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COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) No 231/2012 as regards specifications for mono- and diglycerides of fatty acids (E 471)

(Text with EEA relevance)

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amending Regulation (EU) No 231/2012 as regards specifications for mono- and diglycerides of fatty acids (E 471)

(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[1], and in particular Article 14 thereof,

Whereas:

(1) Commission Regulation (EU) No 231/2012[2] lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(2) The specifications for food additives 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[3], either on the initiative of the Commission or following an application from a Member State or an interested party.

(3) Mono- and diglycerides of fatty acids (E 471) is a substance authorised in a variety of foods in accordance with Annexes II and III to Regulation (EC) No 1333/2008.

(4) On 26 September 2017, the Authority issued a scientific opinion on the re-evaluation of mono- and diglycerides of fatty acids (E 471) as food additives[4], which concluded that there was no need for a numerical acceptable daily intake and that the food additive was of no safety concern when used in food for the general population. The Authority considered that the uses in food for infants under the age of 16 weeks would require a specific risk assessment. The Authority recommended some modifications to the specifications for food additive E 471 set out in Regulation (EU) No 231/2012.

(5) Following the publication of that scientific opinion, as part of the re-evaluation of the safety of food additives permitted in food category 13.1 (food for infants and young children) of Annex II to Regulation (EC) No 1333/2008, the Commission requested the Authority to address the data gaps specified in the recommendations of that scientific opinion.

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1 OJ L 354, 31.12.2008, p. 16.

2 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).

3 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 (OJ L 354, 31.12.2008, p. 1).

4 EFSA Journal 2017;15(11):5045.

(6) On 29 November 2018, the Authority launched a public call for technical and toxicological data on food additive E 471. This allowed the interested parties to provide the requested information for completing its risk assessment of E 471 as a food additive in food for all population groups and to assess the safety of its use in food for infants below 16 weeks of age.

(7) In 2020, there was a RASFF notification concerning findings of high levels of genotoxic and carcinogenic glycidyl fatty acids esters (expressed as glycidol) in the food additive E 471 used in the production of a bread spread. On the basis of that notification and pending the recommendations of the Authority for the setting of maximum limits for glycidyl fatty acids esters in the food additive, follow-up actions were undertaken on the basis of Article 14 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[5]. A broad concentration range and high levels of glycidyl esters (expressed as glycidol) were detected in commercial samples of the food additive analysed by the industry in response to the call for data during the same period.

(8) Considering that the food additive E 471 is authorised at *quantum satis* in food categories for which the setting of maximum levels for the presence of glycidyl fatty acids esters is envisaged or is already in place, maximum levels for glycidyl fatty acids esters (expressed as glycidol) in food additive E 471 should be established to avoid the placing on the market of unsafe food.

(9) In its scientific opinion adopted on 30 September 2021[6], the Authority concluded that there is no reason for a safety concern when the food additive E 471 is used in food categories 13.1.1 (infant formulae) and 13.1.5.1 (dietary foods for infants for special medical purposes and special formulae for infants) of Annex II to Regulation (EC) No 1333/2008 and in accordance with Annex III to that Regulation. The Authority recommended adapting the current specifications for mono- and diglycerides of fatty acids (E 471), in particular by reducing the maximum limits for toxic elements and including maximum limits for impurities and constituents of safety concern.

(10) In light of the Authority's recommendation and the maximum levels for certain contaminants in foods as laid down in Regulation (EU) 2023/…[7], it is therefore appropriate to amend the specifications for mono- and diglycerides of fatty acids (E 471). 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 of the food additive E 422. A maximum content of erucic acid should be established in the current entry 'assay' for mono- and diglycerides of fatty acids (E 471). The current maximum limits for arsenic, lead, mercury and cadmium should be reduced and maximum limits for the sum of 3-monochloropropane diol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD), and glycidyl fatty acids esters (expressed as glycidol) should be established in accordance with the opinion of the Authority. In order to exclude high exposure to those impurities and components of concern resulting from the consumption of food containing the food additive E 471 by vulnerable consumers, it is necessary to establish stricter maximum limits for erucic

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5 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

6 EFSA Journal 2021;19(11):6885.

7 Commission Regulation (EU) 2023/…of …on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L x, xxxxxx, p. x).

acid and the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) applicable for foods for infants and young children[8]. Those maximum limits take into account the level which is currently reasonably achievable by the application of good manufacturing practices.

