



24 March 2023

(24-2134)

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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 Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476) (Text with EEA relevance). Language(s): English. Number of pages: 16 https://members.wto.org/crnattachments/2023/SPS/EEC/23_8435_00_e.pdf https://members.wto.org/crnattachments/2023/SPS/EEC/23_8435_01_e.pdf
6. Description of content: The text revises the EU specifications of the authorised food additives glycerol (E 422), polyglycerol esters of fatty acids (E 475) and, polyglycerol polyricinoleate (E 476) and authorises an extension of use of polyglycerol polyricinoleate (E 476) based on the recent scientific opinions from the European Food Safety Authority (EFSA). For glycerol (E 422), the current specifications are adapted by reducing the maximum limits for toxic elements (arsenic, lead, mercury and cadmium), by deleting the identification method based on acrolein formation during heating, by deleting the test for the presence of acrolein, by including a maximum limit for acrolein and by modifying the definition of glycerol (E 422). For polyglycerol esters of fatty acids (E 475), 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 polyglycerol esters of fatty acids (E 475). For polyglycerol polyricinoleate (E 476), 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) and glycidyl fatty acid esters (expressed as glycidol) and by modifying the definition of polyglycerol polyricinoleate (E 476). The text also authorises the use of polyglycerol polyricinoleate (E 476) in food category 03 'Edible ices' at a maximum level of 4,000 mg/kg and in food category 12.6 'Sauces' at an increased maximum level of 8,000 mg/kg for emulsified sauces with a fat content of 20% or more.

In order to allow for a smooth transition, the text lays down that the use of the food additives glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinolate (E 476) 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'. The food additive polyglycerol esters of fatty acids (E 475) 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 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. Objective and rationale: food safety, animal health, plant protection, protect humans from animal/plant pest or disease, protect territory from other damage from pests.

8. Is there a relevant international standard? If so, identify the standard:

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

World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):

International Plant Protection Convention (e.g. ISPM number):

None

Does this proposed regulation conform to the relevant international standard?

Yes No

If no, describe, whenever possible, how and why it deviates from the international standard: The food additive specifications of glycerol (E 422) developed by JECFA do not contain maximum levels for arsenic, mercury, cadmium and acrolein.

For polyglycerol esters of fatty acids (E 475), the food additive specifications by JECFA 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.

For polyglycerol polyricinolate (E 476), the food additive specifications by JECFA 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) and glycidyl fatty acid esters (expressed as glycidol).

In the Codex General Standard for Food Additives (GSFA), Polyglycerol polyricinolate (E 476) is currently authorised in food category 3 'Edible ices, including sherbet and sorbet' at a maximum level of 5000 mg/kg and in food categories 12.6.1. 'Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dip)' and 12.6.3. 'Mixes for sauces and gravies' at a maximum level of 5000 mg/kg.

9. Other relevant documents and language(s) in which these are available:

– EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes M, Aquilina G, Castle L, Engel K, Fowler P, Frutos Fernandez MJ, Gundert-Remy U, Gürtler R, Husøy T, Manco M, Mennes W, Moldeus P, Passamonti S, Shah R, Waalkens-Berendsen I, Wölfle D, Wright M, Cheyins K, Mirat M, Rincon AM and Fürst P, 2022. Scientific Opinion on the follow-up of the reevaluation of glycerol (E 422) as a food additive. EFSA Journal 2022;20(6):7353, 18 pp.

<https://doi.org/10.2903/j.efsa.2022.7353>

<https://www.efsa.europa.eu/en/efsajournal/pub/7353>

– EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes M, Aquilina G, Castle L, Engel K, Fowler P, Frutos Fernandez MJ, Gundert-Remy U, Gürtler R, Husøy

<p>T, Manco M, Mennes W, Moldeus P, Passamonti S, Shah R, Waalkens-Berendsen I, Wölfle D, Wright M, Cheyns K, Mirat M, Rincon AM and Fürst P, 2022. Scientific Opinion on the follow-up of the reevaluation of polyglycerol esters of fatty acids (E 475) as a food additive. EFSA Journal 2022;20 (5):7308, 21 pp. https://doi.org/10.2903/j.efsa.2022.7308 https://www.efsa.europa.eu/en/efsajournal/pub/7308</p> <p>– EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes M, Aquilina G, Castle L, Engel K, Fowler P, Frutos Fernandez MJ, Gundert-Remy U, Gürtler R, Husøy T, Manco M, Mennes W, Moldeus P, Passamonti S, Shah R, Waalkens-Berendsen I, Wölfle D, Wright M, Cheyns K, Mirat M, Rincon AM, Tard A and Fürst P, 2022. Scientific Opinion on the follow-up of the reevaluation of polyglycerol polyricinoleate (E 476) as a food additive. EFSA Journal 2022;20(5):7294, 30 pp. https://doi.org/10.2903/j.efsa.2022.7294 https://www.efsa.europa.eu/en/efsajournal/pub/7294</p> <p>(available in English)</p>
<p>10. Proposed date of adoption (dd/mm/yy): Foreseen for Q3 2023. Proposed date of publication (dd/mm/yy): Foreseen for Q3 2023.</p>
<p>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 (with transitional provisions for a six-month period). <input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: [X] Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 23 May 2023 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:</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 Fax: +(32 2) 29 98090 E-mail: sps@ec.europa.eu</p>
<p>13. Text(s) available from: [X] 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 A4-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>