



25 April 2022

(22-3262)

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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 the Annex to Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the presence of ethylene oxide in food additives (Text with EEA relevance). <b>Language(s):</b> English. <b>Number of pages:</b> 6 <a href="https://members.wto.org/crnattachments/2022/SPS/EEC/22_3022_00_e.pdf">https://members.wto.org/crnattachments/2022/SPS/EEC/22_3022_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2022/SPS/EEC/22_3022_01_e.pdf">https://members.wto.org/crnattachments/2022/SPS/EEC/22_3022_01_e.pdf</a>
<b>6. Description of content:</b> The text revises the part of the EU specifications of food additives related to ethylene oxide. Currently, Regulation (EU) No 231/2012 provides that ethylene oxide may not be used for sterilizing purposes in food additives. However, there is no quantified limit for the presence of ethylene oxide regarding all food additives. Recently, in the European Union, there have been several notifications concerning findings of ethylene oxide in particular in a number of food additives used for the manufacture of a variety of foodstuffs. However, it is difficult to establish whether the presence of ethylene oxide results from its use in the sterilization of the food additives in breach of Regulation No 231/2012 or from any other reason.  In order to avoid those difficulties and to ensure a high level of protection of human health, it is therefore appropriate to lay down that the presence of ethylene oxide, irrespective of its origin, is not authorized for all food additives. For this purpose, a maximum limit for residues of ethylene oxide specific for food additives should be set out at the limit of quantification in those products, that is, at the validated lowest residue concentration, which can be currently quantified and reported by routine monitoring with validated control methods. This corresponds to maximum limit of 0.1 mg/kg of ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide) applicable to all authorized food additives.
<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.

<p><b>8. 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b> Ethylene oxide is a substance of concern as regards carcinogenicity, mutagenicity and toxicity for reproduction. The food additive specifications developed by JECFA do not contain any general limit for ethylene oxide. The generally applicable limit addressing the presence of ethylene oxide in food additives, irrespective of its origin, proposed for the EU specifications is a follow up to the recent findings of ethylene oxide in a number of food additives and it intends to ensure a high level of protection of human health.</p>
<p><b>9. Other relevant documents and language(s) in which these are available:</b></p>
<p><b>10. Proposed date of adoption (dd/mm/yy):</b> Foreseen for August 2022.</p> <p><b>Proposed date of publication (dd/mm/yy):</b> Foreseen for August 2022.</p>
<p><b>11. Proposed date of entry into force:</b> <input type="checkbox"/> <b>Six months from date of publication, and/or (dd/mm/yy):</b> 20 days after publication in the Official Journal of the European Union.</p> <p><input type="checkbox"/> <b>Trade facilitating measure</b></p>
<p><b>12. Final date for comments:</b> <input checked="" type="checkbox"/> <b>Sixty days from the date of circulation of the notification and/or (dd/mm/yy):</b> 24 June 2022</p> <p><b>Agency or authority designated to handle comments:</b> <input checked="" type="checkbox"/> <b>National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b></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: <a href="mailto:sps@ec.europa.eu">sps@ec.europa.eu</a></p>
<p><b>13. Text(s) available from:</b> <input checked="" type="checkbox"/> <b>National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</b></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: <a href="mailto:sps@ec.europa.eu">sps@ec.europa.eu</a></p>