



22 February 2016

(16-1077)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

<p>1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved:</p>
<p>2. Agency responsible: European Commission, Health and Food Safety Directorate-General</p>
<p>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): Foods, flavourings</p>
<p>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:</p>
<p>5. Title of the notified document: Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of certain flavouring substances (Text with EEA relevance) Language(s): English Number of pages: 6 http://members.wto.org/crnattachments/2016/SPS/EEC/16_0730_00_e.pdf http://members.wto.org/crnattachments/2016/SPS/EEC/16_0730_01_e.pdf</p>
<p>6. Description of content: The Union list of flavourings and source materials is laid down in Annex I to Regulation (EC) No 1334/2008. The Union list was established by Commission Implementing Regulation (EU) No 872/2012 which is now amended by the notified measure.</p> <p>This amendment concerns the withdrawal of the following four substances belonging to chemical subgroup 2.2 of FGE.19: 2,6,6-trimethyl-1-cyclohexen-1-carboxaldehyde (FL no. 05.121), myrtenyl formate (FL no. 09.272), myrtenyl-2-methylbutyrate (FL no. 09.899), and myrtenyl-3-methylbutyrate (FL no. 09.900).</p> <p>The European Food Safety Authority (EFSA) requested additional scientific data for completion of their evaluation as flavouring substances, which are part of group FGE.208. EFSA evaluated the data on this group of substances in its opinion of 24 June 2015 and concluded that the representative substance of the group <i>p</i>-mentha-1,8-dien-7-al (FL-no 05.117) is genotoxic <i>in vivo</i> and therefore its use as a flavouring substance raises a safety concern.</p> <p>The EFSA opinion is available as Scientific Opinion on Flavouring Group Evaluation 208 Revision 1 (FGE.208Rev1): Consideration of genotoxicity data on representatives for 10 alicyclic aldehydes with the α,β-unsaturation in ring/side-chain and precursors from chemical subgroup 2.2 of FGE.19. EFSA Journal 2015;13(7):4173, 28 pp. doi:10.2903/j.efsa.2015.4173 Online at: http://www.efsa.europa.eu/efsajournal.</p> <p>No support has been expressed for the four substances 2,6,6-trimethyl-1-cyclohexen-1-carboxaldehyde (FL no. 05.121), myrtenyl formate (FL no. 09.272), myrtenyl-2-methylbutyrate (FL no. 09.899) and myrtenyl-3-methylbutyrate (FL no. 09.900).</p>

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 (<i>e.g. title or serial number of Codex standard or related text</i>)</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (<i>e.g. Terrestrial or Aquatic Animal Health Code, chapter number</i>)</p> <p><input type="checkbox"/> International Plant Protection Convention (<i>e.g. ISPM number</i>)</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.	Other relevant documents and language(s) in which these are available:
10.	<p>Proposed date of adoption (dd/mm/yy): December 2015</p> <p>Proposed date of publication (dd/mm/yy): April 2016</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 20 days after its 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): 22 April 2016</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 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>
13.	<p>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 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>