# COMMISSION IMPLEMENTING REGULATION (EU) 2023/949

## of 12 May 2023

## authorising the placing on the market of iron milk caseinate as a novel food and amending Implementing Regulation (EU) 2017/2470

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 12(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ([2]) has established a Union list of novel foods.

(3) On 16 June 2020, the company Société des Produits Nestlé S.A. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place iron milk proteinate, a complex of iron with casein obtained from bovine milk stabilised by phosphate, on the Union market as a novel food. The applicant requested for iron milk proteinate to be used as a source of iron in milk and dairy powder products, soft-drinks marketed in relation to physical exercise, powder cocoa beverage preparations, powder or liquid malt-based coffee substitutes, cereal bars, noodles other than glass noodles, stock cubes or granulates (bouillon bases), single meal replacements for weight control, total diet replacement for weight control as defined in Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]), foods for special medical purposes as defined in Article 2 of Regulation (EU) No 609/2013 excluding foods for infants and young children, and in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ([4]) intended for the general population excluding infants and young children. The proposed use levels in food supplements indicated in the application were up to 700 mg/day corresponding to up to 14 mg iron per day. The applicant also proposed that food supplements containing iron milk proteinate should not be used if other foods with added iron milk proteinate are consumed the same day.

([1]) OJ L 327, 11.12.2015, p. 1.

([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

([3]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

([4]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

(4) On 16 June 2020, the applicant also made a request to the Commission for the protection of proprietary data for an *in vitro* study on the digestibility of iron milk proteinate under simulated gastric conditions ([5]); the certificates of the compositional analyses of the production batches of iron proteinate ([6]); an in vitro study on the impact of ascorbic acid on the iron bioavailability of iron milk proteinate ([7]); a randomised human study with a cross over design on the bioavailability of iron from whole milk containing iron milk proteinate as compared to ferrous sulfate ([8]); an acute oral toxicity study in rodents ([9]); a report on the intake assessment of iron milk proteinate resulting from the proposed uses ([10]); a literature search study strategy and results conducted by the applicant ([11]); and an iron bioaccessibility study from iron casein complexes produced with milk ([12]), submitted in support of the application.

(5) On 9 October 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of iron milk proteinate as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283, and an assessment on the bioavailability of iron in the context of Directive 2002/46/EC.

(6) On 4 August 2022, the Authority adopted its scientific opinion on the 'Safety of iron milk proteinate as a Novel food pursuant to Regulation (EU) 2015/2283 and bioavailability of iron from this source in the context of Directive 2002/46/EC' ([13]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) The Commission considered that the term 'iron milk proteinate' used to describe the identity of the novel food is rather wide as it would encompass any bovine milk protein which could be used whereas the novel food is made using specifically casein. Consequently the term 'iron milk caseinate' would be a more accurate term to describe it. The Commission therefore requested the applicant to accept the designation 'iron milk caseinate' for the novel food instead of 'iron milk proteinate'. In response to the Commission's request, the applicant agreed to the designation of the novel food as 'iron milk caseinate.'

(8) In its scientific opinion, the Authority concluded that iron milk caseinate is safe under the proposed conditions of use for the proposed target populations, and that it is a source from which iron is bioavailable. In that opinion however, the Authority noted that, since it had not set a tolerable Upper intake Limit ('UL'), the intake of iron from some foods and food supplements containing the novel food could exceed population guidance levels that have been set by Member States, and that the combined intake of iron from foods and food supplements containing the novel food and the background diet would be high. In light of the Authority's considerations and of the pivotal role of iron in human physiology, growth and development, particularly in the early stages of life, and the rather fine line between beneficial and adverse health effects of iron depending on intakes, the Commission considers that a precautionary approach is needed.

(9) The Commission therefore requested the applicant to reconsider the levels of iron milk caseinate proposed in their application for some of the foods most likely to contribute the most to the iron daily intake, namely, milk and dairy products (levels up to 950 mg/100 gr or ml that would correspond to up to 19 mg iron/100 gr or ml of food), cocoa beverage preparations (levels up to 800 mg/100 gr or ml that would correspond to up to 16 mg iron/100 gr or ml of food), cereal bars (levels up to 700 mg/100 gr or ml that would correspond to up to 14 mg iron/100gr or ml of food), and for food supplements (levels up to 700 mg/day that would correspond to up to 14 mg iron per day). In response to the Commission's request, the applicant modified its request and proposed the use of iron milk caseinate in milk and dairy products at levels not exceeding 500 mg/100 gr or ml of food corresponding to up to 10 mg of iron/100 gr or ml of food, in cocoa beverage preparations at levels not exceeding 400 mg/100 gr or ml of

