NOTIFICATION

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| **1.** | **Notifying Member:** European Union  **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:**  **[****X]** **All trading partners**  **[ ]****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: [****X]****food safety, [ ]****animal health, [ ]****plant protection, [ ]****protect humans from animal/plant pest or disease, [ ]****protect territory from other damage from pests.** |
| **8.** | **Is there a relevant international standard? If so, identify the standard:**  **[ ]****Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:**  **[ ]****World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:**  **[ ]****International Plant Protection Convention *(e.g. ISPM number)*:**  **[****X]** **None**  **Does this proposed regulation conform to the relevant international standard?**  **[ ]****Yes [ ]****No**  **If no, describe, whenever possible, how and why it deviates from the international standard:** |
| **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> |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** First quarter 2022  **Proposed date of publication *(dd/mm/yy)*:** First quarter 2022 |
| **11.** | **Proposed date of entry into force: [ ]****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.  **[ ]****Trade facilitating measure** |
| **12.** | **Final date for comments: [****X]****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: [****X]****National Notification Authority, [****X]****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 |
| **13.** | **Text(s) available from: [****X]****National Notification Authority, [****X]****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 |