



2024/1987

31.7.2024

COMMISSION REGULATION (EU) 2024/1987
of 30 July 2024
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 food ⁽¹⁾, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EU) 2023/915 ⁽²⁾ 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 water ⁽³⁾. 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-sensitised 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) 2016/1111 ⁽⁴⁾ 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/2023/915/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. 70, ELI: <http://data.europa.eu/eli/reco/2016/1111/oj>).

⁽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>.

- (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.’;
- (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, 30 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

In Section 3: 'Metals and other elements' of Annex I to Regulation (EU) 2023/915, the following entry is added:

3.6	Nickel	Maximum level (mg/kg)	Remarks
3.6.1	Tree nuts		The maximum level applies to the edible part. The maximum level does not apply to tree nuts for crushing and oil refining, provided that the remaining pressed tree nuts are not placed on the market as food. In case the remaining pressed tree nuts are placed on the market as food, the maximum level applies, taking into account Article 3(1) and (2).
3.6.1.1	Tree nuts except products listed in 3.6.1.2	3,5	
3.6.1.2	Chestnuts, pine nuts, walnuts, Brazil nuts, and cashew nuts	10	
3.6.2	Root and tuber vegetables and bulb vegetables	0,90	The maximum level applies to the wet weight. The maximum level applies after washing and separating the edible part. For potatoes, the maximum level applies to peeled potatoes.
3.6.3	Fruiting vegetables	0,40	The maximum level applies to the wet weight. The maximum level applies after washing and separating the edible part.
3.6.4	Brassica vegetables	0,50	The maximum level applies to the wet weight. The maximum level applies after washing and separating the edible part.
3.6.5	Leafy vegetables		The maximum level applies to the wet weight. The maximum level applies after washing and separating the edible part.
3.6.5.1	Leafy vegetables except products listed in 3.6.5.2	0,50	
3.6.5.2	Fresh herbs	1,2	
3.6.6	Legume vegetables		The maximum level applies to the wet weight. The maximum level applies after washing and separating the edible part.

3.6.6.1	Legume vegetables except products listed in 3.6.6.2	1,0	
3.6.6.2	Soy beans / edamame (<i>Glycine max</i>)	6,0	
3.6.7	Stem vegetables	0,40	The maximum level applies to the wet weight. The maximum level applies after washing and separating the edible part.
3.6.8	Seaweed		For dry seaweed the maximum level applies to the product as placed on the market. For fresh seaweed the maximum level applies after washing and separating the edible part. For fresh seaweed the maximum level applies on a dry matter basis (*).
3.6.8.1	Seaweed except products listed in 3.6.8.2	30	
3.6.8.2	Wakame	40	
3.6.9	Pulses		
3.6.9.1	Pulses except products listed in 3.6.9.2	4,0	
3.6.9.2	Dry beans and dry lupins / lupini beans	12	
3.6.10	Oilseeds		The maximum level does not apply to oilseeds for crushing and oil refining, provided that the remaining pressed oilseeds are not placed on the market as food. In case the remaining pressed oilseeds are placed on the market as food, the maximum level applies, taking into account Article 3(1) and (2).
3.6.10.1	Sunflower seed	8,0	
3.6.10.2	Peanuts	12	
3.6.10.3	Soy beans	15	
3.6.11	Cereals		The maximum level does not apply to cereals used for the production of beer or distillates, provided that the remaining cereal residue is not placed on the market for the final consumer as food. In case the remaining cereal residue is placed on the market for the final consumer as food, the maximum level applies, taking into account Article 3(1) and (2).
3.6.11.1	Cereals except products listed in 3.6.11.2, 3.6.11.3, 3.6.11.4 and 3.6.11.5	0,80 As from 1 July 2026	

3.6.11.2	Durum wheat (<i>Triticum durum</i>) and rice except products listed in 3.6.11.3	1,5 As from 1 July 2026	
3.6.11.3	Husked rice	2,0 As from 1 July 2026	
3.6.11.4	Pseudo cereals and millet	3,0 As from 1 July 2026	
3.6.11.5	Oats	5,0 As from 1 July 2026	The maximum level applies to oats grains without the inedible husk. To calculate the maximum level for oats grains with the inedible husk a processing factor of 1,5 needs to be applied, resulting in an maximum level of 7,5 mg/kg for oats with the inedible husk.
3.6.12	Cocoa and chocolate products ⁽¹⁴⁾		
3.6.12.1	Milk chocolate with < 30 % total dry cocoa solids	2,5	
3.6.12.2	Milk chocolate with ≥ 30 % total dry cocoa solids and chocolate	7,0	
3.6.12.3	Cocoa powder and fat reduced cocoa powder placed on the market for the final consumer or as an ingredient in sweetened cocoa powder or powdered chocolate placed on the market for the final consumer (drinking chocolate)	15	
3.6.13	Infant formulae, follow-on formulae, food for special medical purposes intended for infants and young children ^(?) and young-child formulae ⁽⁴⁾		The maximum level applies to the product as placed on the market.
3.6.13.1	placed on the market as powder except products listed in 3.6.13.2	0,25	
3.6.13.2	placed on the market as powder and manufactured from soy protein isolates, alone or in a mixture with cow's milk proteins	0,40	
3.6.13.3	placed on the market as liquid	0,10	
3.6.14	Processed cereal-based food for infants and young children ^(?)	3,0	The maximum level applies to the product as placed on the market.
3.6.15	Baby food ^(?) except products listed in 3.6.16.	0,50	The maximum level applies to the product as placed on the market.

3.6.16	Fruit juices ^(*) , fruit nectars ^(*) and vegetable juices including fruit juices ^(*) , fruit nectars ^(*) and vegetable juices intended as babyfood ^(*) .		
3.6.16.1	Fruit juices, fruit nectars and vegetable juices except products listed in 3.6.16.2	0,25	
3.6.16.2	Fruit juices and fruit nectars containing juices and nectars from passion fruits, cocoa fruits, and from small fruits and berries and coconut water	1,0	

(*) Dry matter is determined in accordance with Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29, ELI: <http://data.europa.eu/eli/reg/2007/333/oj>).