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**COMMISSION REGULATION (EU) .../...**

**of XXX**

**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)

# COMMISSION REGULATION (EU) .../...

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**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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives<sup>1</sup>, and in particular Article 10(3) and Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings<sup>2</sup>, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012<sup>3</sup> lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) The Union lists of food additives and the specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council, either on the initiative of the Commission or following an application.
- (4) Glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476) are substances authorised in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008.
- (5) On 15 March 2017, the Authority issued a scientific opinion on the re-evaluation of glycerol (E 422) as a food additive<sup>4</sup>, which concluded that there was no need for a numerical acceptable daily intake (ADI) and that the food additive was of no safety concern for the reported uses. The Authority recommended some modifications to the

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1.

<sup>3</sup> Commission Regulation (EU) No 231/2012 of 9 March 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 (OJ L 83, 22.3.2012, p. 1).

<sup>4</sup> EFSA Journal 2017;15(3):4720.

specifications for E 422 set out in Regulation (EU) No 231/2012 and that more information on the uses and use levels is made available to the Authority.

- (6) On 23 November 2018, the Commission launched a public call for technical data on the food additive glycerol (E 422), targeting the data needs identified by the Authority.
- (7) Following the data submission by interested business operators, the Commission requested the Authority to provide a scientific opinion to confirm that the technical data provided by interested business operators adequately supported an amendment to the specifications for the food additive glycerol (E 422) to bring them in line with current standards, as recommended by the Authority.
- (8) In its scientific opinion adopted on 18 May 2022<sup>5</sup>, the Authority concluded that the current specifications for glycerol (E 422) were to be adapted in particular 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).
- (9) It is therefore appropriate to amend the specifications for glycerol (E 422). The definition of the food additive should be amended to restrict it to the manufacturing processes for which data were assessed by the Authority. The current maximum limits for toxic elements should be reduced in accordance with the scientific opinion of the Authority, taking into account the currently achievable levels by the application of good manufacturing practices. The identification method for glycerol based on acrolein formation during heating should be deleted considering that the content of glycerol in E 422 is to be determined by an appropriate analytical method. The test for the presence of acrolein should be deleted and a maximum numerical limit for acrolein should be included in accordance with the scientific opinion of the Authority and taking into account the currently achievable level by the application of good manufacturing practices.
- (10) Food business operators should be granted enough time to adapt their production processes and therefore it is appropriate that the revised maximum levels for toxic elements and the new maximum level for acrolein only apply from ... [*6 months after the date of entry into force of this Regulation*]. Considering that the Authority did not identify an immediate health concern linked to the presence of toxic elements and acrolein and in order to allow for a smooth transition to the revised specifications, it is appropriate to allow foods containing the food additive glycerol (E 422) not complying with the revised maximum levels for toxic elements and the new maximum level for acrolein placed on the market before that date to remain on the market until their date of minimum durability or 'use-by-date'.
- (11) On 20 December 2017, the Authority issued a scientific opinion on the re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive<sup>6</sup>, which concluded that there was no need for a numerical acceptable daily intake and that the food additive was of no safety concern at the reported uses and use levels. The Authority recommended some modifications to the specifications for E 475 set out in Regulation (EU) No 231/2012.

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<sup>5</sup> EFSA Journal 2022;20(6):7353.

<sup>6</sup> EFSA Journal 2017;15(12):5089.