([5]) Société des Produits Nestlé S.A. (2020, unpublished).
([6]) Société des Produits Nestlé S.A. (2020, unpublished).
([7]) Sabatier M, Rytz A, Husny J, Dubascoux S, Nicolas M, Dave A, Singh H, Bodis M and Glahn RP, 2020 Impact of ascorbic acid on the in vitro iron bioavailability of a casein-based ironfortificant. Nutrients, 12, 2776.https://doi.org/10.3390/nu12092776
([8]) Henare SJ, Singh NN, Ellis AM, Moughan PJ, Thompson AK and Walczyk T, 2019. Iron bioavailability of a casein-based iron fortificant compared with that of ferrous sulfate in whole milk: a randomized trial with a crossover design in adult women. The American Journal of Clinical Nutrition, 110, 1362–1369.
([9]) Société des Produits Nestlé S.A. (2019, unpublished).
([10]) Société des Produits Nestlé S.A. (2020, unpublished).
([11]) Société des Produits Nestlé S.A. (2020, unpublished).
([12]) Société des Produits Nestlé S.A. (2021, unpublished).
([13]) *EFSA Journal* 2022;20(9):7549.

food corresponding to up to 8 mg of iron/100 gr or ml of food, and in cereal bars at levels not exceeding 350 mg/100 gr or ml of food correspond to up to 7 mg of iron/100 gr or ml of food. The applicant also modified its request as regards the use of iron milk caseinate in food supplements, and proposed its use at levels not exceeding 700 mg/day corresponding to up to 14 mg iron/day in food supplements intended for the adult population, and at levels not exceeding 350 mg/day corresponding to up to 7 mg iron/day in food supplements intended for children and adolescents under 18 years of age, excluding infants and young children. In addition, the applicant indicated that it will adjust the levels of iron milk caseinate in foods and in food supplements placed on the market of a Member State to limit the corresponding maximum levels of iron to the guidance values set by that Member State for each age group of the population. The Commission considers that the revised uses would fulfil the conditions for the placing on the market of iron milk caseinate in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(10) Therefore that scientific opinion gives sufficient grounds to establish that iron milk caseinate, when used as a source of iron in milk and dairy powder products, soft-drinks marketed in relation to physical exercise, powder cocoa beverage preparations, powder or liquid malt-based coffee substitutes, cereal bars, noodles other than glass noodles, stock cubes or granulates (bouillon bases), single meal replacements for weight control, total diet replacement for weight control as defined in Article 2 of Regulation (EU) No 609/2013, foods for special medical purposes as defined in Article 2 of Regulation (EU) No 609/2013 excluding foods for infants and young children, and in food supplements as defined in Article 2 of Directive 2002/46/EC at levels not exceeding 700 mg/day (14 mg iron/day) in food supplements intended for the adult population, and at levels not exceeding 350 mg/day (7 mg iron/day) in food supplements intended for children and adolescents under 18 years of age, excluding infants and young children, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(11) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on scientific data from the *in vitro* study on the digestibility of iron milk caseinate under simulated gastric conditions; the certificates of the compositional analyses of the production batches of iron milk caseinate; the in vitro study on the impact of ascorbic acid on the iron bioavailability of iron milk caseinate; and, the randomised human study with a cross over design on the bioavailability of iron from whole milk containing iron milk caseinate as compared to ferrous sulfate, contained in the applicant's file, without which it could not have assessed the novel food and reached its conclusion.

(12) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those scientific studies and data, and to clarify its claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.

(13) The applicant declared that it held proprietary and exclusive rights of reference to the scientific studies and data submitted in support of the application, namely, the *in vitro* study on the digestibility of iron milk caseinate under simulated gastric conditions; the certificates of the compositional analyses of the production batches of iron milk caseinate; the in vitro study on the impact of ascorbic acid on the iron bioavailability of iron milk caseinate; and, the randomised human study with a cross over design on the bioavailability of iron from whole milk containing iron milk caseinate as compared to ferrous sulfate, and that third parties cannot lawfully access, use or refer to those data.

(14) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific studies and data from the *in vitro* study on the digestibility of iron milk caseinate under simulated gastric conditions; the certificates of the compositional analyses of the production batches of iron milk caseinate; the in vitro study on the impact of ascorbic acid on the iron bioavailability of iron milk caseinate; and the randomised human study with a cross over design on the bioavailability of iron from whole milk containing iron milk caseinate as compared to ferrous sulfate, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place iron milk caseinate on the market within the Union during a period of five years from the entry into force of this Regulation.

(15) However, restricting the authorisation of iron milk caseinate and the reference to the scientific data contained in the applicant's file for its sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(16) In line with the conditions of use of food supplements containing iron milk caseinate as proposed by the applicant, and the Authority's opinion as regards the rather high intake of iron from the combined intake of iron from foods and food supplements containing the novel food and the background diet, it is necessary to inform consumers by appropriate labelling that food supplements containing iron milk caseinate should not be consumed by infants and children under 3 years of age and should not be consumed if other foods with added iron milk caseinate or other foods with added iron containing compounds are consumed the same day.

(17) As the source of the novel food comes from bovine milk, which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([14]) as one of a number of substances or products which cause allergies or intolerances, foods containing iron milk caseinate, should be appropriately labelled following the requirements of Article 21 of that Regulation.

