Iron milk caseinate authorised as a novel food in certain foods and supplements

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Commission authorises iron milk caseinate as a source of iron in diet and medical foods

Commission Delegated Regulation (EU) 2024/2791 of 29 January 2024 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of iron milk caseinate as a source of iron in total diet replacement for weight control and in food for special medical purposes, excluding food for infants and young children

Commission Regulation (EU) 2024/1821 of 25 June 2024 amending Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards iron milk caseinate added to foods and used in the manufacture of food supplements

Update

The EU has authorised the use of iron milk caseinate as a source of iron in total diet replacements for weight control and foods for special medical purposes (excluding for infants and young children). This follows its authorisation as a novel food in May 2023, and its approval in June 2024 as a source of iron that may be added to foods and used in food supplements.

What is changing?

This Regulation adds iron milk caseinate to the list of approved sources of iron set out in the Annex to Regulation 609/2013. It allows this specific source of iron to be used in foods for special medical purposes, and in total diet replacements for weight control (excluding for infants and young children).

Why?

Under the laws on adding vitamins/minerals to food (Regulation 1925/2006) and food supplements (Directive 2002/46/EC), and to foods for particular nutritional uses (Regulation 609/2013), only those vitamins and minerals that are listed, and the specific vitamin and mineral sources listed, may be used in these products. To be used in each of these types of food, iron milk caseinate must be listed as an iron source in the Annex to each of these Regulations.

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EFSA (2022) evaluated the safety of iron milk caseinate as a novel food, and concluded that it is safe under the proposed conditions of use (excluding uses for infants and young children), and that it is a source from which iron is bioavailable.

Timeline

Iron milk caseinate may be used in total diet replacement for weight control and in food for special medical purposes, excluding food for infants and young children, from **20 November 2024**.

What are the major implications for exporting countries?

Under Regulation 2023/949, only the company Société des Produits Nestlé S.A. may sell iron milk caseinate on the EU market until June 2028, unless Nestlé permits it, or if another company obtains a novel food authorisation for these uses on the basis of its own scientific data (without using Nestlé's protected data).

Background

Regulation 2023/949 authorised iron milk caseinate as a novel food in certain foods and food supplements. Iron milk caseinate was therefore included in the Union list of authorised novel foods in the Annex to Regulation 2017/2470. It was subsequently added to lists of approved sources of iron that may be used in foods (Annex II to Regulation 1925/2006) and in food supplements (Annex II to Directive 2002/46/EC).

Resources

EFSA (2022) 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. EFSA Journal, 20(9): 7549.

Directive 2002/46/EC relating to food supplements

Regulation (EU) 2023/949 authorising the placing on the market of iron milk caseinate as a novel food

Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

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Regulation 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control

Regulation 2015/2283 on novel foods

Regulation 2017/2470 establishing the Union list of novel foods

Sources

Commission Delegated Regulation (EU) 2024/2791 to allow the use of iron milk caseinate as a source of iron in total diet replacement for weight control and in food for special medical purposes, excluding food for infants and young children

Commission Regulation (EU) 2024/1821 as regards iron milk caseinate added to foods and used in the manufacture of food supplements

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