method, AOAC-IUPAC-IFJU Method. This method was adopted by AOAC International in 1995. The method was published in JAOAC 79(2):452-455, 1996.

Material between asterisks is new or revised.

Issued: 10/22/2001
Revised: 5/2005
Updated: 11/29/05

5. Ochratioxin A

Ochratioxin A

Ochratoxin A is a mycotoxin produced by certain Aspergillus and Penicillium molds. It's been found in contaminated grains, such as wheat, rye, oat, and barley, and in coffee, grapes and wine. Contamination generally occurs when these foods are not stored and/or dried properly.

We know that ochratoxin A can cause kidney damage in animals. It may possibly cause cancer in humans, but more research is needed to know exactly how this toxin affects humans.

B. Hypoglycin A and Ackee Fruit

Hypoglycin A and Ackee Fruit

Hypoglycin A is a heat stable toxin that occurs in ackee fruit, a tropical fruit used in Caribbean cuisine. Although native to West Africa, ackee fruit is found in south Florida, Central and South America, and many Caribbean countries.

The edible part of a fully ripe, properly processed ackee fruit is safe to eat. Unripe fruit, and the rind and seeds of ripe fruit, are never safe to eat because they can contain dangerous amounts of hypoglycin A.

People who eat unsafe levels of hypoglycin A may have no symptoms or mild symptoms, such as vomiting. However, others can have severe reactions, such as vomiting with profound hypoglycemia, drowsiness, muscular exhaustion, prostration, and possibly coma and death.

CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products - Hypoglycin A Toxin

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Regulatory Affairs

April 2014

Contains Nonbinding Recommendations

Table of Contents

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements

of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction:

The purpose of this Compliance Policy Guide is to provide guidance for FDA staff on canned ackee, frozen ackee, and other ackee products that contain the toxin hypoglycin A.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background:

Ackee is a tropical fruit that grows to be approximately 4 inches long when mature. The immature, unripe fruit is green. When the healthy fruit is mature, the rind is yellow with more or less of an overlay of bright red and has three bulging seams. As the fruit ripens, it splits open along the seams into three sections revealing the edible part of the fruit, i.e., the fleshy, pale yellow arils. At the top of the arils is a round, black, glossy, hard seed. Between the seed and each aril is a pinkish membrane (raphe).

Hypoglycin A, a heat stable toxin, is found at high levels in the unripe arils, seeds, raphe, and rind of ackee (roughly at a level of 1000 parts per million (ppm)). Ingestion of hypoglycin A may result in no symptoms or symptoms that range from mild (e.g., some vomiting) to severe (e.g., vomiting with profound hypoglycemia, drowsiness, muscular exhaustion, prostration, and possibly coma and death). When ackee is fully ripe, the hypoglycin A drops to negligible levels in the arils and raphe, making them safe to consume (although the raphe is removed prior to packaging). However, the rind and seeds still have high levels of hypoglycin A when the fruit is fully ripe and should not be consumed. If the fruit is not properly processed, the finished product may contain more than a negligible level of hypoglycin A and could pose a health risk.

Ackee can be picked from the tree when fully ripe (i.e., when the rind is fully open) and processed the same day. However, the usual practice for most processors is to purchase fruit that is mature (i.e., when the fruit is mostly yellow in color with more or less of an overlay of bright red) and unopened or just beginning to split along the seams (i.e., when the fruit is not fully ripe). The fruit is typically spread out on ripening racks where it continues to ripen (splitting wide open). Processing staff monitor the fruit while it ripens looking for fruit that has fully opened and is ready for processing. Staff will also remove and discard ackees that are not fit for processing (e.g., fruits that fail to open). If the fruit does not ripen by splitting fully open within three to four days, the fruit is discarded. If the fruit does ripen, there is a dramatic, rapid loss of hypoglycin A

in the arils and raphe. The ripened fruit is selected for processing and the outer rind and any attached debris are removed and discarded. Additionally, the fruit is inspected for bruising or damage to the arils or seeds and other blemishes that indicate the fruit is not suitable for processing. Such bruised and damaged fruit are also discarded. Prior to further processing and packaging, the black seeds and raphe are removed, and the arils are visually inspected for damage, blemishes, or signs of spoilage. Prior to canning or freezing, the arils are carefully washed in brine solutions. Additional visual inspections are performed to identify any arils that show signs of damage or spoilage or signs of any raphe that may still be present. Although complete removal of the raphe may not always be possible, if the fruit is fully ripe, the amount of hypoglycin A in the raphe is negligible.

The presence of hypoglycin A in the finished ackee product at levels above 100 ppm can be attributed to improper processing of the product and may pose a health risk. Problems during the processing of ackee that can lead to potentially harmful levels of hypoglycin A above 100 ppm in the finished product include (1) the inability of employees to identify and select fruit that is ripe and fully opened; (2) purchasing fruit that appears ripened but may have been opened by the supplier before the fruit is naturally ripe; (3) heat shocking the fruit to make it split open faster than nature intended (such that the levels of hypoglycin A would not drop to negligible levels in the arils and raphe); and (4) improper cleaning and washing of the arils.

FDA has determined that canned ackee, frozen ackee, or other ackee products containing concentrations of hypoglycin A above 100 ppm have not been processed properly and that finished product may be injurious to health.

III. Policy:

Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(4)), a food shall be deemed adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. Canned ackee, frozen ackee, and other ackee products may be considered adulterated within the meaning of section 402(a)(4) of the FD&C Act when hypoglycin A is present in the food at levels greater than 100 ppm.

Canned ackee, frozen ackee, and other ackee products offered for import and that appear to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that the products appear to have been prepared and packed under insanitary conditions whereby they may have been rendered injurious to health, shall be refused admission under section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)).

IV. Regulatory Action Guidance:

The following represents criteria for recommending seizure or import refusal to CFSAN/Office of Compliance/Division of Enforcement (HFS-605):

Canned ackee, frozen ackee, or other ackee product contains greater than 100 ppm of hypoglycin A.

The method of analysis for hypoglycin A is described in the *Journal of AOAC International*, volume 85, no. 4: 933-937, 2002 (G. Ware. "Method Validation Study of Hypoglycin A Determination in Ackee Fruit").

V. Specimen Charges:

Domestic Seizure

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(4), in that it has been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health.

Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that it appears to have been prepared and packed under insanitary conditions whereby it may have been rendered injurious to health.

Issued: 04/09/2014

C. Poison

COMPLIANCE POLICY GUIDE (CPG)

CPG Sec 540.250 Clams, Mussels, Oysters, Fresh, Frozen or Canned - Paralytic Shellfish Poison

NOVEMBER 2005

Final

Issued by:

(/regulatory-information/search-fda-guidance-documents/cpg-sec-540250-clams-mussels-oysters-fresh-frozen-or-canned-paralytic-shellfish-poison)
Office of Regulatory Affairs
Center for Food Safety and Applied Nutrition

BACKGROUND:

Paralytic shellfish poison is a marine biotoxin, produced in single celled marine protozoa of the order Dinoflagellata. This poison accumulates in the tissue of bivalve shellfish that have ingested certain species of dinoflagellates of the genus Gonvaulax or closely related genera.

Toxin levels in shellfish are associated with algal "blooms" of toxic dinoflagellates in shellfish growing waters of the Pacific Coast and the Bay of Fundy region.

Ordinary cooking does not insure safety of shellfish since the poison is very stable and is not destroyed completely by the usual heat treatments.

REGULATORY ACTION GUIDANCE:

The following represents criteria for recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

Actionable if one sub from a lot shows paralytic shellfish poison value of 80 micrograms, or more, per 100 grams meat when bioanalyzed by current Association of Official Analytical Chemists procedure.

Articles meeting the above criterion represent a potential health hazard. Consequently, recall is the action of choice. Notify CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) immediately if articles meeting the above criterion are encountered.

Notify CFSAN's Office of Seafood (HFS-415) immediately when articles containing any detectable levels of paralytic shellfish poison are encountered.

Material between asterisks is new or revised.

PART 4 Pesticide

A. Pesticides

- Skip -

(None of the presented contents are related to processed food)


5
PART
Micro
-Bacterial

CPG Sec. 527.300 Dairy Products - Microbial Contaminants and Alkaline Phosphatase Activity

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Regulatory Affairs

December 2010

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

Table of Contents

I. Introduction:

*The purpose of this document is to provide guidance for FDA staff regarding its enforcement policies for pathogens and indicators of inadequate pasteurization or post-pasteurization contamination of dairy products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background:

Significant outbreaks of illness associated with dairy products include salmonellosis (including infections with some multi-drug resistant *Salmonella*), enterohemorrhagic *Escherichia coli* (EHEC) O157:H7 infections, listeriosis, staphylococcal food poisoning, botulism, and *Yersinia enterocolitica* infection. (A *Federal Register* notice of availability for draft CPG Sec. 555.320 *Listeria monocytogenes* was published on February 7, 2008 (73 FR 7293)). Symptoms of illnesses from pathogens may include anything from mild discomfort to headaches, nausea, vomiting, watery or bloody diarrhea, cramps, and hemolytic uremic syndrome. In some cases, death may result.

