

This draft has 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. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

SANTE PLAN 2025/2379 Rev0.

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

of XXX

amending Regulation (EU) 2023/915 as regards maximum levels for lead in certain foodstuffs.

(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, including lead in a range of foodstuffs.
- (2) Lead is a natural environmental contaminant, but its use in the past in water pipes, paint and petrol increased its general presence. Food is the major source of human exposure to lead.
- (3) On 18 March 2010, the European Food Safety Authority ('the Authority') adopted an opinion on lead in food³. The Authority identified that lead can cause developmental neurotoxicity in young children and cardiovascular issues and nephrotoxicity in adults. The risk assessment for lead was based on these potentially critical adverse effects. The Authority concluded that there was no evidence for a threshold for a number of critical endpoints, including developmental neurotoxicity and adult nephrotoxicity.

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 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2010. Scientific Opinion on lead in food. EFSA Journal 2010;8(4):1570, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1570>

This draft has 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. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

Therefore, it was not appropriate to derive a tolerable weekly intake. The Authority expressed a concern that there was potential that the current levels of dietary exposure to lead might affect neurodevelopment in fetuses, infants and children.

- (4) The Authority's conclusions were confirmed by the conclusions of the report of the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (FAO/WHO) in 2010.⁴
- (5) Taking into account the most recent occurrence data, the Codex Alimentarius Commission at its 45th Session ('CAC45') established the Codex maximum levels for lead in white sugar, corn and maple syrup and sugar-based candies.
- (6) Taking into account the most recent occurrence data, the Codex Alimentarius Commission at its 46th Session ('CAC46') established the Codex maximum levels for lead in soft brown raw and non-centrifugal sugars.
- (7) Taking into account the most recent occurrence data, the Codex Alimentarius Commission at its 47th Session ('CAC47') established the Codex maximum levels for lead spices other than bark spices.
- (8) Taking into account the most recent occurrence data, the Codex Alimentarius Commission at its 48th Session ('CAC 48') established the Codex maximum levels for lead in bark spices and dried culinary herbs.
- (9) In light of these developments and of the most recent occurrence data, the dietary exposure to lead in food should be reduced within the Union by setting additional maximum levels for aril spices, sugar, corn and maple syrup and confectionary that doesn't contain cocoa or chocolate products.
- (10) The current EU MLs for spices other than aril spices were established by means of Regulation (EU) 2021/1317 on the basis of the occurrence data that were available at the time. In the meanwhile new occurrence data have become available, which were taken into account for establishing Codex MLs for lead in spices. These data showed the necessity for a limited increase of the EU MLs for certain spice categories. As spices are only consumed in small amounts, such limited increase of the EU ML is appropriate, as it will not have a significant impact on the consumer exposure.
- (11) Regulation (EU) 2023/915 should therefore be amended accordingly.
- (12) Taking into account that certain foodstuffs covered by this Regulation have a long shelf life and, in order to prevent food waste, foods that were lawfully placed on the market before the date of entry into force of this Regulation should be allowed to remain on the market until their date of minimum durability or use-by date.

⁴ Evaluation of Certain Food Additives and Contaminants. Seventy-third report of the joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960.

This draft has 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. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

(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 (x) may remain on the market until their date of minimum durability or use-by date:’;

(b) the following point is added:

‘[Publications office, please add the following letter (x)] [Publications office, please include the date of entry into force of this Regulation] as regards the maximum levels for lead set out in points 3.1.12.7, 3.1.12.8, 3.1.29 and 3.1.30 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.