



19 April 2018

(18-2464)

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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 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): Food products
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 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards octyl gallate (E 311) and dodecyl gallate (E 312) (Text with EEA relevance). Language(s): English. Number of pages: 12 https://members.wto.org/crnattachments/2018/SPS/EEC/18_2137_00_e.pdf https://members.wto.org/crnattachments/2018/SPS/EEC/18_2137_01_e.pdf
6. Description of content: The text removes octyl gallate (E 311) and dodecyl gallate (E 312) from the Union list of authorised food additives in Regulation (EC) No 1333/2008, since due to the absence of appropriate toxicological data it is not possible to assess the risk posed by the use of these substances as a food additive to human health. Therefore, the inclusion of these substances in the Union list of authorised food additives can no longer be justified. Annexes II and III to Regulation (EC) No 1333/2008 (authorised uses and use levels for food additives) and the Annex to Regulation (EU) No 231/2012 (specifications for food additives) are amended accordingly.
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. Is there a relevant international standard? If so, identify the standard: <input checked="" type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): Codex General Standard For Food Additives – Codex Stan 192-1995 <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): <input type="checkbox"/> None Does this proposed regulation conform to the relevant international standard?

<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>	
9.	<p>Other relevant documents and language(s) in which these are available:</p> <ul style="list-style-type: none"> - Scientific Opinion on the re-evaluation of octyl gallate (E 311) as a food additive (European Food Safety Authority, EFSA Journal 2015;13(10):4248 https://www.efsa.europa.eu/en/efsajournal/pub/4248 - Scientific Opinion on the re-evaluation of dodecyl gallate (E 312) as a food additive (European Food Safety Authority, EFSA Journal 2015;13(5):4086 https://www.efsa.europa.eu/en/efsajournal/pub/4086
10.	<p>Proposed date of adoption (dd/mm/yy): August 2018</p> <p>Proposed date of publication (dd/mm/yy): August 2018</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 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): 18 June 2018</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, [X] 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, [X] 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>