A. <u>Pathogens</u>

The presence of pathogens in dairy products is an indicator of poor sanitation, temperature abuse, inadequate pasteurization (21 CFR 133.3(d)), fermentation failure, or obtaining milk from diseased animals. Many pathogens originate from the feces of the

dairy animals themselves. Contamination of the udder and teats by the feces may in turn contaminate raw milk. Insanitary practices by milk handlers may contribute to the contamination. Insanitary or inadequate processing conditions also may contaminate the raw milk dairy product. Pasteurization of raw milk is lethal to pathogens. Thus, the presence of pathogens in a dairy product made from milk that was subjected to a pasteurization process indicates inadequate pasteurization or post-pasteurization contamination.

Salmonella - *Salmonella* is a pathogen that, when consumed, can cause an infection. A dose of as little as 15-20 organisms can cause illness. The symptoms of infection include gastroenteritis. *Salmonella* is shed in the feces of infected animals and can contaminate pasture land and milking parlors.

EHEC O157:H7 and other enterohemorrhagic *Escherichia coli* - The infectious dose of EHEC 0157:H7 is estimated to be between 10-100 organisms. When food contaminated with the EHEC O157:H7 is consumed, the pathogen colonizes the intestinal tract where it produces a

toxin and causes haemorrhagic colitis that can progress to more serious complications such as haemolytic uraemic syndrome or thrombotic thrombocytopenic purpura. EHEC O157:H7 is the predominant EHEC strain that has caused illness worldwide. However, other EHEC serotypes have also been implicated in illness and are of public health concern.

Campylobacter jejuni - A dose of 400-500 organisms of *Campylobacter jejuni* can cause infection. Symptoms of infection include abdominal pain, fever, diarrhea, and vomiting. *Campylobacter jejuni* can either be shed in feces or in milk from an infected udder of a dairy animal. Most human outbreaks of infection of *Campylobacter jejuni* that are associated with dairy products have been linked to raw milk or inadequately pasteurized milk.

Yersinia enterocolitica - *Yersinia enterocolitica* is a pathogen which causes infection. Symptoms of infection include gastroenteritis, fever, diarrhea, bloody stools, rash, joint pain, nausea, vomiting, headache, and malaise. Infection by *Yersinia enterocolitica* is also considered a cause of reactive arthritis. *Yersinia enterocolitica* has been found in many different animals and is shed in feces.

Clostridium botulinum - *Clostridium botulinum* produces a neurotoxin. A few nanograms (ng) of the neurotoxin can cause illness. Symptoms include lassitude, weakness, vertigo, double-vision, difficulty speaking, and difficulty swallowing. Symptoms can progress to difficulty of breathing, weakness of other muscles, abdominal distention, and constipation. The incidence of this disease is low, but the mortality rate is high if not treated immediately and properly. Although the neurotoxin is heat labile and can be destroyed when exposed to a minimum of 80 oC for 10 minutes, the time and temperature reached in pasteurization do not destroy the neurotoxin.

Enterotoxigenic *Staphylococcus* – Some species of *Staphylococcus* produce an enterotoxin that is extremely heat stable and is not inactivated at pasteurization

temperatures. When ingested, the enterotoxin may rapidly produce symptoms including nausea, vomiting, retching, abdominal cramps, muscle cramping, headache, and transient changes in blood pressure and pulse rate. The presence of any *Staphylococcus* enterotoxin in a dairy product is of public health concern.

A dairy cow with mastitis may be the source of enterotoxigenic *Staphylococcus* in raw milk, which may subsequently be commingled with other milk. Also, at any point from the milk collection process to the packaging of the finished product, enterotoxigenic *Staphylococcus* species can be introduced by an infected human, inadequate employee hygienic practices, such as inadequate hand washing, equipment and utensils that are not cleaned and sanitized, or contaminated raw material.

Staphylococcus aureus has traditionally been used as a microbiological indicator of insanitation during processing. Because of environmental factors, low levels of *Staphylococcus aureus* may be found in raw milk, even when produced using good manufacturing practices (GMPs). However, excessive numbers of *Staphylococcus aureus* organisms in raw milk or other dairy products, i.e., greater than or equal to 104 cfu/g, indicate that the product was produced under insanitary conditions.

Bacillus cereus - *Bacillus cereus* can cause illness when 106 cfu/g or more are consumed in food. There have been two enterotoxins produced by *Bacillus cereus* identified as causing foodborne illness. Illness is characterized by abdominal pain and diarrhea or nausea and vomiting. *Bacillus cereus* is commonly found in soil, on vegetables, and in many raw and processed foods, including milk and cheese.

Additional information about foodborne pathogens and associated diseases can be found in the Bad Bug Book.

B. Nontoxigenic *Escherichia coli*

Escherichia coli has traditionally been used as a microbiological indicator of insanitation during processing. *Escherichia coli* are not inherently present in the milk of a dairy animal. *Escherichia coli* in milk and dairy products generally originate from animal or human feces. Thus, the presence of *Escherichia coli* in milk or other dairy product means that the milk or dairy product was exposed either directly or indirectly to feces.

Because of the close association of raw milk with the animal environment, low levels of *Escherichia coli* may be present in raw milk or products made from raw milk, even when properly produced using GMPs. Insanitary conditions, including poor employee hygiene practices, improperly sanitized utensils and equipment, or contaminated raw materials, may also be a source of *Escherichia coli* in milk and other dairy products.

C. Alkaline phosphatase

Alkaline phosphatase is an enzyme that is naturally found in milk. Although the alkaline phosphatase in milk is more thermal resistant than nonsporeforming microorganisms, it is denatured by pasteurization temperatures. Therefore, the presence of alkaline phosphatase indicates the milk was not properly pasteurized. The alkaline phosphatase

level should be negligible in dairy products, other than certain cheese and cheese products.

For some dairy products such as certain cheeses, microorganisms used during production produce alkaline phosphatase. For some cheeses, the maximum level of alkaline is established in the standard of identity for the cheese (21 CFR part 133). For other cheese and related cheese

products required to be made from pasteurized milk, the alkaline phosphatase level should not be greater than 3 µg/0.25 g (12 micrograms phenol equivalents per gram).

III. Policy:

FDA will review the available evidence on a case-by-case basis to determine whether a dairy product is adulterated and, in doing so, will be guided but not bound by the following general statements of policy relating to the presence in those products of pathogens, nontoxigenic *Escherichia coli*, or alkaline phosphatase.

A. Pathogens

***Salmonella* species, EHEC O157:H7 and other enterohemorrhagic *Escherichia coli*, *Campylobacter jejuni*, *Yersinia enterocolitica*, vegetative cells of *Clostridium botulinum*, *Clostridium botulinum* toxin, *Staphylococcus* enterotoxin, or *Bacillus cereus* enterotoxin**

Dairy products may be considered adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342 (a)(1)) in that they bear or contain a poisonous or deleterious substance which may render them injurious to health when *Salmonella* species, EHEC O157:H7 and other enterohemorrhagic *Escherichia coli*, *Campylobacter jejuni*, *Yersinia enterocolitica*, vegetative cells of *Clostridium botulinum, Clostridium botulinim* toxin, *Staphylococcus* enterotoxin, or *Bacillus cereus* enterotoxin are present.

Staphylococcus aureus

Dairy products may be considered adulterated within the meaning of section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health when *Staphylococcus aureus* are present at levels greater than or equal to 104 cfu/g.

Bacillus cereus

Dairy products may be considered adulterated within the meaning of section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health when *Bacillus cereus* are present at levels greater than or equal to 104 cfu/g.

B. Nontoxigenic *Escherichia coli*

Dairy products may be considered adulterated within the meaning of section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth when

Escherichia coli is found at levels greater than 10 MPN per gram in two or more subsamples or greater than 100 MPN per gram in one or more subsamples.

