



2024/2597

7.10.2024

COMMISSION REGULATION (EU) 2024/2597

of 4 October 2024

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sorbic acid (E 200) and potassium sorbate (E 202) and the Annex to Commission Regulation (EU) No 231/2012 as regards the specifications for sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310)

(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 that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) The Union lists of food additives and the specifications 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) Sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310) are substances authorised in accordance with Annexes II and III to Regulation (EC) No 1333/2008.
- (5) On 30 June 2015, the European Food Safety Authority ('the Authority') issued a scientific opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives ⁽⁴⁾. The Authority established a temporary group acceptable daily intake value (ADI) of 3 mg sorbic acid/kg bw per day for sorbic acid (E 200) and potassium sorbate (E 202). In addition, the Authority recommended to perform an extended one-generation reproductive toxicity study in order to reconsider the temporary ADI, to revise the maximum limits for toxic elements in the specifications for sorbic acid (E 200) and potassium sorbate (E 202) set out in Regulation (EU) No 231/2012 and to include in the specifications maximum limits for divalent transition metals if used as catalysts in the manufacturing process of those food additives.
- (6) On 10 June 2016, the Commission launched a public call for data concerning the food additives sorbic acid (E 200) and potassium sorbate (E 202), for addressing the recommendations made by the Authority. Business operators provided data on the reproductive toxicity of those food additives, the toxic elements contained therein as impurities and the use of divalent transition metals as catalysts in their manufacturing.

⁽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, ELI: <http://data.europa.eu/eli/reg/2012/231/2024-04-23>).

⁽⁴⁾ EFSA Journal 2015;13(6):4144.

- (7) On 1 March 2019, the Authority issued a scientific opinion on the follow-up of the re-evaluation of sorbic acid (E 200) and potassium sorbate (E 202) as food additives⁽⁷⁾. Based on new data on the reproductive toxicity, the Authority changed the temporary ADI to a new group ADI of 11 mg sorbic acid/kg bw per day for sorbic acid (E 200) and its potassium salt (E 202). The exposure estimates were well below the new group ADI for all population groups both at the mean and high levels.
- (8) Taking into account the re-evaluation by the Authority and the data submitted by business operators, it is appropriate to amend the specifications for sorbic acid (E 200) and potassium sorbate (E 202). In particular, the current maximum limits for toxic elements should be reduced and a maximum limit for zinc should be established, taking into account the level which is currently achievable by the application of good manufacturing practices. Furthermore, it is appropriate to amend the description of potassium sorbate (E 202) to refer not only to its powder form but also to its granular form, since the former form is produced from the latter by milling and both physical forms, powder and granular, have the same purity. It is also appropriate to make some adaptations as regards the description of sorbic acid (E 200) and potassium sorbate (E 202).
- (9) On 25 July 2022, an application was submitted for the authorisation of the use of sorbic acid (E 200) and potassium sorbate (E 202) as preservatives in fruit-flavoured water-based gelatine desserts. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (10) Fruit-flavoured water-based gelatine desserts are susceptible to microbiological spoilage due to their high-water activity (a_w 0,96-0,98). Sorbic acid (E 200) and potassium sorbate (E 202), when used in the range of the proposed typical and maximum use level of 700 and 1 000 mg/kg, are capable of protecting fruit-flavoured water-based gelatine desserts against deterioration caused by micro-organisms and prolonging their shelf-life. Other alternatives such as hot or aseptic filling technologies are not economically and technologically practicable as they alter the intrinsic characteristics of fruit-flavoured water-based gelatine desserts and are not affordable, in particular to small and medium-sized enterprises.
- (11) 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 II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health. As sorbic acid (E 200) and potassium sorbate (E 202) are authorised for use in a wide variety of foods, including in different desserts in food category 16 'Desserts excluding products covered in categories 1, 3 and 4' in Part E of Annex II to Regulation (EC) No 1333/2008, the extended proposed use in fruit-flavoured water-based gelatine desserts is not expected to have a significant impact on the overall exposure which therefore will remain below the ADI. This is also supported by the estimation provided by the applicant and carried out by using the Food Additive Intake Model⁽⁸⁾ developed by the Authority. Therefore, the extended use of sorbic acid (E 200) and potassium sorbate (E 202) in fruit-flavoured water-based gelatine desserts is not liable to have an effect on human health and consequently it is not necessary to seek the opinion of the Authority.
- (12) On 24 April 2014, the Authority issued a scientific opinion on the re-evaluation of propyl gallate (E 310) as a food additive⁽⁹⁾. The Authority noted that the use of hydrochloric acid in the manufacture of propyl gallate could result in chlorinated by-products and that, despite the fact that the specifications include a limit for chlorinated organic compounds, no information on the identification or quantification of potential chlorinated by-products was available to the Authority.
- (13) On 30 May 2017, the Commission launched a public call for data concerning the food additive propyl gallate (E 310) requesting data on the identity and levels of chlorinated organic compounds in that food additive and data on the toxic elements (arsenic, lead and mercury) contained therein as impurities.

