



21 February 2020

(20-1337)

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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> Food products
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
<b>5. Title of the notified document:</b> 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 use of Annatto, Bixin, Norbixin (E 160b) (Text with EEA relevance). <b>Language(s):</b> English. <b>Number of pages:</b> 32 <a href="https://members.wto.org/crnattachments/2020/SPS/EEC/20_1320_00_e.pdf">https://members.wto.org/crnattachments/2020/SPS/EEC/20_1320_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2020/SPS/EEC/20_1320_01_e.pdf">https://members.wto.org/crnattachments/2020/SPS/EEC/20_1320_01_e.pdf</a>
<b>6. Description of content:</b> The Regulation aims at updating the current authorisation of the food additive Annatto, Bixin, Norbixin (E 160b) in the European Union, in line with the conclusions of the re-evaluation of the safety of this food additive by the European Food Safety Authority (EFSA), which included the assessment of an application for the authorisation of five new annatto-based extracts and some extensions of use. EFSA concluded that the main pigments in annatto extracts, namely bixin and norbixin, have different toxicological properties and therefore a different Acceptable Daily Intake (ADI). Consequently, the text removes food additive Annatto, Bixin, Norbixin (E 160b) from the Union list of permitted food additives in Regulation (EC) No. 1333/2008 and inserts instead in that list two new separate food additives, namely Annatto bixin (E 160b(i)) and Annatto norbixin (E 160b(ii)). As a consequence, the text removes the authorised uses and conditions of use for the food additive Annatto, Bixin, Norbixin (E 160b) from the list of authorised conditions of use in food in to Regulation (EC) No. 1333/2008, and lays down the authorised uses and use levels for the two new food additives Annatto bixin (E 160b(i)) and Annatto norbixin (E 160b(ii)). The Annex to Regulation (EU) No. 231/2012 (specifications for food additives) is amended accordingly.
<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.

8.	<p><b>Is there a relevant international standard? If so, identify the standard:</b></p> <p><input checked="" type="checkbox"/> <b>Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</b> Codex General Standard for Food Additives - Codex Stan 192-1995</p> <p><input type="checkbox"/> <b>World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</b></p> <p><input type="checkbox"/> <b>International Plant Protection Convention (e.g. ISPM number):</b></p> <p><input type="checkbox"/> <b>None</b></p> <p><b>Does this proposed regulation conform to the relevant international standard?</b></p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b></p>
9.	<p><b>Other relevant documents and language(s) in which these are available:</b></p> <p>The safety of annatto extracts (E 160b) as a food additive (European Food Safety Authority, EFSA Journal 2016;14(8):4544, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/4544">https://www.efsa.europa.eu/en/efsajournal/pub/4544</a>)</p> <p>Exposure assessment of annatto colouring principles bixin and norbixin (E 160b) when used as food additives (European Food Safety Authority, EFSA Journal 2017;15(8):4966, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/4966">https://www.efsa.europa.eu/en/efsajournal/pub/4966</a>)</p> <p>Safety of annatto E and the exposure to the annatto colouring principles bixin and norbixin (E 160b) when used as a food additive (European Food Safety Authority, EFSA Journal 2019;17(3):5626, <a href="https://www.efsa.europa.eu/en/efsajournal/pub/5626">https://www.efsa.europa.eu/en/efsajournal/pub/5626</a>). (available in English)</p>
10.	<p><b>Proposed date of adoption (dd/mm/yy):</b> June 2020</p> <p><b>Proposed date of publication (dd/mm/yy):</b> June 2020</p>
11.	<p><b>Proposed date of entry into force:</b> <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 (with transitional provisions for a six-month period).</p> <p><input type="checkbox"/> <b>Trade facilitating measure</b></p>
12.	<p><b>Final date for comments:</b> <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 21 April 2020</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: +(322) 295 4263 Fax: +(322) 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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