C. Alkaline phosphatase

Dairy products made from bovine milk may be considered adulterated within the meaning of section 402(a)(4) of the Act (21 U.S.C. 342 (a)(4)) when:

• For cheese and related cheese products required to be made from pasteurized milk (21 CFR part 133), alkaline phosphatase levels are:

o Greater than 5 µg/0.25 g (20 micrograms phenol equivalents per gram) in one or more subsamples for brick (21 CFR 133.108), semisoft (21 CFR 133.187), and semisoft part-skim cheeses (21 CFR 133.188);

o Greater than 4 µg/0.25g (16 micrograms phenol equivalents per gram) in one or more subsamples for Limburger cheese (21 CFR 133.152); or

o Greater than 3 µg/0.25 g (12 micrograms phenol equivalents per gram) in one or more subsamples for all other cheese and related cheese products.

• For dairy products other than cheese and related cheese products, alkaline phosphatase level is greater than or equal to 2.0 micrograms phenol equivalents per gram in one or more subsamples.

IV. Regulatory Action Guidance:

Interstate Milk Shippers

Dairy products produced in an Interstate Milk Shippers (IMS) listed plant that may be considered adulterated under the Act should first be referred to the appropriate State regulatory agency for follow-up. This includes a non-IMS product manufactured in an IMS-listed plant for which the State is providing a regulatory program to address these issues. If the State is unable to take appropriate action, the appropriate program field office should proceed to initiate FDA action as indicated below.

Direct Reference

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, for direct reference import detention by the appropriate division within the Human and Animal Food Program, and for direct reference requests for detention without physical examination (DWPE) to ORA, Office of Enforcement and Import Operations (OEIO) *:

Analysis of the dairy product demonstrates that one or more subsamples is positive for *Salmonella* species, *Campylobacter jejuni*, *Yersinia enterocolitica*, *Staphylococcu*s enterotoxin, or *Bacillus cereus* enterotoxin.

Recommendations

The following represent criteria for recommending seizure, import detention, or DWPE to CFSAN/Office of Compliance/Division of Enforcement (HFS-605):

1. For all dairy products:

. EHEC O157:H7 or other enterohemorrhagic *Escherichia coli*, or vegetative cells of *Clostridium botulinum*, or *Clostridium botulinum* toxin found in one or more subsamples; or

. *Escherichia coli* found at levels greater than 10 MPN per gram in two or more subsamples or greater than 100 MPN per gram in one or more subsamples; or

. *Staphylococcus aureus* found at levels greater than or equal to 104 cfu/g in one or more subsamples; or

. *Bacillus cereus* found at levels greater than or equal to 104 cfu/g in one or more subsamples.

. 2. For cheese and related cheese products made from pasteurized bovine milk:

. • Alkaline phosphatase level in:

. o Brick, semisoft, and semisoft part-skim cheeses - greater than 5 µg/0.25 g (20 micrograms phenol equivalent per gram) in one or more subsamples;

. o Limburger cheese - greater than 4 µg/0.25g (16 micrograms phenol equivalent per gram) in one or more subsamples for Limburger cheese;

. o All other cheese and related cheese products - greater than 3 µg/0.25g (12 micrograms phenol equivalent per gram) in one or more subsamples.

3. For all other dairy products made from bovine milk, except cheese and related cheese products:

. Alkaline phosphatase level is greater than or equal to 2.0 micrograms phenol equivalents per gram in one or more subsamples.

Other Considerations

This guidance does not establish acceptable levels of pathogens, nontoxigenic *Escherichia coli*, or alkaline phosphatase in dairy products. FDA may choose to take action against adulterated food that does not meet the criteria under this Section.

V. Specimen Charges:

Domestic Seizure

A. Pathogens

***Salmonella* species, EHEC O157:H7 or other enterohemorrhagic *Escherichia coli, Campylobacter jejuni, Yersinia enterocolitica,* vegetative cells of *Clostridium botulinum, Clostridium botulinum* toxin, *Staphylococcus* enterotoxin, *Bacillus cereus* enterotoxin**

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely _____, which may render it injurious to health.

Staphylococcus aureus

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C. 342(a)(4), in that it has been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.

Bacillus cereus

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C. 342(a)(4), in that it has been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.

B. Nontoxigenic *Escherichia coli*

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of the

Act, 21 U.S.C. 342(a)(4), in that it has been prepared, packed, and held under insanitary conditions whereby it may have become contaminated with filth.

C. Alkaline phosphatase

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of the Act, 21 U.S.C. 342(a)(4), in that it has been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.

Import Detention

A. Pathogens

***Salmonella* species, EHEC O157:H7 or other enterohemorrhagic *Escherichia coli, Campylobacter jejuni, Yersinia enterocolitica,* vegetative cells of *Clostridium botulinum, Clostridium botulinum* toxin, *Staphylococcus* enterotoxin, *Bacillus cereus* enterotoxin**

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous and deleterious substance, namely , which may render it injurious to health.

Staphylococcus aureus

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that it has been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.

Bacillus cereus

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that it has been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.

B. Nontoxigenic *Escherichia coli*

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that it has been prepared, packed, and held under insanitary conditions whereby it may have become contaminated with filth.

C. <u>Alkaline phosphatase</u>

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that it has been prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.*

Material between asterisks is new or revised.

Issued: 10/1/80 Revised: 7/1/83, 8/1/86, 3/95, 8/96, 12/2010

COMPLIANCE POLICY GUIDE (CPG)

CPG Sec 555.320 Listeria monocytogenes

FEBRUARY 2008

Draft

Not for implementation. Contains non-binding recommendations.

Issued by:

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Contains Nonbinding Recommendations
Draft - Not for Implementation

Compliance Policy Guide
Guidance for FDA Staff
Sec. 555.320
Listeria monocytogenes

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1400.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs
February 2008

TABLE OF CONTENTS

Compliance Policy Guide
Guidance for FDA Staff
Sec. 555.320
Listeria monocytogenes

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. INTRODUCTION:

The purpose of this Compliance Policy Guide is to provide guidance to FDA Staff on FDA's enforcement policy for *Listeria monocytogenes* (*L. monocytogenes*) in foods.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND:

L. monocytogenes is a pathogenic bacterium that is widespread in the environment and may be introduced into a food processing facility. *L. monocytogenes* can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, illness (called invasive listeriosis). Foods that have been implicated in outbreaks of invasive listeriosis have been foods that are ready-to-eat (RTE).

RTE foods can be contaminated if ingredients in the foods are contaminated with *L. monocytogenes* and are not treated to destroy viable cells of this pathogen, or if *L. monocytogenes* is allowed to contaminate the RTE food because of improper sanitary conditions or practices. Most RTE foods do not contain detectable numbers of *L. monocytogenes*. For many RTE foods, contamination with *L. monocytogenes* can be avoided – *e.g.*, through the application of current good manufacturing practice requirements that establish controls on ingredients, listericidal processes, segregation of foods that have been cooked from those that have not, and sanitation. Sanitation controls include effective environmental monitoring programs designed to identify and eliminate *L. monocytogenes* in and on surfaces and areas in the plant.

In 2003, FDA and the Food Safety and Inspection Service of the United States Department of Agriculture, in consultation with the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, released a quantitative assessment (the Risk Assessment) of relative risk associated with consumption of certain categories of RTE foods that had a history of contamination with *L. monocytogenes*, or that were implicated epidemiologically with an outbreak or a sporadic case of listeriosis. The Risk Assessment estimated that the risk of listeriosis would vary widely among these food categories.

According to the Risk Assessment, foods estimated to pose the highest risk of being associated with listeriosis are RTE foods that support the growth of *L. monocytogenes*. Examples of RTE foods that support the growth of *L. monocytogenes* include:

- Milk;
- High fat and other dairy products (*e.g.*, butter and cream);
- Soft unripened cheeses (greater than 50 percent moisture) (*e.g.*, cottage cheese and ricotta cheese);
- Cooked crustaceans (*e.g.*, shrimp and crab);
- Smoked seafood (*e.g.*, smoked finfish and mollusks);
- Raw seafood that will be consumed as sushi or sashimi;
- Many vegetables (such as broccoli, cabbage, and salad greens);
- Non-acidic fruit (such as melon, watermelon, and papaya); and
- Some deli-type salads and sandwiches (particularly those containing seafood and those prepared at retail establishments without acidification and/or the addition of antimicrobial substances).

In contrast, the foods estimated to pose the lowest risk of being associated with listeriosis are foods that, because of intrinsic factors, extrinsic factors, and/or processing factors do not support the growth of *L. monocytogenes*. Intrinsic factors include chemical and physical factors that are normally within the structure of the food, *e.g.*, pH and water activity. Extrinsic factors are those that refer to the environment surrounding the food, e.g., storage temperature. Processing factors include substances added to adjust the pH of food (e.g., acids) and substances that, alone or in combination with other substances, have antimicrobial properties (e.g., sorbates and benzoates). It is well established that *L. monocytogenes* does not grow when:

- The pH of the food is less than or equal to 4.4;
- The water activity of the food is less than or equal to 0.92; or
- The food is frozen.