(18) Iron milk caseinate should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

(1) Iron milk caseinate is authorised to be placed on the market within the Union.

Iron milk caseinate shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

(2) The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

*Article 2*

Only the company 'Société des Produits Nestlé S.A.' ([15]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 4 June 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of 'Société des Produits Nestlé S.A.'.

*Article 3*

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of 'Société des Produits Nestlé S.A.'.

([14]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

([15]) Address: Avenue Nestlé 55, 1800 Vevey, Switzerland.

*Article 4*

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 12 May 2023.

*For the Commission*
*The President*
Ursula VON DER LEYEN

*ANNEX*

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | Data protection |
|---|---|---|---|---|---|
| 'Iron milk caseinate | ***Specified food category*** | ***Maximum levels*** | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'iron milk caseinate'.<br>The labelling of food supplements containing iron milk caseinate shall bear a statement that<br>(a) they should not be consumed by children under 3 years of age;<br>(b) they should not be consumed if other foods containing iron milk caseinate and/or if other foods with added iron are consumed the same day. | | Authorised on 4 June 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.<br>Applicant: "Société des Produits Nestlé S.A.", Avenue Nestlé 55, 1800 Vevey, Switzerland. During the period of data protection, the iron milk caseinate is authorised for placing on the market within the Union only by "Société des Produits Nestlé S.A." unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of "Société des Produits Nestlé S.A.".<br>End date of the data protection: 4 June 2028.' |
| | Milk and dairy powder products | 500 mg/100 g (≤ 10 mg Fe/100 g) | | | |
| | Soft-drinks marketed in relation to physical exercise | 85 mg/100 g (≤ 1,7 mg Fe/100 g) | | | |
| | Powder cocoa beverage preparations | 400 mg/100 g (≤ 8 mg Fe/100 g) | | | |
| | Powder or liquid malt-based coffee substitutes | 1 050 mg/100 g (≤ 21 mg Fe/100 g) | | | |
| | Cereal bars | 350 mg/100 g (≤ 7 mg Fe/100 g) | | | |
| | | | | | |
| | Noodles other than glass noodles | 75 mg/100 g (≤ 1,5 mg Fe/100 g) | | | |
| | Stock cubes or granulates (bouillon base) | 4 750 mg/100 g (≤ 95 mg Fe/100 g) | | | |
| | Single meal replacements for weight control | 120 mg/100 g (≤ 2,4 mg Fe/100 g) | | | |
| | Total diet replacement for weight control as defined under Regulation (EU) No 609/2013 | 235 mg/meal (≤ 4,7 mg Fe/meal) or 700 mg/day (≤ 14,0 mg/Fe/day) | | | |
| | Foods for special medical purposes as defined under Regulation (EU) No 609/2013 excluding foods for infants and young children | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | Data protection |
|---|---|---|---|---|---|
| | Food supplements as defined in Directive 2002/46/EC, for the adult population | 700 mg/day (≤ 14 mg Fe/day) | | | |
| | Food supplements as defined in Directive 2002/46/EC, for children and adolescents under 18 years of age, excluding infants and young children | 350 mg/day (≤ 7 mg Fe/day) | | | |

(2) in Table 2 (Specifications), the following entry is inserted:

| Authorised novel food | Specification |
|---|---|
| '**Iron milk caseinate** | **Description:**<br>Iron milk caseinate is an iron-casein-phosphate complex in the form of a creamy or beige powder produced by the dissolution of ferric iron salts (ferric sulfate or ferric chloride) in a casein solution obtained from bovine milk in the presence of potassium orthophosphate following a series of steps involving pasteurisation, concentration, and drying.<br><br>**Characteristics/Composition:**<br>Protein (%): 50,0 – 65,0<br>Ash (%): 20,0 – 40,0<br>Moisture (%): < 8,0<br>Fat (%): < 1,0<br>Iron (%): 2,0 – 4,0<br>Potassium (%): 5,0 – 15,0<br>Phosphorus (%): 2,0 – 6,0<br>Sodium (%): < 4,0<br>**Heavy metals:**<br>Lead: < 0,5 mg/kg<br>Arsenic: ≤ 1,0 mg/kg<br>Cadmium: < 0,5 mg/kg<br>Mercury: < 0,1 mg/kg<br>**Mycotoxins:**<br>Aflatoxin M1: ≤ 0,02 mg/kg<br>**Microbiological criteria:**<br>Aerobic plate count: ≤ 1 000 CFU/g<br>Coliforms: ≤ 10 CFU/g<br>*Salmonella* spp.: Absence in 25 g<br>Yeast and mould: ≤ 10 CFU/g |

| Authorised novel food | Specification |
|---|---|
| | *Escherichia coli:* ≤ 10 CFU/g<br>*Staphylococcus aureus*: Absence in 1 g<br>CFU: Colony Forming Units' |