



13 October 2021

(21-7749)

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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 supplements
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 green tea extract containing (-)-epigallocatechin-3-gallate (Text with EEA relevance). Language(s): English. Number of pages: 6 https://members.wto.org/crnattachments/2021/SPS/EEC/21_6540_00_e.pdf
6. Description of content: This draft Commission Regulation concerns the inclusion of green tea catechins in Annex III of Regulation (EC) No 1925/2006 ('the Regulation'). In its opinion, adopted on 14 March 2018, EFSA concluded that while catechins from green tea infusions prepared in a traditional way were considered safe for use, catechins taken as a food supplement, at and above 800mg of (-)-epigallocatechin-3-gallate, had been shown to cause elevated serum transaminases, which is indicative of liver injury. Therefore, pursuant to the procedure of Article 8 of the Regulation, this substance should be included in Annex III (Part B) to the Regulation. Furthermore, as EFSA could not identify a safe dietary intake of green tea catechins, and therefore, there is still the possibility of harmful effects on health but scientific uncertainty persists in this regard, this substance should be placed under Union scrutiny (Part C of Annex III to the Regulation).
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. Is there a relevant international standard? If so, identify the standard: <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):

<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>
<p>9. Other relevant documents and language(s) in which these are available: 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 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1925&qid=1634044973427&from=EN</p>
<p>10. Proposed date of adoption (dd/mm/yy): First quarter 2022 Proposed date of publication (dd/mm/yy): First quarter 2022</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): Twenty days following that of its publication in the Official Journal of the European Union. <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): 12 December 2021 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: European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 Fax: +(32 2) 29 98090 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: European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 Fax: +(32 2) 29 98090 E-mail: sps@ec.europa.eu</p>