Foods may naturally have a pH or water activity that prevents growth of *L. monocytogenes* or processing factors may be deliberately used to achieve those characteristics (*e.g.*, by adding acid to deli-type salads to bring the pH to less than or equal to 4.4). At pH values above 4.4, processing factors generally are used in combination to prevent the growth of *L. monocytogenes* (e.g., sorbates or benzoates may be used in combination with organic acids such as acetic acid, lactic acid, and citric acid in foods such as deli-type salads). The effectiveness of a particular listeristatic control measure in preventing growth in a particular RTE food generally is determined case-by-case, for example, using the results of growth studies specific to the food matrix.

Examples of RTE foods that generally are considered to not support the growth of *L. monocytogenes* include:

- Fish that are preserved by techniques such as drying, pickling, and marinating;
- Ice cream and other frozen dairy products;
- Processed cheese (*e.g.*, cheese foods, spreads, slices);
- Cultured milk products (*e.g.*, yogurt, sour cream, buttermilk);
- Hard cheeses (less than 39 percent moisture) (*e.g.*, cheddar, colby, and parmesan);
- Some deli-type salads, particularly those processed to a pH less than 4.4 and those containing antimicrobial substances such as sorbic acid/sorbates or benzoic acid/benzoates under conditions of use documented to be effective in preventing the growth of *L. monocytogenes*;
- Some vegetables (such as carrots); and
- Crackers, dry breakfast cereals, and other dry foods.

Fruits, vegetables, and cheeses (e.g., soft and semi-soft cheeses) not listed in this CPG may include some products that support growth as well as other products that do not support growth.

III. **POLICY:**

FDA will review the available evidence on a case-by-case basis to determine if a food is a RTE food that supports growth or a RTE food that does not support growth.

A. **Ready-to-Eat Food**

"Ready-to-eat food" (RTE food) means a food that is customarily consumed without cooking by the consumer, or that reasonably appears to be suitable for consumption without cooking by the consumer.

A food may be considered to be suitable for consumption without cooking by the consumer, and thus a RTE food, even though cooking instructions are provided on the label. For examples, fresh and frozen crabmeat and individually quick frozen (IQF) peas and corn may be RTE foods. Some consumers eat such products without cooking, because they appear to be ready-to-eat.

B. **Ready-to-Eat Foods that Support Growth of *L. monocytogenes***

Generally, we intend to consider that a RTE food will support the growth of *L. monocytogenes* if it does not meet the characteristics of a RTE food that does not support growth, as indicated in section III.C.

FDA may regard a RTE food that supports growth of *L. monocytogenes* to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act; the FD&C Act) (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present in the food based on the detection method indicated in section IV.A.

C. **Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes***

A RTE food does not support the growth of *L. monocytogenes* if the food:

- Has a pH that is less than or equal to 4.4; or
- Is customarily held and consumed in a frozen state; or
- Has a water activity that is less than 0.92; or
- Is processed using an effective listeristatic control measure (e.g., an antimicrobial substance or a combination of factors such as pH, water activity, and antimicrobial substances).

FDA may regard a RTE food that does not support the growth of *L. monocytogenes* to be adulterated within the meaning of section 402(a)(1) of the Act (21 U.S.C. 342(a)(1)) when *L. monocytogenes* is present at or above 100 colony forming units per gram of food (cfu/g)

IV. **REGULATORY ACTION GUIDANCE:**

A. **Ready-to-Eat Foods that Support Growth of *L. monocytogenes***

The following represents criteria for recommending legal action to CFSAN/Office of Compliance/Division of Enforcement (HFS-605):

- *L. monocytogenes* is detected in one or more subsamples of a RTE food that supports the growth of *L. monocytogenes*.

Use Bacteriological Analytical Manual Online, Chapter 10 - "*Listeria monocytogenes*," "Detection and Enumeration of *Listeria monocytogenes* in Foods" as the method for detecting and confirming presence of *L. monocytogenes* (available at http://www.cfsan.fda.gov/~ebam/bam-10.html (http://www.cfsan.fda.gov/~ebam/bam-10.html)).

B. **Ready-to-Eat Foods that Do Not Support Growth of *L. monocytogenes***

Consult with CFSAN/Office of Compliance/Division of Enforcement (HFS-605) before recommending legal action for RTE foods that do not support the growth of *L. monocytogenes*. Use ISO 11290-2:1998(E) "Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of *Listeria monocytogenes* - Part 2: Enumeration method" as the method for enumerating *L. monocytogenes*. (ISO 11290-2:1998/Amd. 1:2004(E) "Microbiology of food and animal feeding stuffs - Horizontal method for the detection and enumeration of *Listeria monocytogenes* - Part 2: Enumeration method AMENDMENT 1: Modification of the enumeration medium" amends ISO 11290-2:1998(E). The amendment uses ALOA agar instead of PALCAM agar. If ALOA agar is not commercially available in the United States, use PALCAM according to ISO 11290-2:1998(E)). ISO methods are available from the International Organization for Standardization at http://www.iso.org/iso/en/ISOOnline.frontpage (http://www.iso.org/iso/en/ISOOnline.frontpage) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Use rapid biochemical test kits according to the Bacteriological Analytical Manual Online, Chapter 10 – "Detection and Enumeration of *Listeria monocytogenes* in Foods" Section E-11 (available at http://www.cfsan.fda.gov/~ebam/bam-10.html (http://www.cfsan.fda.gov/~ebam/bam-10.html)), instead of ISO 11290-2:1998(E) Section 9.5, for confirmation of *L. monocytogenes* isolates.

C. **Foods that are Not RTE Foods**

Consult with CFSAN/Office of Compliance/Division of Enforcement (HFS-605) when *L. monocytogenes* is present in a food that is not a RTE food.

D. **Other Considerations**

The criteria in this guidance do not establish an acceptable level of *L. monocytogenes* in food. FDA may choose to take legal action against adulterated food that does not meet the criteria for recommending legal action to CFSAN.

Further, the criteria in this guidance do not excuse violations of the requirement in section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)) that food may not be prepared, packed, or held under insanitary conditions or the requirements in FDA's good manufacturing practices regulation (21 CFR part 110). As set out in 21 CFR 110.80, food manufacturers must take "[a]ll reasonable precautions ... to ensure that production procedures do not contribute contamination from any source."

V. **SPECIMEN CHARGES:**

A. **Domestic Seizure**

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within the meaning of the Act, 21 U.S.C. 342(a)(1), in that it bears and contains a poisonous or deleterious substance, namely *Listeria monocytogenes*, which may render it injurious to health.

B. **Import Detention**

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(1) of the FD&C Act in that it bears and contains a poisonous or deleterious substance, *Listeria monocytogenes*, which may render it injurious to health.

Issued: [insert date]

CPG Sec. 540.275 Crabmeat – Fresh and Frozen – Adulteration with Filth, Involving the Presence of *Escherichia coli*

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services

Food and Drug Administration

Center for Food Safety and Applied Nutrition

Office of Regulatory Affairs

April 2016

Table of Contents

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction:

The purpose of this document is to provide guidance for FDA staff on adulteration with filth involving the presence of *Escherichia coli* in fresh and frozen crabmeat. In the remainder of this guidance, “we” or “our” refers to FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Escherichia coli (*E. coli*) has traditionally been used as a microbiological indicator of insanitation during processing. *E. coli* is commonly associated with feces of warm blooded animals. Its presence in foods and water suggests fecal contamination. In the production of

commercially processed fresh or frozen crabmeat, the cook step (boiling or steaming the in-shell crabs) destroys nonsporeforming bacteria including *E. coli*, if they are present on the raw product. Therefore, the presence of *E. coli* in finished product indicates that either the cook step was inadequate or the product was recontaminated after the cook step. As applied to fresh or frozen crabmeat discussed in this CPG, cooking is a heat treatment, usually performed before the product is placed in the finished product container and distributed either refrigerated or frozen.

Recontamination of the crabmeat after the cook step could be a result of either insanitary practices by the employees in the processing plant or the presence of insects in the processing plant that may have served as vectors for the dissemination of bacteria to the food after the cook step. Strict in-plant sanitation measures should be instituted to prevent the presence of *E. coli* in the finished product. Although most strains of *E. coli* are harmless, some strains can cause severe illness. The confirmed presence of *E. coli* at levels of 3.6 Most Probable Number per gram (MPN/g) or greater in crabmeat indicates insanitary conditions, which may include poor employee hygiene practices, improperly sanitized utensils and equipment, or insects or other pests.