(11) As new manufacturing techniques resulting in the production of mono- and diglycerides of fatty acids (E 471) with lower levels of glycidyl fatty acid esters (expressed as glycidol) are being implemented, it is appropriate to provide the manufacturers of this food additive with a transitional period to reach a maximum level of 5 mg/kg for glycidyl fatty acid esters (expressed as glycidol) in the food additive E 471. However, given that glycidyl fatty acid esters have a genotoxic and carcinogenic potential, an intermediate maximum level of 10 mg/kg for glycidyl fatty acid esters (expressed as glycidol) should apply from the date of the entry into force of this Regulation except for uses in food for infants and young children.

(12) Considering that the Authority did not identify an immediate health concern linked to the presence of toxic elements, erucic acid, the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters and glycidyl fatty acid esters, it is appropriate to allow during a transitional period the use of the food additive mono- and diglycerides of fatty acids E 471, lawfully placed on the market before the date of entry into force of this Regulation and to allow foods containing such food additive to continue to be placed on the market during the transitional period and to 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 esters set out in this Regulation for use in foods for infants and young children should not be allowed to 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.

(13) For the same reasons and considering its reduced contents of glycidyl fatty acid esters, the food additive mono- and diglycerides of fatty acids (E 471) complying with the reduced intermediate maximum level for glycidyl fatty acid esters (expressed as glycidol) should be 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'.

(14) Regulation (EU) No 231/2012 should therefore be amended accordingly.

(15) The measures provided for in this regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

[8] As defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

The food additive mono- and diglycerides of fatty acids (E 471) that has been lawfully placed on the market before … [*date of the entry into force of this Regulation*] and that does not comply with the maximum limits for arsenic, lead, mercury, cadmium, 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD), or erucic acid applicable from … [*date of the entry into force of this Regulation*] may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 and Regulation (EU) 2023/… until … [*6 months after the date of entry into force of this Regulation*].

The food additive mono- and diglycerides of fatty acids (E 471) that has been lawfully placed on the market before … [*date of the entry into force of this Regulation*] and that does not comply with the maximum limits for glycidyl fatty acids esters (expressed as glycidol) applicable from … [*date of the entry into force of this Regulation*] may be added to food, except for foods for infants and young children, in accordance with Annexes II and III to Regulation (EC) No 1333/2008 and Regulation (EU) 2023/… until … [*6 months after the date of entry into force of this Regulation*].

Foods containing the food additive mono- and diglycerides of fatty acids (E 471) that has been lawfully placed on the market before … [*date of the entry into force of this Regulation*] and that does not comply with the maximum limits for arsenic, lead, mercury, cadmium, 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) or erucic acid applicable from … [*date of the entry into force of this Regulation*] 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, except foods for infants and young children, containing the food additive mono- and diglycerides of fatty acids (E 471) that has been lawfully placed on the market before … [*date of the entry into force of this Regulation*] and that does not comply with the maximum limits for glycidyl fatty acids esters (expressed as glycidol) applicable from … [*date of the entry into force of this Regulation*] 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 for infants and young children lawfully placed on the market before … [*date of the entry into force of this Regulation*] and containing the food additive mono- and diglycerides of fatty acids (E 471) that does not comply with the maximum limits glycidyl fatty acids esters (expressed as glycidol) 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'.

The food additive mono- and diglycerides of fatty acids (E 471) that has 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*] and that does not comply with the maximum limits for glycidyl fatty acids esters (expressed as glycidol) applicable from … [*6*

months after the date of entry into force of this Regulation] may be added to food, except foods for infants and young children, in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

Foods, except food for infants and young children, containing the food additive mono- and diglycerides of fatty acids (E 471) that has 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*] and that does not comply with the maximum limits for glycidyl fatty acids esters (expressed as glycidol) applicable from … [*6 months after the date of entry into force of this Regulation*] may continue to be placed on the market and may continue to be marketed until their date of minimum durability or 'use by date'.

Article 3

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