- (12) On 23 November 2018, the Commission launched a public call for technical data on the food additive polyglycerol esters of fatty acids (E 475), targeting the data needs identified by the Authority.
- (13) Following the data submission by interested business operators, the Commission requested the Authority to provide a scientific opinion to confirm that the technical data provided by interested business operators adequately supported an amendment to the specifications for the food additive polyglycerol esters of fatty acids (E 475) to bring them in line with current standards, as recommended by the Authority.
- (14) In its scientific opinion adopted on 1 April 2022<sup>7</sup>, the Authority concluded that the current specifications for polyglycerol esters of fatty acids (E 475) were to be adapted in particular by reducing the maximum limits for toxic elements, by including maximum limits for impurities and constituents of safety concern and by modifying the definition of polyglycerol esters of fatty acids (E 475).
- (15) It is therefore appropriate to amend the specifications for polyglycerol esters of fatty acids (E 475). The definition of the food additive should be amended in order to restrict the use of glycerol for the production of the food additive to glycerol compliant with the specifications for the food additive (E 422). The current maximum limits for toxic elements should be reduced and 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 should be established in accordance with the scientific opinion of the Authority and taking into account the currently achievable levels by the application of good manufacturing practices.
- (16) As new manufacturing techniques resulting in the production of the food additive polyglycerol esters of fatty acids (E 475) with lower levels of glycidyl fatty acid esters (expressed as glycidol) are being implemented, it is appropriate to provide the manufacturers of food additives with a transitional period to reach a maximum level of 5 mg/kg for glycidyl fatty acid esters (expressed as glycerol) in the food additive (E 475). However, given that glycidyl fatty acid esters are genotoxic and carcinogenic, an intermediate maximum level of 10 mg/kg for glycidyl fatty acid esters (expressed as glycerol) should apply from the entry into force of this Regulation. Nevertheless, considering that the Authority did not identify an immediate health concern linked to the presence of glycidyl fatty acid esters, and in order to allow for a smooth transition to the revised specifications, foods containing polyglycerol esters of fatty acids (E 475) not complying with the intermediate maximum level for glycidyl fatty acid esters and placed on the market before ... [*date of the entry into force of this Regulation*] should be allowed to remain on the market for a limited period of time. On account of their genotoxic and carcinogenic characteristics, this period should be limited to ... [*6 months after the entry into force of this Regulation*]. For the same reasons, foods containing polyglycerol esters of fatty acids (E 475) complying with the reduced intermediate maximum level for glycidyl fatty acid esters should be allowed to remain on the market until their date of minimum durability or 'use-by-date'.
- (17) Food business operators should be granted enough time to adapt their production processes, therefore it is appropriate that the revised maximum levels for toxic elements and the new maximum levels for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) and erucic acid only

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<sup>7</sup> EFSA Journal 2022;20(5):7308.

apply from ... [6 months after the date of entry into force of this Regulation]. Given that the Authority did not identify an immediate health concern linked to the presence of toxic elements, 3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and erucic acid and in order to allow for a smooth transition to the revised specifications, it is appropriate to allow foods containing polyglycerol esters of fatty acids (E 475) not complying with the revised maximum levels for toxic elements and the new maximum levels for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) and erucic acid placed on the market before ... [6 months after the date of entry into force of this Regulation] to remain on the market until their date of minimum durability or 'use-by-date'.

- (18) On 24 March 2017, the Authority issued a scientific opinion on the re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive<sup>8</sup>. The Authority concluded that the data set gave reason to increase the acceptable daily intake to 25 mg/kg bw per day. The Authority recommended some modifications to the specifications for E 476 set out in Regulation (EU) No 231/2012.
- (19) On 23 November 2018, the Commission launched a public call for technical data on the food additive polyglycerol polyricinoleate (E 476), targeting the data needs identified by the Authority.
- (20) On 18 March 2020, an application was submitted for the authorisation of the use of polyglycerol polyricinoleate (E 476) as an emulsifier in edible ices for fat and oil emulsion of water-in-oil type and emulsified sauces with a fat content of more than 20 %. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (21) Polyglycerol polyricinoleate (E 476) is capable of producing stable water-in-oil emulsions with smaller droplet sizes that can be frozen to produce soft, creamy, edible ices requiring less energy in the manufacturing process and having enhanced stability in the frozen supply chain. It allows the use of low saturated fats and oils and lower amounts of sugars in edible ices. The level of polyglycerol polyricinoleate (E 476) needed to achieve the intended technological function is 4000 mg/kg.
- (22) Polyglycerol polyricinoleate (E 476) also enables oil reduction in emulsified sauces (e.g. mayonnaise or salad dressings) without having the negative effect on mouthfeel. The currently authorised maximum level of 4000 mg/kg is not sufficient for products with a fat content of more than 20 %. The level of use of polyglycerol polyricinoleate (E 476) needed to achieve the intended technological function in products with a fat content of more than 20 % is 8000 mg/kg.
- (23) Following the data submission by interested business operators in response to the public call for technical data and the submission of the application on the extension of use of polyglycerol polyricinoleate (E 476), the Commission requested the Authority to provide a scientific opinion to confirm that the technical data provided by interested business operators adequately supported an amendment to the specifications for the food additive polyglycerol polyricinoleate (E 476) to bring them in line with current standards, as recommended by the Authority.
- (24) In its scientific opinion adopted on 30 March 2022<sup>9</sup>, the Authority concluded that the proposed extension of use would not give rise to a safety concern. The Authority also

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<sup>8</sup> EFSA Journal 2017;15(3):4743.

<sup>9</sup> EFSA Journal 2022;20(5):7294.

concluded that the current specifications for polyglycerol polyricinoleate (E 476) were to be adapted in particular by reducing the maximum limits for toxic elements, by including maximum limits for impurities of safety concern and by modifying the definition of polyglycerol polyricinoleate (E 476).