III. Policy

FDA may consider that crabmeat has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth and, thus, is adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)) when, based on examination of a sample consisting of a minimum of six subsamples of fresh or frozen crabmeat:

• *E. coli* at levels of 3.6 MPN/g or greater is present in two or more of six subsamples, with or without inspectional evidence to indicate the most probable source of the *E. coli*, or

• *E. coli* at levels of 3.6 MPN/g or greater is present in only one of six subsamples, and available inspectional evidence indicates the most probable source of the *E. coli* (i.e., evidence demonstrating an inadequate cook step or likely contamination after cooking). Such inspectional evidence may include observed insanitary conditions, such as poor employee hygiene practices, improperly sanitized utensils and equipment, the presence of insects or other pests, and possible routes of contamination of the cooked crabs or crabmeat (e.g., contact between raw crabmeat and cooked crabs or crabmeat).

Under section 801(a)(3) of the FD&C Act (21 U.S.C. 381(a)(3)), FDA may refuse admission of crabmeat that is offered for import into the United States and that appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act.

IV. Regulatory Action Guidance

Direct Reference

The following represents criteria for direct reference seizure recommendations to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

When upon examination of a sample consisting of a minimum of six subsamples of fresh or frozen crabmeat, *E. coli* at levels of 3.6 MPN/g or greater is present in two or more of six subsamples, with or without inspectional evidence to indicate the most probable source of the *E. coli*.

Recommendations

The following represent criteria for recommending seizure or import refusal to CFSAN, Office of Compliance, Division of Enforcement (HFS-605): When upon examination of a sample consisting of a minimum of six subsamples of fresh or frozen crabmeat, *E. coli* at levels of 3.6 MPN/g or greater is present in only one of six subsamples, and available inspectional evidence indicates the most probable source of the *E. coli*.

Available inspectional evidence indicating the most probable source of the *E. coli* (i.e., evidence demonstrating an inadequate cook step or likely contamination after cooking) should be included in the recommendation. Such inspectional evidence may include observed insanitary conditions, such as poor employee hygiene practices, improperly sanitized utensils and equipment, the presence of insects or other pests, and potential routes of contamination of the cooked crabs or crabmeat (e.g., contact between raw crabmeat and cooked crabs or crabmeat).

While assessing recommendations based on the criteria above, the Division of Enforcement will also assess whether a charge under section 402(a)(3) of the FD&C Act (21 U.S.C. 342(a)(3)) can be supported.

V. Specimen Charges

Domestic Seizure

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(a)(4), in that the food has been prepared, packed, and held under insanitary conditions whereby it may have been contaminated with filth.

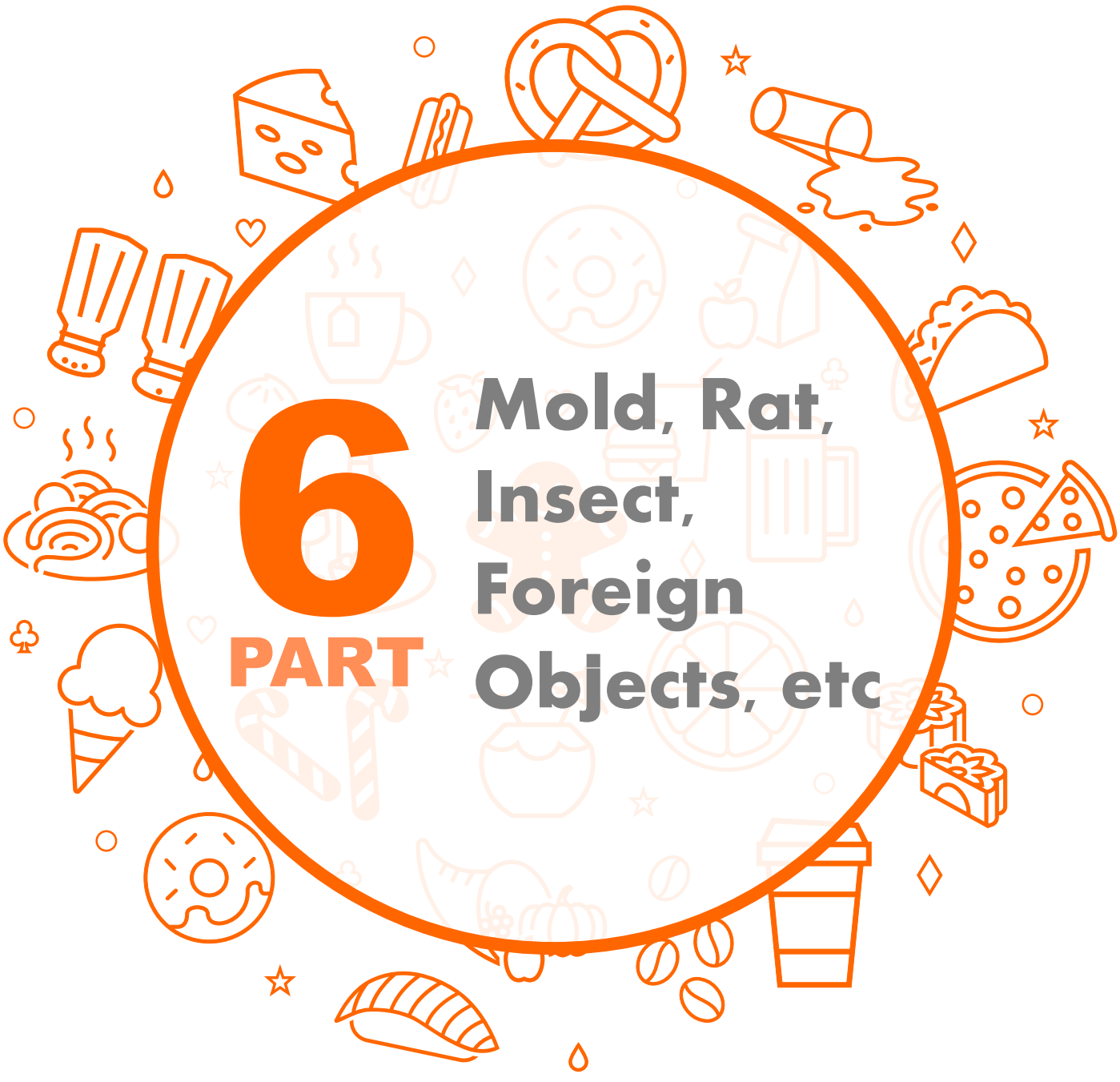
Import Refusal

The article of food is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be adulterated within the meaning of section 402(a)(4) of the FD&C Act in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth.*

Material between asterisks is new or revised

Issued: 10/1/82

Revised: 10/30/89, 3/95, 5/2005, 11/29/2005, 4/25/2016



PART 6

Mold, Rat, Insect, Foreign Objects, etc

CPG Sec. 540.590 Fish - Fresh and Frozen, as Listed - Adulteration by Parasites

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure recommendations to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

Parasite findings meet or exceed the following tolerances:

1. Tullibees, Ciscoes, Inconnus, Chubs and White Fish
   50 cysts per 100 pounds (whole fish or fillets), provided that 20% of the fish examined are infested.

2. Blue Fin and Other Fresh Water Herring

   a. Fish averaging one pound or less:
      60 cysts per 100 fish, provided that 20% of the fish examined are infested.

   b. Fish averaging over one pound:
      60 cysts per 100 pounds of fish, provided that 20% of the fish examined are infested.

3. Rose Fish (Red Fish and Ocean Perch):
   3 percent of the fillets examined contain one or more copepods accompanied by pus pockets.

REMARKS:

If there is reason to believe that a lot was packed under the supervision of or certified by the National Marine Fisheries Service National Oceanic and Atmospheric Administration, US Department of Commerce, *e-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number

Article Involved

Amount of Lot

Codes

Date of Shipment

Dealer

Shipper

Analytical Conclusions

SPECIMEN CHARGE:

The article was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce within meaning of 21 U.S.C. 342(a)(3), in that it consists wholly or in part of a filthy substance by reason of presence therein of parasitic cysts.

Material between asterisks is new or revised.

Issued: 10/1/80
Revised: 10/30/89, 3/95, 5/2005
Updated: 11/29/2005

CPG Sec. 550.100 Apple Butter - Adulteration with Mold; Rodent Filth, Insect

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

A minimum of six subsamples is required for examination.

