



20 December 2016

(16-6955)

Page: 1/3

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): Foods, 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: Commission Regulation (EU) amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards certain flavouring substances (Text with EEA relevance). Language(s): English. Number of pages: 37 http://members.wto.org/crnattachments/2016/SPS/EEC/16_5226_00_e.pdf http://members.wto.org/crnattachments/2016/SPS/EEC/16_5226_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 1334/2008. The Union list was established by Commission Implementing Regulation (EU) No 872/2012. This list will be amended by the notified measure. <p>This amendment concerns the modification of the conditions of use of the twenty flavouring substances mentioned in the annex of the measure.</p> <p>The European Food Safety Authority (EFSA) evaluated the genotoxicity of these substances taking into account the data on the following two substances selected as representative of the group, hexa-2(trans),4(trans)-dienal (FL-no: 05.057), and deca-2(trans),4(trans)-dienal (FL-no: 05.140) in its scientific opinion of 26 March 2014. Overall, EFSA concluded that the safety concern regarding genotoxicity cannot be ruled out for both representative substances of the group and that this conclusion is likewise applicable to the other substances of this FGE group 203.</p> <p>The current measure concerns a modification of the conditions of use of the abovementioned substances of group FGE.203 to prevent the further extension of their uses to other food categories where currently there is no use and to more closely reflect the current real uses in the food categories specified by establishing maximum levels for the food categories where they are used in order to contain the consumer exposure to these substances.</p> <p>The measure takes into account the current uses reported by industry and therefore it is unlikely that international trade in foods containing these flavourings, flavourings or mixtures of flavourings containing these flavourings will be affected. Nevertheless, transitional measures will apply for products en route to the European Union and here will be a period of 20 days after the publication before entry into force.</p>

<p>EFSA will evaluate further data on the genotoxicity of these substances. However, it is anticipated that the complete evaluation of first the genotoxicity and subsequently, if appropriate, the complete evaluation of each of the twenty substances will take well beyond a year. Therefore, it is appropriate to adopt this measure at this stage.</p> <p>The provisions of Article 15 g of Regulation 1334/2008 on flavourings will also be applicable to these flavourings as it is the case for all flavourings with maximum levels in foods.</p> <p>The draft measure has been the object of a public request for comments under the Better Regulation approach established by the Commission. The operators have had therefore additional time to consider any adjustment in their practices if necessary before the measure enters into force.</p> <p>Any follow-up measure regarding these substances will also be notified under this mechanism.</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 (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>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>
<p>9. Other relevant documents and language(s) in which these are available: Scientific Opinion on Flavouring Group Evaluation 203 Rev 1 (FGE.203 Rev1): alpha,betaunsaturated aliphatic aldehydes and precursors from chemical subgroup 1.1.4 of FGE.19 with two or more conjugated double-bonds and with or without additional non-conjugated double-bonds. EFSA Journal 2014;12(4):3626, 31 pp. doi:10.2903/j.efsa.2014.3626. Available online: http://www.efsa.europa.eu/efsajournal.</p>
<p>10. Proposed date of adoption (dd/mm/yy): February 2017</p> <p>Proposed date of publication (dd/mm/yy): March 2017</p>
<p>11. 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. Final date for comments: Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 18 February 2017

Agency or authority designated to handle comments: National Notification Authority, National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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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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