



2024/2791

31.10.2024

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ⁽¹⁾, and in particular Article 16(1) thereof,

Whereas:

- (1) The Annex to Regulation (EU) No 609/2013 establishes a Union list of substances that may be added to one or more of the categories of food referred to in Article 1(1) of that Regulation.
- (2) Commission Implementing Regulation (EU) 2023/949 ⁽²⁾ authorised the use of iron milk caseinate as a novel food in, among other products, food for special medical purposes, excluding food for infants and young children and total diet replacement for weight control, subject to certain conditions.
- (3) During the process of authorisation, on 4 August 2022, the European Food Safety Authority ('the Authority') issued a scientific opinion ⁽³⁾ where it concluded that iron milk caseinate is safe under the proposed conditions of use and that it is a source from which iron is bioavailable.
- (4) The Commission considers that the Authority's opinion gives sufficient grounds to establish that iron milk caseinate, as authorised by Regulation (EU) 2023/949, is not of safety concern as a source of iron when used in food for special medical purposes, excluding food for infants and young children and in total diet replacement for weight control. Therefore, it is appropriate to allow the use of iron milk caseinate as a source of iron in food for special medical purposes, excluding food for infants and young children and in total diet replacement for weight control.
- (5) That substance should therefore be included in the Union list of substances that may be added to certain categories of food.
- (6) The Annex to Regulation (EU) No 609/2013 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 609/2013 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 181, 29.6.2013, p. 35.

⁽²⁾ 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 (OJ L 128, 15.5.2023, p. 60).

⁽³⁾ EFSA NDA Panel. 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* 2022;20(9):7549.

Article 2

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, 29 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Regulation (EU) No 609/2013, within the category of substance 'Minerals', under 'Iron', the following entry is added after the entry for 'ferrous L-pidolate':

'iron milk caseinate (*)			X (in products not intended for infants and young children)	X
(*) As listed in the Union list of novel foods in Commission Implementing Regulation (EU) 2017/2470.'				