1. Mold: The apple butter has an average mold count of 12% or more;

or

2. Rodent Filth: The apple butter contains an average of 4 or more rodent hairs per 100 grams;

or

3. Insects: The apple butter contains an average of 5 or more whole or equivalent insects (not counting mites, aphids, thrips or scale insects) per 100 grams.

REMARKS:

Seizures of canned apple butter must be discussed with the U.S. Department of Agriculture. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number	Date of Shipment
Article Involved	Dealer
Amount of Lot	Shipper
Codes	Analytical Conclusions

SPECIMEN CHARGE:

Article adulterated when introduced into and while in interstate commerce, within the meaning of 21 U.S.C. 342(a)(3), in that it consists wholly or in part of a filthy substance by reason of presence therein of insects and rodent hairs; and of a decomposed substance by reason of presence therein of decomposed apple butter.

CPG Sec. 550.150 Apricots - Canned - Adulteration with Insects

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

A minimum of 10 subsamples is required for examination.

The apricots contain an average of 2 percent or more by count of insect infested or insect damaged fruit.

REMARKS:

Seizures of these products must be discussed with the U.S. Department of Agriculture. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number

Date of Shipment

Article Involved

Dealer

Amount of Lot

Shipper

Codes

Analytical Conclusions

SPECIMEN CHARGE:

Article adulterated when introduced into and while in interstate commerce within the meaning of 21 U.S.C. 342(a)(3) in that it consists wholly or in part of a filthy substance by reason of presence therein of insects, insect fragments, insect webbing, insect excreta and insect damaged apricots.

CPG Sec. 550.155 Apricot, Peach and Pear Nectars and Purees - Adulteration with Mold

REGULATORY ACTION GUIDANCE:

1. Apricot, Peach and Pear Nectars

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

If the average Howard mold count for six or more subsamples is 12% or above.

2. Apricot, Peach and Pear Purees

The following represents criteria for recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

If the average Howard mold count for six or more subsamples of purees is 12% or above.

REMARKS:

After mixing nectar or puree well, make mold count according to the procedure specified in 44.096 AOAC, 13th edition, that begins "Clean Howard cell ..."

After September 16, 1983, prepared nectar and puree samples according to the AOAC Official First Action method for Howard mold count of Fruit Nectars, Purees, and Pastes.

Seizures involving these products must be discussed with the U.S. Department of Agriculture because some lots may have been graded by them. Submit the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number

Date of Shipment

Article Involved

Dealer

Amount of Lot

Shipper

Codes

Analytical Conclusions

SPECIMEN CHARGE:

Article (apricot/peach/pear nectar) (apricot/peach/pear puree) adulterated (when introduced into and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of 21 U.S.C. 342(a)(3), in that it consists in part of a decomposed substance by reason of presence therein of (moldy/decomposed apricot/peach/pear material) (mold).

NOTES:

1. Samples of nectars and infant food purees (apricot, peach, pear) collected during the FY 1977 Retail Market Survey contained such low levels of insect and rodent filth that an action level is not established for such filth. However, since this indicates that significant amounts of insect and rodent filth are avoidable, the absence of an action level does not preclude recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) based on findings of relatively low levels of insect and/or rodent filth in either infant or adult foods.

2. Only use direct citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory issuances.

Material between asterisks is new or revised

Issued: 4/1/83
Revised: 3/95, 5/2005

Updated: 11/29/05

CPG Sec. 550.200 Drupelet Berries (Blackberries, Raspberries, Etc.) - Common or Usual Names of Varieties; Canned and Frozen - Adulteration with Rot and Insects

BACKGROUND:

There has been much confusion about the labeling of foods containing various varieties of blackberries. Certain varieties of blackberries are known by specific names. The standard of identity for canned berries designates blackberries, boysenberries, dewberries, loganberries, and youngberries as the names for varieties of berries. The standards of identity for fruit jelly, preserves, and jams were based in part on a finding of fact that stated:

Botanically, blackberries are divided into two general classes of varieties, the first class being those which grow with erect canes and are commonly known as blackberries, and the second being those which grow with trailing canes and as a class are sometimes referred to as dewberries. Three varieties of the second class are commonly known as boysenberries, loganberries, and youngberries, and the other varieties of that class are commonly known as dewberries.

In the past, we have expressed the opinion that the olallie variety of blackberry should be designated on labels as "olallieberries" or "olallie blackberries." However, we have now learned that this is a variety of dewberry, growing on trailing canes as do the boysenberry, loganberry, and youngberry. Hence it may be designated either by the name "dewberries" or by its own specific common or usual name. The standards do not mention the olallieberry, therefore, it should be designated on labels for preserves, jam and the canned article by the term "dewberries."

POLICY:

For purposes of label declarations in accordance with Section 403(i) of the Act, the terms "boysenberry," "loganberry" and "youngberry" are each considered the common or usual name, respectively, for specific varieties of blackberries. These names are also recognized by the standards of identity for jelly, preserves, jams, and canned berries *(21 CFR 150.140, 21 CFR 150.160, and 21 CFR 145.120, respectively).*

The term "dewberries" is considered the specific common or usual name for varieties of blackberries that are obtained from trailing canes. Olallieberries should be designated as "dewberries," when used in standard jelly, preserves, jams, and canned berries. Olallieberries may also be designated as "dewberries" when used in nonstandardized foods such as pies.

However, we have not objected to use of the specific name "olallieberries." The term "olallie blackberries" should not be used since it may be misleading for berries which are now specifically designated as dewberries. The term "blackberries" is considered an acceptable common or usual name for the labeling of any variety of blackberries obtained from erect canes.

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *review to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

1. Rot
   The berries have an average mold count of 60% or more.

or

2. Insects
   a. The berries contain an average of 4 or more larvae per 500 grams.

or

b. The berries contain an average of 10 or more whole insects or equivalent (excluding thrips, aphids, and mites) per 500 grams.

REMARKS:

Seizures of these products must be discussed with the U.S. Department of Agriculture. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number
Article Involved
Amount of Lot
Codes

Date of Shipment
Dealer
Shipper
Analytical Conclusions

SPECIMEN CHARGE:

1. Mold - Article adulterated when introduced into and while in interstate commerce, within the meaning of 21 U.S.C. 342(a)(3) in that it consists wholly or in part of a decomposed substance by reason or presence therein of decomposed raspberries.

2. Insects - Article adulterated when introduced into and while in interstate commerce, within the meaning of 21 U.S.C. 342(a)(3) in that it consists wholly or in part of a filthy substance by reason of presence therein of insects.

Material between asterisks is new or revised.

Issued: 10/1/80
Revised: 3/95, 5/2005

Updated: 11/29/05

CPG Sec. 550.225 Cherries Brined, Fresh, Canned and Frozen - Adulteration Involving Rot and Insect

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

Brined and maraschino - Maggots

The cherries contain an average of 5% or more rejects due to maggots.

Fresh, canned or frozen

1. Rot: The cherries contain an average of 7% or more rejects due to rot.

   or

2. Insects other than maggots: The cherries contain an average of 4% or more rejects due to insects other than maggots.

SPECIMEN CHARGE:

Article adulterated (when introduced into and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of *21 U.S.C. 342(a)(3),* in that it consists in part of a (filthy) (decomposed) substance by reason of the presence therein of (maggots) (insects) (rotten/decomposed cherries).

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

Material between asterisks is new or revised

Issued: 11/1/81
Revised: 3/95, 5/2005

Updated: 11/29/05

CPG Sec. 550.235 Cherry Jam - Adulteration with Mold

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

The jam has an average Howard mold count of 30% or more.

SPECIMEN CHARGE:

Article adulterated (when introduced into and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of 21 U.S.C. 342(a)(3), in that it consists in part of a decomposed substance by reason of the presence therein of mold.

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

Material between asterisks is new or revised.

Issued: 10/1/80
Revised: 11/1/81, 3/95

CPG Sec. 550.250 Citrus Fruit Juices, Canned - Adulteration with Fly Filth and Mold

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

1. Canned Citrus Juices (Single Strength)
    a. Mold Count

The canned juice has an average mold count of 10% or more

2. or
    a. Fly Filth
        i. The canned juice contains an average of 5 or more Drosophila and other fly eggs per 250 ml.

or

        ii. The canned juice contains an average of 1 or more Drosophila maggots per 250 ml.

3. Lemon and Lime Juice, et. al.

The above tolerances can be applied to citrus juices and are concentrates when they are converted to a single strength basis.

SPECIMEN CHARGE:

Article adulterated (when introduced into and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of 21 U.S.C. 342(a)(3), in that it consists in part of a (decomposed) (filthy) substance by reason of the presence therein of (mold) (flies/fly eggs/maggots).

