



5 August 2016

(16-4191)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
<b>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):</b> Foods, flavourings
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> <b>All trading partners</b> <input type="checkbox"/> <b>Specific regions or countries:</b>
<b>5. Title of the notified document:</b> Commission Regulation (EU) 2016/1244 of 28 July 2016 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances from a group related with an alpha beta unsaturation structure (Text with EEA relevance) <b>Language(s):</b> English, French and Spanish <b>Number of pages:</b> 4 <a href="http://members.wto.org/crnattachments/2016/SPS/EEC/16_3126_00_e.pdf">http://members.wto.org/crnattachments/2016/SPS/EEC/16_3126_00_e.pdf</a> <a href="http://members.wto.org/crnattachments/2016/SPS/EEC/16_3126_00_f.pdf">http://members.wto.org/crnattachments/2016/SPS/EEC/16_3126_00_f.pdf</a> <a href="http://members.wto.org/crnattachments/2016/SPS/EEC/16_3126_00_s.pdf">http://members.wto.org/crnattachments/2016/SPS/EEC/16_3126_00_s.pdf</a>
<b>6. Description of content:</b> 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 will be amended by the notified measure.  This amendment concerns the modification of the conditions of use of the following five substances belonging to the chemical subgroup 2.2 of FGE.19 (FGE.208): <i>p</i> -mentha-1,8-dien-7-ol (FL no. 02.060), myrtenol (FL no. 02.091), myrtenal (FL no. 05.106), <i>p</i> -mentha-1,8-dien-7-yl acetate (FL no. 09.278), and myrtenyl acetate (FL no. 09.302).  The European Food Safety Authority (EFSA) had requested additional scientific data for completion of the evaluation as flavouring substances of the group of substances FGE.208 composed of ten substances which includes these substances. 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-ol (FL-no 05.117) is genotoxic <i>in vivo</i> and therefore its use as a flavouring substance raises a safety concern. This substance was withdrawn from the Union list with Commission Regulation (EU) 2015/1760 in an urgent procedure. This measure had been notified earlier in G/SPS/N/EU/149.  The EFSA opinion is available as Scientific Opinion on Flavouring Group Evaluation 208 Revision 1 (FGE.208Rev1): consideration of genotoxicity data on representatives for ten alicyclic aldehydes with the $\alpha,\beta$ -unsaturation in ring/side-chain and precursors from chemical subgroup 2.2 of FGE.19.

<p>EFSA Journal 2015;13(7):4173, 28 pp. doi:10.2903/j.efsa.2015.4173 Online at: <a href="http://www.efsa.europa.eu/efsajournal">http://www.efsa.europa.eu/efsajournal</a>.</p> <p>Four additional substances from this group (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), not supported by industry, were also withdrawn from the Union list in a separate, later, measure (Commission Regulation (EU) 2016/637). This measure was notified in notification G/SPS/N/EU/157.</p> <p>The current measure concerns a modification of the conditions of use of the abovementioned five remaining substances of the group FGE.208 to better reflect the current real uses in the food categories specified and not in others, pending the evaluation by EFSA of further additional safety studies which were formally requested by the Commission to interested parties. Once the process of evaluation of these new data is completed (which includes the EFSA risk assessment) these substances will be subject of consideration of an appropriate legislative measure taking into account the EFSA assessment.</p>
<p><b>7. Objective and rationale:</b> <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.</p>
<p><b>8. Is there a relevant international standard? If so, identify the standard:</b></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><b>Does this proposed regulation conform to the relevant international standard?</b></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><b>9. Other relevant documents and language(s) in which these are available:</b></p>
<p><b>10. Proposed date of adoption (dd/mm/yy):</b> 28 July 2016</p> <p><b>Proposed date of publication (dd/mm/yy):</b> 29 July 2016</p>
<p><b>11. Proposed date of entry into force:</b> <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 18 August 2016</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p><b>12. Final date for comments:</b> <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 4 October 2016. Comments received will be taken into account during the next revision of the Commission Regulation.</p> <p><b>Agency or authority designated to handle comments:</b> <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. 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 D2-Multilateral International Relations  
Rue Froissart 101  
B-1049 Brussels  
Tel: +(32 2) 29 54263  
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E-mail: sps@ec.europa.eu