EUROPEAN
COMMISSION

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[…](2020) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the list of substances that may be added to infant and follow-on formula, baby food and processed cereal-based food

(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] lays down requirements for the Union list, set out in the Annex to this Regulation, with respect to the substances that may be added to one or more categories of food referred to in Article 1(1), which are:

- infant formula and follow-on formula;
- processed cereal-based food and baby food;
- food for special medical purposes;
- total diet replacement for weight control.

In order to take into account the technical progress, scientific developments or the protection of consumers' health, 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 (EFSA) on the matter. EFSA's Scientific Opinion on Calcium L-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food[2] 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[3] between 20 January 2020 and 31 January 2020 as well as between 26 March 2020 and 10 April 2020.

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 Article 1(1) of Regulation (EU) No 609/2013 is updated in accordance with Article 16 of that Regulation to authorise the addition of calcium L-methylfolate as a source of folate to infant and follow-on formula, processed cereal-based food and baby food on the basis of EFSA's advice.

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1 OJ L 181, 29.6.2013, p. 35.

2 EFSA NDA Panel, Scientific Opinion on Calcium l-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food, EFSA Journal doi: 10.2903/j.efsa.2020.5947

3 Reference E02893 in the Register of Commission Expert Groups and other similar entities.

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(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[4], and in particular Article 16 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) The Annex to Regulation (EC) No 609/2013 currently authorises the addition of calcium L-methylfolate as a source of folate to food for special medical purposes and to total diet replacement for weight control.

(3) Following an application requesting that the use of calcium L-methylfolate as a source of folate is authorised also in infant formula, follow-on formula, processed cereal-based food and baby food, at the levels necessary to meet the compositional requirements for folate set out by the Union legislation for those foodstuffs, the Commission requested the European Food Safety Authority ('the Authority') to provide an opinion on the safety and bioavailability of that substance when added to the concerned foodstuffs. In its opinion of 27 November 2019[5], the Authority concluded that calcium L-methylfolate is a source from which folate is bioavailable and that it is safe under the proposed uses and use levels for the target population that is infants (<12 months) and young children (12-<36 months.

(4) The Commission considers that the Authority's opinion gives sufficient grounds to establish that calcium L-methylfolate is not of a safety concern as a source of folate when used in infant formula, follow-on formula, processed cereal-based food and baby food at the required levels. Therefore, calcium L-methylfolate should be included in

[4] OJ L 181, 29.6.2013, p. 35.

[5] EFSA NDA Panel, Scientific Opinion on Calcium l-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food, EFSA Journal, doi: 10.2903/j.efsa.2020.5947.

the list set out in Annex to Regulation (EC) No 609/2013, as a source of folate in those categories of foods.

(5) Regulation (EC) 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,

For the Commission
The President
Ursula VON DER LEYEN