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence

necessary to support a prosecution is specified in existing regulatory procedures issuances.

Material between asterisks is new or revised

Issued: 10/1/80
Revised: 11/1/81, 3/95

CPG Sec. 550.260 Cranberry Sauce - Adulteration with Mold

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

The average Howard Mold Count for six or more subsamples exceeds 15% or if the Howard Mold Count for any one subsample exceeds 50%.

SPECIMEN CHARGE:

Article adulterated (when introduced and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of 21 U.S.C. 342(a)(3), in that it consists in part of a decomposed substance by reason of the presence therein of moldy, decomposed cranberries.

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

Material between asterisks is new or revised

Issued: 10/1/80
Revised: 11/1/81, 3/95

CPG Sec. 550.270 Currants - Adulteration Involving Wormy Fruits

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *request to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

The currants contain an average of 5% or more wormy fruits, by count.

SPECIMEN CHARGE:

Article adulterated (when introduced and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of 21 U.S.C. 342(a)(3), in that it consists in part of a filthy substance by reason of the presence therein of wormy currants.

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

Material between asterisks is new or revised

Issued: 10/1/80, 11/1/81
Revised: 3/95

CPG Sec. 550.300 Dates and Date Material; Imported and Domestic - Adulteration Involving Mold, Insect Excreta, Sour, Dirty, Worthless and Pits

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN*, direct reference citation requests, and detention of imported products by the appropriate *Field Office within the Human and Animal Food Program*:

A. Dates - (Whole or Pitted) - Mold, dead insects, insect excreta, sour, dirty and worthless (e.g., mite infested, immature, grossly fibrous or woody, etc.) dates.

The sample (collected according to criteria in Table II), examined in accordance with the sequential analysis plan of Table I, shows a number of reject dates that meets or exceeds the indicated reject number.

See FDA Technical Bulletin Number 5, Macroanalytical Procedures Manual, pages V-53 through V-58 for (1) definitions of reject dates, (2) methodology for determining rejects, and (3) reporting requirements (including findings chart).

B. Pitted Dates - Pits

The dates contain an average of 2 or more pits and/or pit fragments 2 mm or longer measured in the longest dimension per 100 dates.

C. Date Material (Chopped, Sliced or Macerated) - Dead Insects, Pits

Examination of 100 gram representative portions from each subsample collected according to procedures in Table II, shows the following:

1. One or more subs contain 10 or more dead insects (whole or equivalent);

or

2. The dates contain an average of 5 or more dead insects (whole or equivalent) per 100 grams;

or

3. The dates contain an average of 2 or more pits and/or pit fragments 2 mm or longer measured in the longest dimension per 900 grams.

REMARKS

- skip –

CPG Sec. 550.350 Figs; Fig Paste - Adulteration Involving Insect Infestation; Mold, Dirt

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

1. Figs

The figs contain an average of 10% or more by count insect infested and/or moldy and/or dirty fruit or pieces of fruit.

2. Fig Paste

The fig paste contains 13 or more insect heads per 100 grams of fig paste in each of 2 or more subsamples when examined by AOAC methods of analysis, 44.083(a) and (b), AOAC 12th Ed. or 44.A02 1st Suppl. 12th Ed.

REMARKS:

Seizures involving these products must be discussed with the U.S. Department of Agriculture. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding.

Sample Number

Date of Shipment

Article Involved

Dealer

Amount of Lot

Shipper

Codes

Analytical Conclusions

SPECIMEN CHARGE:

Article adulterated when introduced into and while in interstate commerce, within meaning of 21 U.S.C. 342(a)(3) in that it consists wholly or in part of a filthy substance by reason of presence therein of insects, insect webbing, insect excreta, insect damaged figs; dirt; and of a decomposed substance by reason of presence therein of moldy, decomposed figs.

Material between asterisks is new or revised.

Issued: 10/1/80
Revised: 3/95, 5/2005

Updated: 11/29/05

CPG Sec. 550.450 Jam, Black Currant - Adulteration with Mold

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

The jam has an average Howard mold count of 75 percent or more.

SPECIMEN CHARGE:

Article adulterated (when introduced into and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of 21 U.S.C. 342(a)(3), in that it consists in part of a decomposed substance by reason of the presence therein of mold.

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

Material between asterisks is new or revised

Issued: 10/1/80
Revised: 11/1/81, 3/95

CPG Sec. 550.500 Lingon Berries, Canned - Adulteration by Insects

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

Of a minimum of 12 subsamples examined:

The canned lingon berries contain an average of 3 or more larvae per pound (net weight).

REMARKS:

Seizures of these products must be discussed with the U.S. Department of Agriculture. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number

Date of Shipment

Article Involved

Dealer

Amount of Lot

Shipper

Codes

Analytical Conclusions

SPECIMEN CHARGE:

Article adulterated when introduced into and while in interstate commerce within the meaning of 21 U.S.C. 342(a)(3) in that it consists wholly or in part of a filthy substance by reason of the presence therein of insects.

Material between asterisks is new or revised

CPG Sec. 550.590 Cloudberries (Multer Berries), Canned - Adulteration by Insects

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

The canned berries contain an average of 40 or more thrips per No. 2 can and 20% of the subs are materially infested.

SPECIMEN CHARGE:

Article adulterated (when introduced into and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of 21 U.S.C., 342(a)(3), in that it consists in part of a filthy substance by reason of the presence therein of thrips.

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

1Winton & Winton "Structure and Composition of Foods," Volume II, 1935.

Material between asterisks is new or revised

Issued: 10/1/80
Revised: 11/1/81, 3/95

CPG Sec. 550.600 Olives - Adulteration Involving Pits; Rot; Insect Infestation

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

1. PITS

    a. Pitted Whole - (Examine a minimum of 500 olives from each code or from the lot if no codes are present).

The average is 1.3 percent or more by count of olives with whole pits and/or pit fragments 2 mm or longer measured in the longest dimension.

    b. Pitted Salad Olives, Including Broken Pitted, Halved, Quartered, Sliced and Chipped or Minced - (Examine a minimum of 1,500 grams from each code or from the lot if no codes are present).

The average is 1.3 or more fragments per 300 grams, including whole pits and fragments 2 mm or longer measured in the longest dimension.

2. INSECT INFESTATION

    a. Salt Cured Olives - (Examine a minimum of 6 subs from each code or from the lot if no codes are present). The average is 10 percent or more by count of olives with 10 or more scale insects each.

    b. Imported Black - Actionable if 10 percent or more by count show damage by Dacusa (olive fruit fly).

    c. Imported Green - Actionable if 7 percent or more by count show damage by Dacusa (olive fruit fly).

    d. Salad Type, Including Broken, Pitted, Halved, Quartered, Sliced, and Chopped or Minced - (Actionable if 9 percent or more by weight of olives show damage by Dacusa (Olive fruit fly)

NOTE: "Damage by Dacus" means presence of any form or part thereof of the olive fruit fly and/or maggot tunneling affecting an area of 1/4 inch or greater average diameter.

3. ROT

Salt Cured Olives - (Examine a minimum of 6 subs from each code or from the lot if no codes are present).

The average is 25 percent or more by count of moldy olives.

COMPLIANCE POLICY GUIDE (CPG)

CPG Sec 550.650 Peaches, Canned, Frozen - Adulteration Due to Insects and Mold

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Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs

REGULATORY ACTION GUIDANCE:

The following represents the criteria for recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

1. The average of all subs is 3% or more wormy or moldy fruit by count;

   or

2. In twelve (12) one (1) pound cans or equivalent of canned or frozen peaches there is present one or more larvae and/or larval fragments whose aggregate length exceeds 5 mm.

CPG Sec. 550.680 Pineapple, Canned; Pineapple Juice - Adulteration with Mold

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

1. Pineapple, canned -- The average Howard mold count for six or more subsamples is 15% or more; or the Howard mold count for any subsample is 40% or more.

2. Pineapple Juice -- The average Howard mold count for six or more subsamples is 15% or more; or the Howard mold count for any one subsample is 40% or more.

Article (canned pineapple) (pineapple juice) adulterated (when introduced into and while in interstate commerce) (while held for sale after introduction into interstate commerce), within the meaning of 21 U.S.C. 342(a)(3), in that it consists in part of a decomposed substance by reason of the presence therein of (moldy/decomposed pineapple) (mold).

NOTE: Only use direct reference citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specific in existing regulatory procedures issuances.

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CPG Sec. 550.690 Plums, Canned - Adulteration with Rot

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure*requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

NOTE: Examine a minimum of 12 subsamples for the lot, or 6 subsamples for each violative code. Confirm rot microscopically by presence of mold.

