EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EC) No 1333/2008 of the European Parliament and the Council and Commission Regulation (EU) No 231/2012 as regards the use of shellac (E 904) in food for special medical purposes in tablet and coated tablet forms

(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 10(3) and 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.

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

(3) Those lists 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.

(4) Pursuant to Annex II to Regulation (EC) No 1333/2008, shellac (E 904) is authorised for use as a food additive in several food categories.

(5) On 25 October 2018, an application was submitted to the Commission for the authorisation of use of shellac (E 904) as a glazing agent in food category 13.2 'Foods for special medical purposes as defined by Regulation (EU) No 609/2013 (excluding products from food category 13.1.5)' for foods in tablet and coated tablet forms. The application was subsequently made available to Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(6) Shellac (E 904) used as a glazing agent provides a protective coating of foods for special medical purposes in tablet and coated tablet forms. In particular, shellac (E 904), when applied to the external surface of tablets protects them from disintegration

[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/oj.

[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, ELI: http://data.europa.eu/eli/reg/2012/231/oj).

until reaching intestines, which ensures that active ingredients of tablets are appropriately supplied.

(7) On 1 August 2024, the European Food Safety Authority ('the Authority') issued a scientific opinion on the re-evaluation of shellac (E 904) as a food additive and the new application on the extension of use of shellac (E 904) in dietary foods for special medical purposes[4]. The Authority derived an ADI of 4 mg/kg bw per day for wax-free shellac (E 904) produced by physical decolouring and noted that for several age groups the ADI was exceeded at the 95th percentile of exposure. However, taking into account the low exceedance and the fact that both the exposure estimation and the toxicological evaluation of shellac were conservative, the Authority considered that in this case the exceedance of the ADI would not indicate a safety concern. In addition, the Authority recommended deleting information on wax-containing shellac from the specifications since it is not used as a food additive and no data to confirm its safety were available. The Authority also recommended to collect data on the identity and levels of the organochlorine impurities in E 904, in order to reconsider the temporary ADI for shellac produced by chemical bleaching, to revise the definition of the food additive, to separate specifications for shellac obtained by chemical bleaching and physical decolouring, to lower the maximum limits for lead and to consider introducing limits for other toxic elements potentially present in shellac.

(8) It is, therefore, appropriate to authorise the use of shellac (E 904) as a glazing agent in food for special medical purposes in tablet and coated tablet forms.

(9) Since wax-containing shellac is not used as a food additive and no data to confirm its safety were available, it is appropriate to delete information on wax-containing shellac from the specifications for shellac (E 904).

(10) Regulations (EC) No 1333/2008 and (EU) No 231/2012 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,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

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

[4] EFSA Panel on Food Additives and Flavourings, (2024). Re-evaluation of shellac (E 904) as a food additive and a new application on the extension of use of shellac (E904) in dietary foods for special medical purposes. EFSA Journal, 22(8), e8897. https://doi.org/10.2903/j.efsa.2024.8897.

Article 3

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