⁽⁷⁾ EFSA Journal 2019;17(3):5625.

⁽⁸⁾ <https://www.efsa.europa.eu/en/applications/food-improvement-agents/tools>.

⁽⁹⁾ EFSA Journal 2014;12(4):3642.

- (14) Business operators provided data on the toxic elements contained as impurities in propyl gallate (E 310) and clarified that hydrochloric acid is not used as catalyst during the manufacturing process of propyl gallate as a food additive.
- (15) In light of the opinion of the Authority and the information provided by business operators, a definition of the food additive propyl gallate (E 310) should be included in the specifications in order to restrict the use of catalysts in the manufacturing process of the food additive. Furthermore, 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 in food while taking into account the level which is currently achievable by the application of good manufacturing practices.
- (16) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (17) Considering that the Authority did not identify an immediate health concern linked to the presence of toxic elements and catalysts 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 the new purity specifications for the food additives sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310), and the definition of propyl gallate (E 310) should be deferred and a transitional period should be provided for food additives placed on the market before the date of application.
- (18) For the same reasons, it is appropriate that a transitional period is provided for foods, containing sorbic acid (E 200), potassium sorbate (E 202) or propyl gallate (E 310) that has been lawfully placed on the market before the date of application.
- (19) 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.

Article 3

The food additives sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310) that have been lawfully placed on the market before 27 April 2025 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

Foods, containing sorbic acid (E 200), potassium sorbate (E 202) or propyl gallate (E 310) that has been lawfully placed on the market before 27 April 2025, may be placed on the market until their date of minimum durability or 'use-by date'.

Article 4

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

Points (1)(b), (2)(b) and (3) of Annex II shall apply from 27 April 2025.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 October 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

In Part E of Annex II to Regulation (EC) No 1333/2008, in food category 16 ‘Desserts excluding products covered in categories 1, 3 and 4’, the entry for the use of sorbic acid – potassium sorbate (E 200-202) in *frugtgrød, rote Grütze and pasha* at 1 000 mg/kg is replaced by the following:

	E 200-202	Sorbic acid – potassium sorbate	1 000	(1) (2)	only <i>frugtgrød, rote Grütze</i> and <i>pasha</i> ; fruit-flavoured water-based gelatine desserts’
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ANNEX II

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) the entry for ‘E 200 sorbic acid’ is amended as follows:

(a) the specification ‘Description’ is replaced by the following:

Description	Colourless needles or white free flowing crystalline powder, having a slight characteristic odour and showing no change in colour after heating for 90 minutes at 105 °C’;
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(b) the specification ‘Purity’ is replaced by the following:

Purity	
Water content	Not more than 0,5 % (Karl Fischer method)
Sulphated ash	Not more than 0,2 %
Aldehydes	Not more than 0,1 % (as formaldehyde)
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,01 mg/kg
Zinc	Not more than 0,1 mg/kg’;

(2) the entry for ‘E 202 potassium sorbate’ is amended as follows:

(a) the specification ‘Description’ is replaced by the following:

Description	White crystalline powder or granules showing no change in colour after heating for 90 minutes at 105 °C’;
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(b) the specification ‘Purity’ is replaced by the following:

Purity	
Loss on drying	Not more than 1,0 % (105 °C, 3 hours)
Acidity or alkalinity	Not more than about 1,0 % (as sorbic acid or K ₂ CO ₃)
Aldehydes	Not more than 0,1 %, calculated as formaldehyde
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,01 mg/kg
Zinc	Not more than 0,1 mg/kg’;

(3) the entry for ‘E 310 propyl gallate’ is amended as follows:

(a) the specification ‘Definition’ is replaced by the following:

Definition	Propyl gallate is produced by the esterification of gallic acid with propanol. The reaction is catalysed by sulphuric acid.
Einecs	204-498-2
Chemical name	Propyl gallate; Propyl ester of gallic acid; n-propyl ester of 3,4,5-trihydroxybenzoic acid

Chemical formula	C ₁₀ H ₁₂ O ₅
Molecular weight	212,20
Assay	Content not less than 98 % on the anhydrous basis;

(b) the specification 'Purity' is replaced by the following:

Purity

Loss on drying	Not more than 0,5 % (110 °C, 4 hours)
Sulphated ash	Not more than 0,1 %
Free acid	Not more than 0,5 % (as gallic acid)
Specific absorption in ethanol	$E_{1cm}^{1\%}$ (275 nm) not less than 485 and not more than 520
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,3 mg/kg
Mercury	Not more than 0,1 mg/kg'.