The average for any code, or for the lot if no code is present, is 5% or more by count of plums with rot spots larger than the area of a circle 12 mm. in diameter.

REMARKS:

Seizures involving these products must be discussed with the U.S. Department of Agriculture. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number
Article Involved
Amount of Lot
Codes

Date of Shipment
Dealer
Shipper
Analytical Conclusions

SPECIMEN CHARGE:

Article adulterated when introduced into and while in interstate commerce, within meaning of 21 U.S.C. 342(a)(3) in that it consists wholly or in part of a decomposed substance by reason of presence therein of decomposed plums.

Material between asterisks is new or revised

CPG Sec. 550.700 Dried Prunes, Dehydrated Low Moisture Prunes, and Pitted Prunes - Adulteration Involving Insects; Decomposition; Dirt; Pits; and Pit Fragments

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

NOTE: Examine a minimum of ten subsamples.

1. Dried and Dehydrated Low Moisture Prunes - The average of the subsamples is 5 percent or more by count insect infested, moldy or decomposed, dirty and/or otherwise unfit prunes.
2. Pitted Prunes - Examination of a minimum of 50 prunes from each of 10 subs from each code, or from the lot if no codes are present, by microanalytical manual method M13K3 shows the following:

An average of 2% or more by count of prunes with whole pits and/or pit fragments 2mm or longer;

and

Four or more of the 10 subs examined contain 2% or more prunes by count with whole pits and/or pit fragments 2 mm or longer.

REMARKS:

Seizures of these products must be discussed with U.S.D.A. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number

Article Involved

Amount of Lot

Codes

Date of Shipment

Dealer

Shipper

Analytical Conclusions

SPECIMEN CHARGE:

1. Filth adulteration - Article adulterated when introduced into and while in interstate commerce, within the meaning of U.S.C. 342(a)(3) in that it consists wholly or in part of a filthy substance by reason of presence therein of insects, insect webbing, insect excreta, insect damaged prunes and dirt; and of a decomposed substance by reason of presence therein of moldy, decomposed prunes.

2. Pitted Prunes - Article adulterated when introduced into and while in interstate commerce, within the meaning of U.S.C. 342(b)(2) in that prunes with pits and/or pit fragments have been substituted wholly or in part for pitted prunes.

Article misbranded when introduced into and while in interstate commerce, within meaning of *21 U.S.C. 343(a)(1)* in that label statement "Pitted Prunes" is false and misleading as applied to a product containing prunes with pit fragments.

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CPG Sec. 550.750 Raisins - Adulteration Involving Mold, Sand, Grit, & Insects

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

NOTE: Examine a minimum of 10 subs from each code or from the lot if no codes are present.

MOLD: Natural raisins average 5 percent or more by count moldy.

SAND: The average is 40 milligrams or more of sand and grit per 100 grams of natural or Golden Bleached raisins.

INSECTS: The following represents the criteria for recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605):

Golden Bleached raisins contain an average of 10 or more whole insects or equivalent and 35 Drosophila eggs per 8 ounces.

REMARKS:

Seizure of this product must be discussed with the U.S. Department of Agriculture. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number
Article Involved
Amount of Lot
Codes

Date of Shipment
Dealer
Shipper
Analytical Conclusions

SPECIMEN CHARGE:

MOLD: Article adulterated when introduced into and while in interstate commerce, within meaning of 21 U.S.C. 342(a)(3) in that it consists wholly or in part of a decomposed substance by reason of presence therein of moldy, decomposed raisins.

SAND AND GRIT: Article adulterated when introduced into and while in interstate commerce, within meaning of 21 U.S.C. 342(a)(3) in that it is unfit for food by reason of presence therein of sand and grit.

Material between asterisks is new or revised

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CPG Sec. 550.850 Strawberries; Frozen, Whole, or Sliced - Adulteration with Sand, Mold

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

1. Mold: The strawberries have an average mold count of 45% or more and the mold count of at least one-half of the subsamples is 55% or more.

or

2. Sand: The berries taste gritty.

REMARKS:

Seizures involving these products must be discussed with the U.S. Department of Agriculture. *E-mail* or FAX the following information to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) and await reply before proceeding:

Sample Number
Article Involved
Amount of Lot
Codes

Date of Shipment
Dealer
Shipper
Analytical Conclusions

SPECIMEN CHARGE:

1. Article adulterated when introduced into and while in interstate commerce, within meaning of 21 U.S.C. 342(a)(3), in that it consists wholly or in part of a decomposed substance by reason of presence therein of decomposed strawberries.

2. Article adulterated when introduced into and while in interstate commerce, within meaning of 21 U.S.C. 342(a)(3), in that it is unfit for food by reason of being gritty to the taste.

CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects

BACKGROUND:
Hard or sharp foreign objects in food may cause traumatic injury including laceration and perforation of tissues of the mouth, tongue, throat, stomach and intestine as well as damage to the teeth and gums. From 1972 through 1997, the FDA Health Hazard Evaluation Board evaluated approximately 190 cases of hard or sharp foreign objects in food. These include cases of both injury and non-injury reported to FDA. The Board found that foreign objects that are less than 7 mm, maximum dimension, rarely cause trauma or serious injury except in special risk groups such as infants, surgery patients, and the elderly. The scientific and clinical literature supports this conclusion.

Hard or sharp natural components of a food (e.g. bones in seafood, shell in nut products) are unlikely to cause injury because of awareness on the part of the consumer that the component is a natural and intrinsic component of a particular product. The exception occurs when the food="s" label represents that the hard or sharp component has been removed from the food, e.g., pitted olives. The presence of the naturally occurring hard or sharp object in those situations (e.g., pit fragments in pitted olives) is unexpected and may cause injury. FDA has established Defect Action Levels for many of these types of unavoidable defects in other Compliance Policy Guides and therefore they are not subject to the guidance in this document.

REGULATORY ACTION GUIDANCE:
The following represent the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and direct reference import detention to the appropriate Field Offices within the Human and Animal Food Program*.

a. The product contains a hard or sharp foreign object that measures 7 mm to 25 mm, in length.

and

b. The product is ready-to-eat, or according to instructions or other guidance or requirements, it requires only minimal preparation steps, e.g., heating, that would not eliminate, invalidate, or neutralize the hazard prior to consumption.

Samples found to contain foreign objects that meet criteria a. and b., above should be considered adulterated within the meaning of 21 U.S.C. 342(a)(1).

The following represent the criteria for recommending legal action to CFSAN Office of *Compliance, Division of Enforcement* (HFS-605).

c. The product contains a hard or sharp foreign object that measures 7 mm to 25 mm in length, and the product requires additional preparation or processing that may have an effect on the presence of the foreign objects in the finished food. For example, additional sifting of a product may or may not remove foreign objects, depending on the measurements of the objects and the mesh aperture of the sifter. In these situations, the preparation or processing of the food must be described in the recommendation submitted by the appropriate *office within the Human and Animal Food Program*.

or

d. The product contains a hard or sharp foreign object less than 7 mm in length and if a special-risk group, as defined in the background section, is among the intended consumers of the product.

or

e. The product contains a hard or sharp foreign object over 25 mm in length.

A sample found to contain a foreign object that meets criterion c., d., or e., above should be considered adulterated within the meaning of 21 U.S.C. 342(a)(1) if a health hazard is established by CFSAN review. The CFSAN health hazard review in this case will consider various factors including the intended use of the product, subsequent processing steps, official guidance and requirements concerning unavoidable natural defects, and other mitigating factors that could eliminate, invalidate or neutralize the hazard prior to consumption of the food product.

REMARKS:
If CFSAN review finds no health hazard associated with a sample containing a hard or sharp foreign object that meets criterion c., or d., above, the sample should be considered adulterated within the meaning of *21 U.S.C. 342(a)(3)* if a CFSAN review finds the article unfit for food. The CFSAN review in this case will consider various factors including subsequent processing steps, extent of contamination, and intended use of the product.

CPG 515.350 addresses imbedded objects in confectionary, which may cause such foods to be adulterated within the meaning of 21 U.S.C. 342(d)(1).

SPECIMEN CHARGES:
The following charges are appropriate for a product that satisfies criteria a. and b. for direct reference seizure:

Article (was adulterated when introduced into and while in interstate commerce)(is adulterated while held for sale after shipment in interstate commerce), within the meaning of 21 U.S.C. 342 (a)(1), in that it bears or contains a deleterious substance which may render the food injurious to health.

Article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article appears to bear or contain a deleterious substance which may render it injurious to health.

Material between asterisks is new or revised

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