



Health  
Canada

Santé  
Canada

# Notice of Modification to the *List of Permitted Food Enzymes* to Extend the Use of Thermolysin from *Anoxybacillus caldiproteolyticus* TP7 to Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0181

March 24, 2022



Canada

## Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (Regulations). Approved food additives and their permitted conditions of use are set out in the [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs and published on the Canada.ca website. A petitioner can request that Health Canada approve a new additive, a new source or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada's Food Directorate received a food additive submission seeking approval for the use of the thermolysin (a type of protease) from *Anoxybacillus caldiproteolyticus* TP7<sup>1</sup> in bread, flour, whole wheat flour, and unstandardized bakery products. This food enzyme is intended to be used at a level consistent with Good Manufacturing Practice.<sup>2</sup>

Thermolysin from *A. caldiproteolyticus* TP7 was already permitted for use in certain hydrolyzed foods, but it previously appeared in the [List of Permitted Food Enzymes](#) as "Protease from *Geobacillus stearothermophilus* TP7". Protease from other sources is already permitted for use in the same foods as those requested by the petitioner.

The results of the Food Directorate's evaluation of available scientific data support the safety of thermolysin from *A. caldiproteolyticus* TP7 for its requested uses. Therefore, Health Canada has modified the *List of Permitted Food Enzymes* to extend the use of this enzyme by adding a new entry for thermolysin, as a new subitem P.6(ii), at the end of Item P.6 in the List, as shown in the table below.

## Housekeeping Modification

The new entry for thermolysin also includes the permitted uses of this enzyme in hydrolyzed animal, milk, and vegetable protein, and hydrolyzed yeast, that had previously appeared as the entry for "Protease from *Geobacillus stearothermophilus* TP7". This change specifies that this particular protease is "thermolysin". It also corrects the name of the source to *A. caldiproteolyticus* TP7 (to match the current taxonomic classification).

---

<sup>1</sup> The petitioner indicated that there was a taxonomic change in the name of the strain from *Geobacillus stearothermophilus* TP7 to *Anoxybacillus caldiproteolyticus* TP7.

<sup>2</sup> See the definition of Good Manufacturing Practice in the [Marketing Authorization for Food Additives That May Be Used as Food Enzymes](#).

## Modification to the *List of Permitted Food Enzymes*

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
P.6	(ii) Thermolysin	<i>Anoxybacillus caldiproteolyticus</i> TP7	(1) Hydrolysed animal, milk and vegetable protein	(1) Good Manufacturing Practice
			(2) Hydrolysed yeast	(2) Good Manufacturing Practice
			(3) Bread; Flour, Whole wheat flour	(3) Good Manufacturing Practice
			(4) Unstandardized bakery products	(4) Good Manufacturing Practice

## Rationale

Health Canada's Food Directorate completed a premarket safety assessment of thermolysin from *A. caldiproteolyticus* TP7 for use as a food enzyme in the foods requested by the petitioner. The Department concluded that information related to allergenicity, chemistry, microbiology, molecular biology, nutrition and toxicology supports the safety of thermolysin from *A. caldiproteolyticus* TP7 for its requested uses. Therefore, the Department has enabled the requested uses of thermolysin from *A. caldiproteolyticus* TP7 by adding to the *List of Permitted Food Enzymes* the entries to new subitem P.6(ii), as shown above.

## Other Relevant Information

Food additives such as thermolysin from *A. caldiproteolyticus* TP7 are required to meet food-grade specifications set out in Part B of the Regulations, where such specifications exist, or those set out in the most recent edition of the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications*. The *Food Chemicals Codex* is a compendium of standards for purity and identity for food ingredients, including food additives, published by the United States Pharmacopeial Convention. Specifications in the *Combined Compendium of Food Additive Specifications* and its associated *General Specifications and Considerations for Enzyme Preparations* are prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), both of which are published by the Food and Agriculture Organization of the United Nations.

## Implementation and Enforcement

The above modification came into force **March 24, 2022**, the day it was published in the *List of Permitted Food Enzymes*.

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

## Contact Information

Health Canada's Food Directorate is committed to reviewing new scientific information on the safety in use of any permitted food additive, including thermolysin from *A. caldiproteolyticus* TP7. Anyone wishing to submit an inquiry or new scientific information on the use of this additive may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**thermolysin (NOM-0181)**" in the subject line of your e-mail.

Bureau of Chemical Safety, Food Directorate

251 Sir Frederick Banting Driveway

Tunney's Pasture, PL: 2202C

Ottawa, Ontario K1A 0K9

E-mail: [bcsc-bipc@hc-sc.gc.ca](mailto:bcsc-bipc@hc-sc.gc.ca)