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

of **XXX**

**amending Regulation (EU) 2023/915 as regards maximum levels of nickel in certain
foodstuffs**

(Text with EEA relevance)

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amending Regulation (EU) 2023/915 as regards maximum levels of nickel 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.
- (2) Nickel is a widespread component of Earth's crust and is ubiquitous in the biosphere. Its presence in food can arise from both natural and anthropogenic sources.
- (3) In 2015, the European Food Safety Authority ('the Authority') adopted its Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water³. The opinion identified reproductive and developmental toxicity as the critical effect for the risk characterization of chronic oral exposure to nickel. Eczematous flare-up reactions and worsening of allergic reactions were identified as the critical effect for acute oral exposure to nickel of nickel-sensitized humans.
- (4) Data related to the occurrence of nickel in food and drinking water were available in 15 Member States. However, as 80 % of the total collected data were collected in one Member State, the Authority concluded that a more geographically diverse data set would be needed to verify the occurrence of nickel in food throughout the Union.
- (5) By means of Commission Recommendation (EU) 2016/1111⁴ Member States were recommended to monitor the presence of nickel in food in 2016, 2017 and 2018, in order to collect more occurrence data.
- (6) Taking into account these new occurrence data as well as the availability of new scientific information, on 24 September 2020 the Authority adopted an update of the risk assessment of nickel in food and drinking water.⁵

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/2006/1881/oj>).

³ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on the risks to public health related to the presence of nickel in food and drinking water. EFSA Journal 2015;13(2):4002, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4002>

⁴ Commission Recommendation (EU) 2016/1111 of 6 July 2016 on the monitoring of nickel in food (OJ L 183, 8.7.2016, p. 7, ELI: <http://data.europa.eu/eli/reco/2016/1111/oj>).

- (7) The Authority concluded that nickel may cause both chronic and acute effects. On the basis of the critical chronic effect of pregnancy loss, the Authority established a tolerable daily intake (TDI) of 13 µg/kg bw and the Authority concluded that this TDI was exceeded in toddlers, children between 36 months and 10 years old and also, in some cases, in infants. Even though pregnancy loss is not a relevant effect for the young age groups, the TDI is also protective for other effects relevant for the younger age groups such as neurotoxic effects. Therefore, the Authority concluded that exceedance of the TDI may raise health concerns in those young age groups. The Authority concluded that the critical acute effects are eczematous flare-up reactions in the skin elicited in nickel-sensitised humans, which concerns about 15% of the population, that the lowest observed adverse effect level for those acute effects is 4,3 µg nickel/kg bw and that a margin of exposure (MOE) of 30 or higher is needed to protect against those effects. This MOE of 30 is not achieved for the mean and 95th percentile exposure, which raises a health concern for nickel-sensitised individuals.
- (8) Maximum levels for nickel in food should therefore be set to ensure a high level of human health protection.
- (9) Regulation (EU) 2023/915 should therefore be amended accordingly.
- (10) A reasonable period should be provided to allow for the food business operators to adapt to the maximum levels set out in this Regulation.
- (11) Taking into account that certain foodstuffs covered by this Regulation have a long shelf life or may be processed into products with such a long shelf life, foodstuffs that were lawfully placed on the market before the date of application of this Regulation should be 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 (p) may remain on the market until their date of minimum durability or use-by date.’;
 - (b) the following points are added:
 - ‘(o) 1 July 2025 as regards the maximum levels for nickel set out in the entry 3.6 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 ;
 - (p) 1 July 2026 as regards the maximum levels for nickel set out in points 3.6.11.1 to 3.6.11.5 of Annex I.’;

⁵ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on an update of the risk assessment of nickel in food and drinking water. EFSA Journal 2020;18(11):6268, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6268>.

(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*.

It shall apply from 1 July 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