



3 October 2014

(14-5580)

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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 Consumers 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, flavourings
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 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: 3+2 http://members.wto.org/crnattachments/2014/sps/EEC/14_4333_00_e.pdf http://members.wto.org/crnattachments/2014/sps/EEC/14_4333_01_e.pdf
6.	Description of content: The Union list of flavourings and source materials is laid down in Annex I to Regulation (EC) No. 1334/3008. It was established by Commission Implementing Regulation (EU) No. 872/2012 of 1 October 2012 adopting the list of flavouring substances notified in G/SPS/N/EU/13/Add.1 (12 October 2012). This list is now proposed to be amended by this notified "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". This addendum concerns the removal of the following 5 substances: Flavis no. Name of the substance CAS No. JECFA No. CoE 1. 01.014 1-Methylnaphthalene 90-12-0 1335 11009 2. 13.052 Furfuryl methyl ether 13679-46-4 1520 10944 3. 13.056 Difurfuryl sulfide 13678-67-6 1080 11438 4. 13.061 Difurfuryl ether 4437-22-3 1522 10930 5. 13.123 Ethyl furfuryl ether 6270-56-0 1521 10940 The substance 1-Methylnaphthalene, Flavis No. 01.014, was evaluated by the European Food Safety Authority (EFSA) in 2008 (EFSA Opinion on Flavouring Group Evaluation 78 (FGE. 78), http://www.efsa.europa.eu/en/efsajournal/pub/931.htm) and additional toxicity data on it were requested. This was repeated in the revision of this EFSA opinion of 2011 (Opinion on Flavouring Group Evaluation 78, Revision 1, FGE.78 Rev.1), http://www.efsa.europa.eu/en/efsajournal/pub/2178.htm . The three substances Furfuryl methyl ether, Flavis No. 13.052, Difurfuryl ether, Flavis No. 13.061, and Ethyl furfuryl ether, Flavis No. 13.123, were evaluated by EFSA in 2011 (Opinion on Flavouring Group FGE 67 Rev.1),

<p>http://www.efsa.europa.eu/en/efsajournal/pub/2315.htm and EFSA identified a concern for genotoxicity. Therefore genotoxicity data was required to address this concern.</p> <p>The substance difurfuryl sulphide, Flavis No. 13.056, was evaluated by EFSA in 2009 (opinion on Flavouring Group Evaluation 65 (FGE. 65), http://www.efsa.europa.eu/en/scdocs/doc/1406.pdf and an adequate toxicity study to establish a NOAEL was requested.</p> <p>The Commission Implementing Regulation (EU) No. 872/2012 laid down in 2012 the deadline of 31 December 2013 for the submission of the requested additional scientific data for these five substances.</p> <p>This Regulation also indicated that where the necessary information is not provided by the time requested, the flavouring substance in question will be removed from the Union list.</p> <p>The data requested concerning these five substances has not been submitted by the time of the deadline of 31 December 2013. These five substances are therefore removed from the Union list as sufficient data to support their safety have not been provided.</p>
<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.</p>
<p>8. 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? <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:</p>
<p>10. Proposed date of adoption (dd/mm/yy): 27 November 2014</p> <p>Proposed date of publication (dd/mm/yy): January 2015</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): January 2015</p> <p><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): 2 December 2014</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 Consumers, Unit G6-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 295 4263 Fax: +(32 2) 299 8090 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:

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