



24 April 2023

(23-2914)

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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 Regulation (EU) No 231/2012 as regards specifications for mono- and diglycerides of fatty acids (E 471) (Text with EEA relevance). <b>Language(s):</b> English. <b>Number of pages:</b> 6 + 4 <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_9231_00_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_9231_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2023/SPS/EEC/23_9231_01_e.pdf">https://members.wto.org/crnattachments/2023/SPS/EEC/23_9231_01_e.pdf</a>
<b>6. Description of content:</b> The text revises the EU specifications of the authorised food additives mono- and diglycerides of fatty acids (E 471) based on the recent scientific opinion from the European Food Safety Authority (EFSA). The current specifications are adapted by reducing the maximum limits for toxic elements, by including maximum limits for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD), glycidyl fatty acid esters (expressed as glycidol) and erucic acid and by modifying the definition of mono- and diglycerides of fatty acids (E 471).  In order to allow for a smooth transition, the text lays down that the use of the food additives mono- and diglycerides of fatty acids (E 471), lawfully placed on the market before the date of the entry into force of this Regulation is allowed during a transitional period of six months. Foods containing such food additives may continue to be placed on the market during the same transitional period and may remain on the market until their date of minimum durability or 'use-by-date'. However, in light of the vulnerability of infants and young children, the food additive mono- and diglycerides of fatty acids (E 471) not complying with the maximum level for glycidyl fatty acid ester set out in this Regulation for use in foods for infants and young children should not be added to such foods after the date of entry into force of this Regulation and the marketing of those foods should be allowed only if they were lawfully placed on the market already before that date.  The food additive mono- and diglycerides of fatty acids (E 471) legally placed on the market after the date of entry into force of this Regulation and complying with the reduced intermediate maximum level for glycidyl fatty acid esters (expressed as glycidol) is allowed to be used until the exhaustion of stocks and foods, except food for infants and young children, containing such food additive should be allowed to be placed on the market and to remain on the market until their date of minimum durability or 'use-by-date'.

7.	<b>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 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> The food additive specifications of mono- and diglycerides of fatty acids (INS 471) defined by JECFA (Monograph 1, 2006) do not contain maximum levels for arsenic, mercury, cadmium, the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD), glycidyl fatty acid esters (expressed as glycidol) and erucic acid.</p>
9.	<p><b>Other relevant documents and language(s) in which these are available:</b> Scientific opinion on the re-evaluation of mono- and diglycerides of fatty acids (E471) as food additive in foods for infants below 16 weeks of age and follow-up of their re-evaluation as food additives for uses in foods for all population groups. EFSAJournal2021;19(11):6885,44pp.  <a href="https://doi.org/10.2903/j.efsa.2021.6885">https://doi.org/10.2903/j.efsa.2021.6885</a> (available in English)</p>
10.	<p><b>Proposed date of adoption (dd/mm/yy):</b> Foreseen for Q3 2023.</p> <p><b>Proposed date of publication (dd/mm/yy):</b> Foreseen for Q3 2023.</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): 23 June 2023</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 A4-Multilateral International Relations  Rue Froissart 101  B-1049 Brussels  Tel: +(32 2) 29 54263  E-mail: <a href="mailto:sps@ec.europa.eu">sps@ec.europa.eu</a></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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