



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2021/12766 - D109639/01
[...] (2025) **XXX** draft

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 provisions in this document have not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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 ('the 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. The CONTAM Panel adopted on 21 November 2017 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.
- (3) Glycidyl fatty acid esters are food contaminants found at highest levels in refined vegetable oils and fats. Glycidyl fatty acid esters are hydrolysed into glycidol in the gastrointestinal tract. The CONTAM Panel applied a margin of exposure approach and taking into account exposure scenarios, it concluded that the presence of glycidyl esters in food is of health concern. The CONTAM Panel established an updated group Tolerable Daily Intake (TDI) of 2 µg/kg body weight per day for 3-MCPD and its fatty acid esters and noted that this TDI is not exceeded in the adult population. However, an exceedance of the TDI was observed in case of the high consumers of the younger age groups and in particular in case of infants receiving formula only.
- (4) 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 marine organisms have

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>

been established by Regulation (EU) 2023/915. Considering the health concern for infants, toddlers and young children, specific maximum levels for infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children⁵ and young child formulae⁶ have also been established by the same Regulation.

- (5) 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 children⁵ due to the lack of occurrence data. A specific lower level was established for vegetable oils, fish oils and oils from marine organisms destined for the production of baby food and processed cereal-cereal based food for infants and young children.
- (6) 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. Furthermore, the maximum levels for vegetable oils, fish oils and oils from marine organisms destined for the production of baby food and processed cereal-based food for infants and young children have to be maintained but 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.
- (7) 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 Commission Regulation (EU) 2023/915. To ensure an 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.
- (8) There has been some confusion which maximum level of 3-MCPD and 3-MCPD fatty acid esters is applicable to refined olive oil. It is therefore appropriate to clarify this explicitly.
- (9) 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-monoiodinepropanediol (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.
- (10) Regulation (EU) 2023/915 should therefore be amended accordingly.

⁵ Food as defined in Article 2 of 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 L181, 29.6.2013, p. 35, <http://data.europa.eu/eli/reg/2013/609/oj>).

⁶ ‘Young-child formulae’ refers to milk-based drinks and similar protein-based products intended for young children. These products are outside the scope of Regulation (EU) No 609/2013 (Report from the Commission to the European Parliament and the Council on young-child formulae (COM(2016) 169 final) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016DC0169>

- (11) Given that several points of entries 5.3 Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD and 5.4 Glycidyl fatty acid esters, expressed as glycidol of Annex I to Commission Regulation (EU) 2023/915 are amended, it is appropriate to replace the entries 5.3 and 5.4 to improve the readability.
- (12) 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, fish oils and oils from 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. It is also appropriate to provide for a transitional period for food lawfully placed on the market before the date of application of this Regulation.
- (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

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 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, with the exception of the maximum levels for nickel set out in points 3.6.11.1 to 3.6.11.5 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 20th 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