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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EU) 2023/915 as regards maximum levels of 3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters in certain foods

Delegations will find attached document D111624/02.

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

of **XXX**

**amending Regulation (EU) 2023/915 as regards maximum levels of
3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid
esters in certain foods**

(Text with EEA relevance)

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

of **XXX**

amending Regulation (EU) 2023/915 as regards maximum levels of 3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters in certain foods

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food¹, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EU) 2023/915² sets maximum levels for certain contaminants in foodstuffs.
- (2) The Scientific Panel on Contaminants in the Food Chain ('the CONTAM Panel') of the European Food Safety Authority adopted on 3 March 2016 a scientific opinion on the risks for human health related to the presence of 3- and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food³. On 21 November 2017, the CONTAM Panel adopted a scientific opinion on an update of its assessment of the risks for human health related to the presence of 3-monochloropropanediol ('3-MCPD') and its fatty acid esters in food⁴. The CONTAM Panel concluded that the presence of glycidyl esters in food is of health concern and the presence of 3-MCPD and its fatty acid esters is of health concern in certain exposure scenarios and population groups.
- (3) Maximum levels for glycidyl fatty acid esters, expressed as glycidol, and for the sum of 3-MCPD and 3-MCPD fatty acid esters, expressed as 3-MCPD have been established for vegetable oils and fats, fish oils and oils from other marine organisms in Regulation (EU) 2023/915. Considering the health concern for infants and young children, specific maximum levels for infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children and young child formulae have also been established in that Regulation.

¹ OJ L 37, 13.2.1993, p. 1, ELI: <http://data.europa.eu/eli/reg/1993/315/oj>.

² Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: <http://data.europa.eu/eli/reg/2023/915/oj>).

³ Scientific opinion on the risks for human health related to the presence of 3- and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food. EFSA Journal 2016;14(5): 4426, 159 pp. <https://doi.org/10.2903/j.efsa.2016.4426>.

⁴ Scientific opinion on the update of the risk assessment on 3-monochloropropanediol and its fatty acid esters. EFSA Journal 2018;16(1):5083, 48 pp. <https://doi.org/10.2903/j.efsa.2018.5083>.

- (4) A specific lower level was established for vegetable oils and fats, fish oils and oils from other marine organisms destined for the production of baby food and processed cereal-based food for infants and young children. At the time of adoption of Regulation (EU) 2023/915, no maximum levels for glycidyl fatty acid esters and for the sum of 3-MCPD and 3-MCPD fatty acid esters were established for baby food and processed cereal-based food for infants and young children due to the lack of occurrence data.
- (5) In the meantime, the occurrence data on glycidyl fatty acid esters, 3-MCPD and 3-MCPD fatty acid esters have become available for baby food and processed cereal-cereal based food for infants and young children. It is therefore appropriate to establish maximum levels in these foods on the basis of those data. Furthermore, the maximum levels for vegetable oils and fats, fish oils and oils from other marine organisms destined for the production of baby food and processed cereal-based food for infants and young children should be lowered to ensure consistency with the maximum levels for baby food and processed cereal-based food for infants and young children taking into account their typical vegetable oil content.
- (6) High levels of glycidyl fatty acid esters and the sum of 3-MCPD and 3-MCPD fatty acid esters have been found in compound food containing vegetable oils and difficulties were experienced to assess compliance with Article 3 of Regulation (EU) 2023/915. To ensure effective enforcement, it is necessary to establish additional provisions as regards the application of maximum levels for glycidyl fatty acid esters and the sum of 3-MCPD and 3-MCPD fatty acid esters in compound food containing vegetable oils. As there is evidence that additional contamination of coated fish and meat with 3-MCPD and 3-MCPD fatty acid esters as the consequence of frying occurs, but the factors of such formation are for the moment undetermined. Since the determination of such factors is necessary to apply good practices to mitigate that contamination and to establish appropriate maximum levels for 3-MCPD and 3-MCPD fatty acid esters in these foods as low as reasonably achievable, maximum levels should not be set out as regards those foods pending that determination, which is not expected before 2027.
- (7) There has been some confusion as to which maximum level of 3-MCPD and 3-MCPD fatty acid esters is applicable to refined olive oil. It is therefore appropriate to clarify in the remarks regarding the maximum level for other vegetable oils and fats, fish oils and oils from other marine organisms that the maximum level is also applicable to refined olive oil.
- (8) For the control of the presence of glycidyl fatty acid esters, indirect methods of analysis are routinely used by official control laboratories. Recent research has found that with the use of these indirect methods, 3-monobromopropanediol (3-MBPD) fatty acid esters and 3-monoiodopropanediol (3-MIPD) fatty acid esters are determined together with glycidyl esters due to analytical conversions, particularly in the case of marine oils. It is therefore appropriate to explicitly provide that the maximum levels for glycidyl esters include also the compounds 3-MBPD and 3-MIPD.
- (9) Regulation (EU) 2023/915 should therefore be amended accordingly.
- (10) To enable economic operators to prepare for the new maximum levels for baby food and processed cereal-cereal based food for infants and young children and the lowered maximum level for vegetable oils and fats, fish oils and oils from other marine organisms destined for the production of baby food and processed cereal-based food

for infants and young children, it is appropriate to provide for a reasonable time until the new maximum levels apply.

- (11) Taking into account that baby food and processed cereal based food for infants and young children have a long shelf life, it is appropriate that these foods that were lawfully placed on the market before the date of application of the maximum level for these foods are allowed to remain on the market.
- (12) 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

Regulation (EU) 2023/915 is amended as follows:

(1) Article 10(1) is amended as follows:

(a) the introductory phrase is replaced by the following:

‘Food lawfully placed on the market prior to the dates referred to in points (a) to (r) may remain on the market until their date of minimum durability or use-by date.’;

(b) the following point (r) is added:

‘ (r) 1 January 2027 as regards the maximum levels for sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD set out in points 5.3.2 and 5.3.4 of Annex I and the maximum levels for glycidyl fatty acid esters set out in points 5.4.2 and 5.4.4. of Annex I.’;

(2) Annex I is amended in accordance with the Annex to this Regulation.

Article 2

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