- (25) It is therefore appropriate to authorise polyglycerol polyricinolate (E 476) in food category 03 'Edible ices' at a maximum level of 4000 mg/kg, increase the authorised maximum level in food category 12.6 'Sauces' to 8000 mg/kg for emulsified sauces with a fat content of 20 % or more and amend its specifications in light of the Authority's scientific opinion. The definition of the food additive should be amended in order to restrict the use of glycerol for the production of the food additive to glycerol compliant with the specifications for the food additive (E 422). The current maximum limits for toxic elements should be reduced and 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) should be established in accordance with the scientific opinion of the Authority and taking into account the currently achievable level by the application of good manufacturing practices.
- (26) Given that glycidyl fatty acid esters are genotoxic and carcinogenic, the maximum level for glycidyl fatty acid esters (expressed as glycerol) in polyglycerol polyricinolate (E 476) should apply from the entry into force of this Regulation. Considering that the Authority did not identify an immediate health concern linked to the presence of glycidyl fatty acid esters, and in order to allow for a smooth transition to the revised specifications, foods containing polyglycerol polyricinolate (E 476) not complying with the new maximum level for glycidyl fatty acid esters and placed on the market before ... [*date of the entry into force of this Regulation*] should only be allowed to remain on the market for a limited period of time. On account of the genotoxic and carcinogenic characteristics of the impurity, this period should be limited to ... [*6 months after the entry into force of this Regulation*].
- (27) Food business operators should be granted enough time to adapt their production processes, therefore it is appropriate that the revised maximum levels for toxic elements and the new maximum level for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) only apply from ... [*6 months after the date of entry into force of this Regulation*]. Given that the Authority did not identify an immediate health concern linked to the presence of toxic elements, 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters and in order to allow for a smooth transition to the revised specifications, it is appropriate to allow foods containing polyglycerol polyricinolate (E 476) not complying with the revised maximum levels for toxic elements and the new maximum level for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) placed on the market before ... [*6 months after the date of entry into force of this Regulation*] to remain on the market until their date of minimum durability or 'use-by-date'.
- (28) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (29) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

*Article 2*

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

*Article 3*

Foods containing the food additive glycerol (E 422) that does not comply with the limits for arsenic, lead, mercury, cadmium and acrolein laid down in Annex II may continue to be placed on the market until ... *[6 months after the date of entry into force of this Regulation]* and may continue to be marketed until their date of minimum durability or 'use-by date'.

Foods containing the food additive polyglycerol esters of fatty acids (E 475) that does not comply with the limits for arsenic, lead, mercury, cadmium, the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD), and erucic acid laid down in Annex II may continue to be placed on the market until ... *[6 months after the date of entry into force of this Regulation]* and may continue to be marketed until their date of minimum durability or 'use-by date'.

Foods containing the food additive polyglycerol polyricinoleate (E 476) that does not comply with the limits for arsenic, lead, mercury, cadmium and the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) laid down in Annex II may continue to be placed on the market until ... *[6 months after the date of entry into force of this Regulation]* and may continue to be marketed until their date of minimum durability or 'use-by date'.

Foods, which have been lawfully placed on the market before ... *[date of the entry into force of this Regulation]*, and containing the food additive polyglycerol esters of fatty acids (E 475) that does not comply with the maximum limit for glycidyl fatty acids esters (expressed as glycerol) applicable from ... *[the entry into force of this Regulation]*, may continue to be marketed until ... *[6 months after the entry into force of this Regulation]*. ]

Foods, which have been lawfully placed on the market before ... *[date of the entry into force of this Regulation]*, and containing the food additive polyglycerol polyricinoleate (E 476) that does not comply with the maximum limit for glycidyl fatty acids esters (expressed as glycerol) applicable from ... *[the entry into force of this Regulation]*, may continue to be marketed until ... *[6 months after the entry into force of this Regulation]*.

Foods, which have been lawfully placed on the market before ... *[date of the entry into force of this Regulation]*, and containing the food additive polyglycerol esters of fatty acids (E 475) that complies with the maximum limit for glycidyl fatty acids esters (expressed as glycerol) applicable from ... *[date of the entry into force of this Regulation]*, may continue to be marketed until their date of minimum durability or 'use by date'.

Foods, which have been lawfully placed on the market before ... *[date of the entry into force of this Regulation]*, and containing the food additive polyglycerol polyricinoleate (E 476) that complies with the maximum limit for glycidyl fatty acids esters (expressed as glycerol)

applicable from ... [*date of the entry into force of this Regulation*] may continue to be marketed until their date of minimum durability or ‘use by date’.

Foods containing the food additive polyglycerol esters of fatty acids (E 475), which have been lawfully placed on the market after ... [*date of the entry into force of this Regulation*] and up to ... [*6 months after the date of entry into force of this Regulation*], may continue to be marketed until their date of minimum durability or ‘use by date’.

#### *Article 4*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*