



10 September 2024

(24-6213)

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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 (EU) amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards certain botanical species containing hydroxyanthracene derivatives (Text with EEA relevance). Language(s): English. Number of pages: 5 https://members.wto.org/crnattachments/2024/SPS/EEC/24_05893_00_e.pdf
6. Description of content: This draft Commission Regulation concerns the prohibition of use in food of certain plant preparations containing hydroxyanthracene derivatives based on the scientific opinion of EFSA and following a period of Union scrutiny during which food business operators, or any other interested parties, may submit scientific data to demonstrate the safety of plant preparations in question. On 22 November 2017, the European Food Safety Authority (EFSA) adopted a scientific opinion on the evaluation of the safety of hydroxyanthracene derivatives for use in food. In that opinion it concluded that there is a possibility of harmful effects on health associated with the use of <i>Rheum</i> , <i>Cassia</i> and <i>Rhamnus</i> and their preparations in food, but scientific uncertainty persists. Consequently, pursuant to the procedure laid down in Article 8(2) of Regulation (EC) No 1925/2006, the plant preparations concerned were put under Union scrutiny by means of Regulation (EU) 2021/468 of 18 March 2021 for a period of four years from the entry into force of that Regulation, which allowed interested parties to provide EFSA with evidence of safety within 24 months. On 20 March 2024, EFSA adopted a scientific opinion on additional scientific data related to the safety of preparations of <i>Rheum palmatum</i> L., <i>Rheum officinale</i> Baill. and their hybrids, <i>Rhamnus purshiana</i> DC., <i>Rhamnus frangula</i> L., and <i>Cassia senna</i> L. submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006. In its opinion, EFSA concluded that the safety of plant preparations under evaluation cannot be established based on the submitted studies. Therefore, pursuant to the procedure of Article 8(5) of Regulation (EC) No 1925/2006, the plant preparations concerned should be included in Part A of Annex III to Regulation (EC) No 1925/2006, which means that their use in food will be prohibited.

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 type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</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 checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
9.	<p>Other relevant documents and language(s) in which these are available:</p> <ul style="list-style-type: none"> - Regulation (EU) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0026:0038:EN:PDF - Scientific opinion on additional scientific data related to the safety of preparations of <i>Rheum palmatum</i> L., <i>Rheum officinale</i> Baill. and their hybrids, <i>Rhamnus purshiana</i> DC., <i>Rhamnus frangula</i> L. and <i>Cassia senna</i> L., submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006. <i>EFSA Journal</i> 2024; 22(5):e8766 (available in English)
10.	<p>Proposed date of adoption (dd/mm/yy): First quarter 2025</p> <p>Proposed date of publication (dd/mm/yy): First quarter 2025</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): Twenty days after publication in the Official Journal of the European Union.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
12.	<p>Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 9 November 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>

13. Text(s) available from: National Notification Authority, National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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