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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EU) 2023/915 as regards maximum levels for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters in infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children and young child formulae

Delegations will find attached document D092106/2.

Encl.: D092106/2



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[...](2023) **XXX** draft

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

of **XXX**

amending Regulation (EU) 2023/915 as regards maximum levels for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters in infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children and young child formulae

(Text with EEA relevance)

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

of **XXX**

amending Regulation (EU) 2023/915 as regards maximum levels for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters in infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children and young child formulae

(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, including for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters in food.
- (2) When the maximum levels for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters in infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children and young child formulae were established by Commission Regulation (EU) 2020/1322³, it was stipulated that those maximum levels are to be reviewed in view of lowering them within 2 years from the date of application of that Regulation.
- (3) In 2018 the European Food Safety Authority ('the Authority') concluded that the presence of 3-MCPD esters and glycidyl esters in certain foodstuffs was a health concern, in particular in foods for infants and young children⁴.
- (4) Maximum levels for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters in infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children and young child formulae were established by Commission Regulation (EU) 2020/1322 and these maximum levels were integrated in Commission Regulation (EU) 2023/915.
- (5) Recent occurrence data from controls performed by Member States and available in the Authority's database of the sampling years 2020 - 2022 indicate that lower levels

¹ OJ L 37, 13.2.1993, p. 1.

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).

³ Commission Regulation (EU) 2020/1322 of 23 September 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of 3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters in certain foods (OJ L 310, 24.9.2020, p. 2).

⁴ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2018. Scientific Opinion on the update of the risk assessment on 3-monochloropropane diol and its fatty acid esters. EFSA Journal 2018;16(1):5083, 48 pp. <https://doi.org/10.2903/j.efsa.2018.5083>

of 3-MCPD and 3-MCPD fatty acid esters in infant formulae, follow-on formulae and food for special medical purposes intended for infants and young children and young child formulae can already be achieved following good practices. Therefore, those maximum levels should be lowered to ensure a high level of human health protection.

- (6) Regulation (EU) 2023/915 should therefore be amended accordingly.
- (7) To enable economic operators to prepare for the new rules introduced by this Regulation, 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.
- (8) 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 I to Regulation (EU) 2023/915 is amended in accordance with the Annex to this Regulation.

Article 2

Food listed in the Annex, lawfully placed on the market before 1 January 2025, may remain on the market 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*.

It shall apply from 1 January 2025.

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