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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium ascorbate (E 301) in vitamin A preparations intended for infant formula and follow-on formula

(Text with EEA relevance)

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amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium ascorbate (E 301) in vitamin A preparations intended for infant formula and follow-on formula

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[1], and in particular Articles 10(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[2], and in particular Article 7(5) thereof,

Whereas:

(1) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.

(2) The Union list of food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application from a Member State or an interested party.

(3) In October 2023, an application was submitted to the Commission for the authorisation of use of sodium ascorbate (E 301) as an antioxidant at the maximum level of 50 000 mg/kg in microencapsulated vitamin A preparations for infant formula and follow-on formula, resulting in a maximum carry-over in those foods of 1 mg/l of sodium ascorbate (E 301). The application was subsequently made available to Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(4) Pursuant to Annex III to Regulation (EC) No 1333/2008, sodium ascorbate (E 301) is currently authorised as a food additive in, among other uses, vitamin D preparations for infant formula and follow-on formula at the maximum level of 100 000 mg/kg and the maximum carry-over in those foods of 1 mg/l. This authorisation is based on the scientific opinion of the European Food Safety Authority ('the Authority'), issued on 22 December 2010[3], concluding that the use of food additive sodium ascorbate (E 301) as an antioxidant for the vitamin D preparations for use in infant formula and follow-on

[1] OJ L 354, 31.12.2008, p. 16, ELI: http://data.europa.eu/eli/reg/2008/1333/oj.

[2] OJ L 354, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1331/oj.

[3] Scientific Opinion on the use of sodium ascorbate as a food additive in vitamin D preparations intended to be used in formulae and weaning food for infants and young children. EFSA Journal 2010;8(12):1942. doi:10.2903/j.efsa.2010.1942.

formula is not of safety concern as the maximum carry-over of 1 mg/l of sodium ascorbate would only marginally contribute to the vitamin C and sodium content in infant formula and follow-on formula.

(5) Furthermore, pursuant to the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council[4], sodium ascorbate may be added to infant formula and follow-on formula as a source of vitamin C. The minimum and maximum amounts of vitamin C and sodium in infant formula and follow-on formula are specified in Commission Delegated Regulation (EU) 2016/127[5].

(6) Microencapsulation is commonly used to protect vitamin A from degradation. In this context, sodium ascorbate (E 301), when used as an antioxidant, ensures the stability of the protective matrix encapsulating vitamin A during the production process and in the final product. The increased stability of vitamin A allows the dose to be better controlled and less overage is required to guarantee the correct vitamin A amount in the final product.

(7) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the Authority in order to update the Union list of food additives set out in Annex III to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.

(8) The requested use of sodium ascorbate (E 301) in microencapsulated vitamin A preparations results in the same maximum carry-over level to infant formula and follow-on formula as the level assessed by the Authority in 2010. Moreover, the maximum amounts for vitamin C and sodium authorised in infant formula and follow-on formula cover their presence from all sources, including carry-over of food additives. Therefore, the proposed extension of use of sodium ascorbate (E 301) is not liable to have an effect on human health.

(9) Therefore, it is appropriate to authorise the use of sodium ascorbate (E 301) as an antioxidant in microencapsulated vitamin A preparations for infant formula and follow-on formula at the maximum level of 50 000 mg/kg and the maximum carry-over level of 1 mg/l in those foods.

(10) Regulation (EC) No 1333/2008 should therefore be amended accordingly.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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4 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 (OJ L 181, 29.6.2013, p. 35, ELI: https://eur-lex.europa.eu/eli/reg/2013/609/oj.

5 Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 25, 2.2.2016, p. 1, ELI: https://eur-lex.europa.eu/eli/reg/2006/127/oj.

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1333/2008 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