EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the food additive L-ascorbyl palmitate (E 304(i))

(Text with EEA relevance)

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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 (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[1], and in particular Article 14 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 II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use. Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives, including carriers, approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.

(2) Commission Regulation (EU) No 231/2012[3] lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives and the specifications may be updated either on the initiative of the Commission or following an application.

(4) L-ascorbyl palmitate (E 304(i)) is a food additive authorised in accordance with Regulation (EC) No 1333/2008.

(5) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority').

(6) On 18 November 2015, the Authority issued a scientific opinion on the re-evaluation of ascorbyl palmitate (E 304(i)) and ascorbyl stearate (E 304(ii)) as food additives[4]. The Authority concluded that the available toxicological data were too limited to establish a numerical acceptable daily intake for ascorbyl palmitate (E 304(i)) or

[1] OJ L 354, 31.12.2008, p. 16, ELI: http://data.europa.eu/eli/reg/2008/1333/2024-04-23.

[2] OJ L 354, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1331/2021-03-27.

[3] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

[4] EFSA Journal 2015; 13(11):4289 (https://doi.org/10.2903/j.efsa.2015.4289).

ascorbyl stearate (E 304(ii)). The Authority also concluded that ascorbyl palmitate and ascorbyl stearate are hydrolysed and not systemically available and that, therefore, their toxicity can be extrapolated from the data available for ascorbic acid, palmitic acid and stearic acid. Considering the available data, the Authority concluded that there is no safety concern for the use of ascorbyl palmitate (E 304(i)) and ascorbyl stearate (E 304(ii)) as food additives at the reported uses and use levels. The Authority considered that the uses in food for infants under the age of 16 weeks would require a specific risk assessment. The Authority recommended some modifications to the specifications for the food additives E 304(i) and E 304(ii) laid down in Regulation (EU) No 231/2012.

(7) On 10 October 2018, the Authority launched a public call for technical and toxicological data on ascorbyl palmitate (E 304(i)) for uses as a food additive in foods for all population groups, including infants below 16 weeks of age, to collect the data needed for the specific risk assessment and for refining its recommendations to modify the specifications for that food additive. Business operators provided data in response to the call.

(8) On 30 June 2020, the Authority issued a scientific opinion on the re-evaluation of ascorbyl palmitate (E 304(i)) as a food additive in foods for infants below 16 weeks of age and on the follow-up of its re-evaluation as a food additive for uses in foods for all population groups[5]. Based on in vitro data, the Authority assumed that ascorbyl palmitate fully hydrolyses pre-systematically to ascorbic acid and palmitate, and concluded that the intake of those metabolites, at the levels resulting from the maximum permitted levels for use of ascorbyl palmitate as a food additive in infant formula belonging to food category 13.1.1 or in food for special medical purposes intended for infants belonging to food category 13.1.5.1, does not raise health concerns. As regards the specifications laid down in Regulation (EU) No 231/2012, the Authority recommended including the CAS number and the dimension of the molecular weight, reducing the maximum limits for toxic elements (arsenic, lead and mercury) and including maximum limits for residual solvents (acetone, petroleum ether, mesityl oxide, ethyl acetate, methyl isobutyl ketone, isododecane). The Authority also recommended harmonising the name of the food additive E 304(i) between Regulation (EC) No 1333/2008 and Regulation (EU) No 231/2012.

(9) In light of the Authority's recommendations, it is appropriate to amend the specifications of the food additive E 304(i) contained in the Annex to Regulation (EU) No 231/2012. In particular, the current maximum limits for toxic elements should be reduced to ensure that the food additive will not be a significant source of exposure to those toxic elements through food, taking into account the level which is currently achievable by the application of good manufacturing practices. It is also appropriate to establish maximum limits for residual solvents to ensure that their levels are kept at levels below those that could raise a safety concern and to amend the definition of that food additive to include, amongst others, a list of the solvents that may be used in the manufacturing process. Furthermore, it is appropriate to harmonise the name of the food additive E 304(i) between Annex II and Annex III of Regulation (EC) No 1333/2008, as well as between Regulation (EC) No 1333/2008 and Regulation (EU) No 231/2012, through a change of the name ascorbyl palmitate (E 304(i)) into the more specific name L-ascorbyl palmitate (E 304(i)).

[5] EFSA Journal 2020; 18(6):6153 (https://doi.org/10.2903/j.efsa.2020.6153).

(10) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

(11) Considering that the Authority did not identify an immediate health concern linked to the current specifications for ascorbyl palmitate (E 304(i)) and to allow the food business operators, including small and medium enterprises, to adapt to the new more stringent specifications laid down in this Regulation, the application of this Regulation should be deferred and a transitional period should be provided for the use of this additive lawfully placed on the market before the date of application.

(12) For the same reasons, a transitional period should be provided for foods containing ascorbyl palmitate (E 304(i)) that has been lawfully placed on the market before the date of application of this Regulation.

(13) To avoid that existing stocks of packaging material referring to 'ascorbyl palmitate' need to be discarded, a transitional period should be provided for using the name 'ascorbyl palmitate' on food packaging.

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

HAS ADOPTED THIS REGULATION:

Article 1

In Annex III, Part 5, Section B to Regulation (EC) No 1333/2008 where a reference is made to 'E 304 (i) Ascorbyl palmitate', it shall be replaced by 'E 304(i) L-ascorbyl palmitate'.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with the Annex to this Regulation.

Article 3

1. The food additive L-ascorbyl palmitate (E 304(i)) that has been lawfully placed on the market before ….[*6 months after the date of entry into force of this Regulation*] may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

2. Foods, to which the food additive L-ascorbyl palmitate (E 304(i)) that has been lawfully placed on the market before ….*[6 months after the date of entry into force of this Regulation]* has been added, may be placed on the market until their date of minimum durability or 'use-by date'.

Article 4

Food packaging bearing the name 'ascorbyl palmitate' that was printed before the date of application of this Regulation may continue to be used until such packaging is exhausted.

Article 5

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*6 months after the date of entry into force of this Regulation*].

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