



COMMISSION DELEGATED REGULATION (EU) 2025/1735

of 4 June 2025

amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of monosodium salt of L-5-methyltetrahydrofolic acid as a source of folate in infant formula and follow-on formula, processed cereal-based food and baby food, total diet replacement for weight control and in food for special medical purposes

(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) On 26 October 2023, the European Food Safety Authority ('the Authority') adopted a scientific opinion (²), where it concluded that monosodium salt of L-5-methyltetrahydrofolic acid is safe under the specified conditions of use, as long as the combined intake of monosodium salt of L-5-methyltetrahydrofolic acid and other sources of folate under their authorised conditions of use is below the tolerable upper intake levels established for the different age groups of the general population. The Authority also considered that it is a source from which folate is bioavailable for all age groups of the general population.
- (3) Commission Implementing Regulation (EU) 2024/1037 (³) authorised, based on the Authority's favourable opinion, the placing on the market of monosodium salt of L-5-methyltetrahydrofolic acid as a novel food for use in, among other products, infant formula and follow-on formula, processed cereal-based food and baby food, total diet replacement for weight control and in food for special medical purposes, subject to certain conditions of use.
- (4) The Commission considers that the Authority's opinion gives sufficient grounds to establish that monosodium salt of L-5-methyltetrahydrofolic acid, as authorized by Implementing Regulation (EU) 2024/1037, is not of safety concern as a source of folate when used in infant formula and follow-on formula, processed cereal-based food and baby food, total diet replacement for weight control and in food for special medical purposes. Therefore, it is appropriate to allow the use of monosodium salt of L-5-methyltetrahydrofolic acid as a source of folate in those categories of food.
- (5) Monosodium salt of L-5-methyltetrahydrofolic acid should therefore be included in the Union list of substances that may be added to certain categories of food.

(¹) OJ L 181, 29.6.2013, p. 35, ELI: <http://data.europa.eu/eli/reg/2013/609/oj>.

(²) EFSA NDA Panel. Safety of monosodium salt of L-5-methyltetrahydrofolic acid as a novel food pursuant to Regulation (EU) 2015/2283 and the bioavailability of folate from this source in the context of Directive 2002/46/EC, Regulation (EU) No 609/2013 and Regulation (EC) No 1925/2006, EFSA Journal, 2023;21:e8417.

(³) Commission Implementing Regulation (EU) 2024/1037 of 9 April 2024 authorising the placing on the market of monosodium salt of L-5-methyltetrahydrofolic acid as a novel food and amending Implementing Regulation (EU) 2017/2470 (OJ L, 2024/1037, 10.4.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/1037/oj).

(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.

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, 4 June 2025.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

In the Annex to Regulation (EU) No 609/2013, within the category of substance 'Vitamins', under subcategory 'Folate', the following entry is added:

'monosodium salt of L-5 methyltetrahydrofolic acid (*)	X	X	X	X
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(*) As listed in the Union list of novel foods in 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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).