



1 March 2024

(24-1950)

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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 and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additives tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354) (Text with EEA relevance). Language(s): English. Number of pages: 16 https://members.wto.org/crnattachments/2024/SPS/EEC/24_01786_00_e.pdf https://members.wto.org/crnattachments/2024/SPS/EEC/24_01786_01_e.pdf
6. Description of content: The text revises the conditions of use of the authorized food additives tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354). These food additives are currently authorized for use at <i>quantum satis</i> and included in Group I, in Annex II, Part C of Regulation (EC) No 1333/2008, which covers food additives, other than colours and sweeteners, with an 'acceptable daily intake not specified' or for which the most recent risk assessment concluded that 'there is no need for a numerical acceptable daily intake'. In addition, tartaric acid (L(+)-) (E 334), sodium tartrates (E 335), potassium tartrates (E 336), sodium potassium tartrate (E 337) and calcium tartrate (E 354) are authorized for use in specific food categories with a numerical maximum level or at <i>quantum satis</i> . The European Food Safety Authority (EFSA) re-evaluated these food additives in 2020 and established a group acceptable daily intake (ADI) of 240 mg/kg bw per day, expressed as tartaric acid, for tartaric acid-tartrates (E 334 - 337 and E 354). Following the EFSA re-evaluation, it is appropriate to remove those food additives from Group I, create a new group for them, review their conditions of use and establish numerical maximum use levels. In order to allow for a smooth transition, the text lays down a transitional period for food business operators to adapt to the new more stringent conditions of use.
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.

<p>8. 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: In the Codex General Standard for Food Additives (GSFA), there are provisions for L(+)-Tartaric acid (INS 334), Sodium L(+)-tartrate (INS 335(ii)), Potassium sodium L(+)-tartrate (INS 337) but not for potassium tartrate and calcium tartrate. Moreover, there are differences in the authorized conditions of use.</p>
<p>9. Other relevant documents and language(s) in which these are available:</p> <ul style="list-style-type: none"> – EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings https://www.efsa.europa.eu/en/efsajournal/pub/6030) – Scientific Opinion on the re-evaluation of L(+)-tartaric acid(E 334), sodium tartrates (E 335), potassium tartrates (E 336), potassium sodium tartrate (E 337) and calcium tartrate (E 354) as food additives. EFSA Journal 2020; 18(3):6030, 58 pp. https://doi.org/10.2903/j.efsa.2020.6030 <p>(available in English)</p>
<p>10. Proposed date of adoption (dd/mm/yy): Foreseen for Q2 2024.</p> <p>Proposed date of publication (dd/mm/yy): Foreseen for Q2 2024.</p>
<p>11. 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 transitional provisions for a six-month period).</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 30 April 2024</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: sps@ec.europa.eu</p>
<p>13. Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: sps@ec.europa.eu</p>