Council of the European Union

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	4 June 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2025) 3411 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 4.6.2025 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

Delegations will find attached document C(2025) 3411 final.

Encl.: C(2025) 3411 final

EUROPEAN
COMMISSION

Brussels, 4.6.2025
C(2025) 3411 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 4.6.2025

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 15 of 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[1] provides that certain types of substances may be added to one or more of those categories of food only if those substances are included in the Union list that is set out in the Annex to that Regulation.

In order to take into account the technical progress, scientific developments or the protection of consumers' health, and subject to the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11 of Regulation (EU) No 609/2013, Article 16(1) of the Regulation empowers the Commission to amend the Annex by means of delegated acts with respect to the addition of substances to the Union list.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted the European Food Safety Authority ('the Authority') on the matter. On 26 October 2023, the Authority adopted its Scientific Opinion on the safety of monosodium salt of L-5-methyltetrahydrofolic acid as a novel food pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods[2] and the bioavailability of folate from this source in the context of 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[3], Regulation (EU) No 609/2013 and Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[4]. That Opinion constitutes the scientific basis for this delegated Regulation.

Member States' experts were consulted in writing in the context of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control[5] between 7 May 2024 and 24 May 2024.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Union list of substances that may be added to the specific categories of food covered by the scope of Regulation (EU) No 609/2013 as set out in its Article 1(1) is updated in accordance with Article 16 of that Regulation and on the basis of the above-mentioned Authority's opinion to authorise the addition of monosodium salt of L-5-methyltetrahydrofolic acid as a source of folate to infant formula and follow-on formula, processed cereal-based food and baby food, total diet replacement for weight control and food for special medical purposes.

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1 OJ L 181, 29.6.2013, p. 35, ELI: http://data.europa.eu/eli/reg/2013/609/oj.
2 OJ L 327, 11.12.2015, pp. 1-22, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.
3 OJ L 183 12.7.2002, p. 51, ELI: http://data.europa.eu/eli/dir/2002/46/2024-07-17.
4 *EFSA Journal*, 2023;21:e8417
5 Reference E02893 in the Register of Commission Expert Groups and other similar entities.

COMMISSION DELEGATED REGULATION (EU) …/...

of 4.6.2025

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

[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).

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.

(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, 4.6.2025

For the Commission
The President
Ursula VON DER LEYEN