



6 March 2017

(17-1338)

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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 the removal of calcium sorbate (E 203) (Text with EEA relevance). Language(s): English. Number of pages: 20 http://members.wto.org/crnattachments/2017/SPS/EEC/17_1180_00_e.pdf http://members.wto.org/crnattachments/2017/SPS/EEC/17_1180_01_e.pdf
6. Description of content: The proposed measure removes calcium sorbate (E 203) from the Union list of authorised food additives in Regulation (EC) No 1333/2008, since due to the absence of appropriate genotoxicity data it is not possible to assess the risk posed by the use of this substance as a food additive to human health. Therefore, the inclusion of this substance 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 additive) 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?**[] Yes [X] No**

If no, describe, whenever possible, how and why it deviates from the international standard: The Codex Alimentarius Standard for food additives includes provisions for the use of calcium sorbate as a food additive in several food categories. In the European Union calcium sorbate (E 203) is authorised as a preservative in a variety of foods, as well as in food colour preparations and food flavourings, in accordance with Annexes II and III to Regulation (EC) No 1333/2008. Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority (EFSA). On 30 June 2015 EFSA delivered a Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives. The opinion stated that there was a lack of genotoxicity data on calcium sorbate. Consequently EFSA was not able to confirm the safety of calcium sorbate as a food additive and concluded that this substance should be excluded from the group Acceptable Daily Intake (ADI) defined for sorbic acid (E 200) and potassium sorbate (E 202). On 10 June 2016 the European Commission launched a public call for genotoxicity data on calcium sorbate (E 203). However, by the closure date of the call (25 November 2016) no business operator committed to providing the requested data. Without those data EFSA cannot complete the re-evaluation of the safety of calcium sorbate as a food additive and consequently it cannot be determined whether this substance still fulfils the conditions pursuant to Article 6(1) of Regulation (EC) No 1333/2008 for inclusion in the Union list of approved food additives. It is therefore appropriate to remove calcium sorbate (E 203) from the Union list of approved food additives.

9. Other relevant documents and language(s) in which these are available: Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives (European Food Safety Authority, EFSA Journal 2015;13(6):4144, <http://www.efsa.europa.eu/en/efsajournal/pub/4144>

10. Proposed date of adoption (dd/mm/yy): Foreseen for September 2017.
Proposed date of publication (dd/mm/yy): Foreseen for September 2017.

11. Proposed date of entry into force: [] Six months from date of publication, and/or (dd/mm/yy): 20 days after publication in the Official Journal of the European Union.
[] Trade facilitating measure

12. Final date for comments: [X] Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 5 May 2017
Agency or authority designated to handle comments: [X] National Notification Authority, [X] 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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