



6 February 2024

(24-0933)

Page: 1/2

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): Preparations of a kind used in animal feeding (HS code(s): 2309)
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 Implementing Regulation withdrawing from the market star anise terpenes from <i>Illicium verum</i> Hook.f. as a feed additive (Text with EEA relevance). Language(s): English. Number of pages: 4 https://members.wto.org/crnattachments/2024/SPS/EEC/24_01145_00_e.pdf
6. Description of content: The draft act concerns the withdrawal from the EU market of star anise terpenes from <i>Illicium verum</i> Hook.f. as a feed additive belonging to the functional group of 'flavouring compounds'. That additive was allowed on the EU market under the previous legislation (Directive 70/524/EEC), as part of a generic entry within the group of 'flavouring and appetising substances' and was the subject of an application for re-authorization submitted under Article 10(2) of Regulation (EC) No 1831/2003. In its opinion of 26 September 2023, the European Food Safety Authority ('EFSA') concluded that the additive star anise terpenes contains up to 25% estragole by specification and is obtained by a manufacturing process which results in the enrichment of this genotoxic carcinogen. EFSA further stated that this does not comply with the principles outlined in the general approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic when used as feed additives. Therefore, EFSA considered that it was inappropriate to perform an assessment of the safety and efficacy of star anise terpenes for its use as a feed additive. The applicant subsequently withdrew the application for re-authorization of that feed additive for all animal species. As a result of the withdrawal of the application, Article 10(5) of Regulation (EC) No 1831/2003 imposes the adoption of a measure requiring the withdrawal from the market of the additive concerned. It is proposed to provide a limited period of time – which is kept to a minimum due to the safety concerns raised in the relevant EFSA opinion - in order to allow operators to comply properly with the measure.
7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input checked="" 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): Code of Practice on Good Animal Feeding CAC/RCP 54-2004</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 checked="" 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: EFSA scientific opinion of 26 September 2023 on the safety and efficacy of a feed additive consisting of a fraction of the essential oil from the fruit and leaves of <i>Illicium verum</i> Hook.f. (star anise terpenes) for use in all animal species. EFSA Journal 2023;21(10):8341. https://doi.org/10.2903/j.efsa.2023.8341 (available in English)</p>
<p>10. Proposed date of adoption (dd/mm/yy): April 2024</p> <p>Proposed date of publication (dd/mm/yy): April 2024</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 after publication of the act in the <i>Official Journal of the European Union</i>.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 30 days after publication of this notification.</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>