



20 June 2024

(24-4578)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved:
2. Agency responsible: European Commission, Health and Food Safety Directorate-General
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Food products
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Draft Commission Regulation 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). Language(s): English. Number of pages: 9 https://members.wto.org/crnattachments/2024/SPS/EEC/24_03860_00_e.pdf https://members.wto.org/crnattachments/2024/SPS/EEC/24_03860_01_e.pdf
6. Description of content: The text revises the EU specifications of the authorized food additives sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310) and authorizes an extension of use of sorbic acid (E 200) and potassium sorbate (E 202) as preservatives in fruit-flavoured water-based gelatine desserts based on the recent scientific opinions from the European Food Safety Authority (EFSA). For sorbic acid (E 200) and potassium sorbate (E 202), the current specifications are adapted by reducing the maximum limits for toxic elements (arsenic, lead and mercury) and by establishing a maximum limit for zinc. Furthermore, the description of potassium sorbate (E 202) is amended by including the granular form. For propyl gallate (E 310), the current specifications are adapted by reducing the maximum limits for toxic elements and by restricting the use of catalysts in the manufacturing process of the food additive. The text also authorizes the use of sorbic acid (E 200) and potassium sorbate (E 202) in food category 16 'Desserts excluding products covered in categories 1, 3 and 4' at a maximum level of 1000 mg/kg for fruit-flavoured water-based gelatine desserts. In order to allow for a smooth transition, 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) is deferred and a transitional period is provided for food additives placed on the market before the date of application. Also, for foods containing sorbic acid (E 200), potassium sorbate (E 202) or propyl gallate (E 310) that have been lawfully placed on the market before the date of application, a transitional period is provided.

7.	Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
8.	<p>Is there a relevant international standard? If so, identify the standard:</p> <p><input checked="" type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): Codex General Standard for Food Additives – Codex Stan 192-1995</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard: The food additive specifications of sorbic acid (E 200) and potassium sorbate (E 202) developed by JECFA do not contain maximum levels for arsenic, mercury and zinc. The inclusion of the granular form in the description of potassium sorbate (E 202) aligns the EU specifications with the JECFA specifications.</p> <p>For propyl gallate (E 310), the food additive specifications by JECFA do not contain maximum levels for arsenic and mercury and do not contain a definition specifying the catalyst used during the manufacturing process.</p> <p>In the Codex General Standard for Food Additives (GSFA), sorbic acid and potassium sorbate are currently authorized in food category 04.1.2.9 'Fruit-based desserts, incl. fruit-flavoured water-based desserts' at a maximum level of 1000 mg/kg. The authorization of the extension of use is in-line with the authorization in the GSFA.</p>
9.	<p>Other relevant documents and language(s) in which these are available:</p> <ul style="list-style-type: none"> – EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2015. Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives. EFSA Journal 2015;13(6):4144, 91 pp. doi:10.2903/j.efsa.2015.4144 https://www.efsa.europa.eu/en/efsajournal/pub/4144 – EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes M, Aquilina G, Castle L, Engel K-H, Fowler P, Frutos Fernandez MJ, Fürst P, Gürtler R, Gundert-Remy U, Husøy T, Mennes W, Moldeus P, Oskarsson A, Shah R, Wölfle D, Lambré C, Christodoulidou A and Waalkens-Berendsen I, 2019. Scientific Opinion on the follow-up of the re-evaluation of sorbic acid (E200) and potassium sorbate (E202) as food additives. EFSA Journal 2019;17(3):5625, 21 pp. doi.org/10.2903/j.efsa.2019.5625 https://www.efsa.europa.eu/en/efsajournal/pub/5625 – EFSA ANS Panel (EFSA Panel on Food additives and Nutrient Sources added to Food), 2014. Scientific Opinion on the re-evaluation of propyl gallate (E 310) as a food additive. EFSA Journal 2014;12(4):3642, 46 pp. doi:10.2903/j.efsa.2014.3642 https://www.efsa.europa.eu/en/efsajournal/pub/3642 <p>(available in English)</p>
10.	<p>Proposed date of adoption (dd/mm/yy): Foreseen for Q4 2024</p> <p>Proposed date of publication (dd/mm/yy): Foreseen for Q4 2024</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 20 days after publication in the Official Journal of the European Union (with a deferred application for a six-month period for some measures and a transitional period).</p> <p><input type="checkbox"/> Trade facilitating measure</p>

12. Final date for comments: Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 19 August 2024

Agency or authority designated to handle comments: National Notification Authority, National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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DG Health and Food Safety, Unit A4-Multilateral International Relations
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13. Text(s) available from: National Notification Authority, National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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