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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)

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)

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 10(3) and 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 (ADI) 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

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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.

the Authority to address the data gaps specified in the recommendations of that scientific opinion.

(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 EFSA 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 of data during the same period. 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 glycerol) in food additive E 471 should be established to avoid the placing on the market of unsafe food.

(8) 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.

(9) In light of the Authority's recommendation and the maximum levels for certain contaminants in foods as laid down in [Commission Regulation (EC) No XXXX/2023[7]], it is therefore appropriate to amend the specifications for mono- and diglycerides of fatty acids (E 471). That amendment includes the deletion of synonyms. 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

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

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 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 achievable by the application of good manufacturing practices.

(10) Food business operators should be granted enough time to adapt their production processes, therefore it is appropriate that the revised maximum levels for arsenic, lead, mercury and cadmium and the new maximum levels for erucic acid and 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*]. Considering that the Authority did not identify an immediate health concern linked to the presence of those impurities and constituents and in order to allow for a smooth transition to the revised specifications, it is appropriate to allow foods containing the food additive mono- and diglycerides of fatty acids (E 471) not complying with the revised maximum levels for toxic elements and the new maximum levels for erucic acid and the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) placed on the market before that date to remain on the market until their date of minimum durability or 'use-by-date'.

(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 are genotoxic and carcinogenic, an intermediate maximum level of 10 mg/kg for glycidyl fatty acid esters (expressed as glycidol) should apply from … [*date of the entry into force of this Regulation*] except for uses in food for infants and young children. 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 the food additive (E471) 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 during 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*]. For the same reasons, foods containing 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 glycerol) should be allowed to remain on the market until their date of minimum durability or 'use-by-date'.

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

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[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).

(13) 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

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

Article 2

Foods containing the food additive mono- and diglycerides of fatty acids (E 471) that does not comply with the limits for arsenic, lead, mercury, cadmium, 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) and erucic acid laid down in the Annex 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 food for infants and young children, which have been 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 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 … [*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 mono- and diglycerides of fatty acids (E 471) that complies with the maximum limits 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 mono- and diglycerides of fatty acids (E 471), 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 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