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COMMISSION REGULATION (EU) 2025/1891

of 17 September 2025

amending Regulation (EU) 2023/915 as regards maximum levels of inorganic arsenic in fish and other seafood

(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, including inorganic arsenic in a range of foodstuffs.

(2) Arsenic is a ubiquitous metalloid present at low concentrations in rocks, soil and natural ground water. Anthropogenic activity has contributed to increasing the levels of arsenic in the environment through industrial emissions (mining, smelting of non-ferrous metals and burning of fossil fuels) as well as through the use of arsenic as an ingredient in fertilisers, wood preservatives, insecticides or herbicides. Although dermal and inhalation exposure is possible, food and drinking water are the principal routes of exposure to arsenic.

(3) On 12 October 2009, the European Food Safety Authority ('the Authority') adopted an opinion on arsenic in food ([3]) in which it concluded that inorganic arsenic can cause lung, bladder and skin cancers and skin lesions and it identified a range of 'benchmark dose lower confidence limit' ($BMDL_{01}$) values between 0,3 and 8 μg/kg b.w. per day. As the estimated dietary exposures to inorganic arsenic for average and high consumers in Europe are within the range of the $BMDL_{01}$ values identified, the possibility of a risk to some consumers cannot be excluded. Therefore, maximum levels were set for inorganic arsenic in various terrestrial foods by means of Commission Regulation (EU) 2015/1006 ([4]).

(4) In its scientific report of 2021 ([5]), the Authority assessed the chronic dietary exposure of the European population to inorganic arsenic, taking into account the most recent occurrence data for inorganic arsenic in food and besides confirming the relevance of terrestrial foods to the exposure, it also concluded that in the adult population food groups such as 'fish and other seafood' were among the apparent sources of inorganic arsenic exposure in certain countries.

(5) On the basis of the most recent occurrence data, and pending consultations as regards potential maximum levels for arsenic in fish and other seafood, Commission Regulation (EU) 2023/465 ([6]) lowered the maximum level for inorganic arsenic in white rice and laid down maximum levels for certain terrestrial foods.

([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 Arsenic in Food, *EFSA Journal*, 2009; 7(10):1351, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2009.1351.
([4]) Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuff (OJ L161, 26.6.2015, p. 14, ELI: http://data.europa.eu/eli/reg/2015/1006/oj).
([5]) Scientific report of EFSA on the chronic dietary exposure to inorganic arsenic, *EFSA Journal*, 2021; 19(1):6380, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6380.
([6]) Commission Regulation (EU) 2023/465 of 3 March 2023 amending Regulation (EC) No 1881/2006 as regards maximum levels of arsenic in certain foods (OJ L 68, 6.3.2023, p. 51, ELI: http://data.europa.eu/eli/reg/2023/465/oj).

(6) On 28 November 2023, the Authority adopted its scientific opinion on an update of the risk assessment on inorganic arsenic in food. ([7]) It concluded that epidemiological studies show that the chronic intake of inorganic arsenic via the diet and/or drinking water is associated with an increased risk of several adverse outcomes including lung, bladder and skin cancers. The Authority used the $BMDL_{05}$ of 0,06 µg /kg b.w. per day and applied a margin of exposure (MOE) approach. It considered that in adults the MOEs are low (range between 2 and 0,4 for average consumers and between 0,9 and 0,2 at the 95th percentile exposure) and it concluded that, therefore, the current exposure to inorganic arsenic raises a health concern despite the uncertainties.

(7) In order to continue lowering the exposure of the population to inorganic arsenic, it is therefore appropriate to establish maximum levels for fish and other seafood, which contribute to that exposure.

(8) Regulation (EU) 2023/915 should therefore be amended accordingly.

(9) Taking into account that certain foodstuffs covered by this Regulation have a long shelf life and in order to prevent food waste, fish and other seafood 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.

(10) 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 (q) may remain on the market until their date of minimum durability or use-by date:';

(b) the following point is added:

'(q) 8 October 2025 as regards the maximum levels for inorganic arsenic set out in points 3.4.5, 3.4.6, 3.4.7 and 3.4.8 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.

Done at Brussels, 17 September 2025.

For the Commission
The President
Ursula VON DER LEYEN

([7]) Scientific opinion on an update of the risk assessment on inorganic arsenic in food, *EFSA Journal,* 2024; 22:e8488, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2024.8488.

ANNEX

In Annex I to Regulation (EU) 2023/915, in section 3 (Metals and other elements), subsection 3.4 (Arsenic) is amended as follows:

(1) the second row is replaced by the following:

		'Inorganic arsenic (sum of $As^{(III)}$ and $As^{(V)}$)	The maximum level for inorganic arsenic applies to products listed in 3.4.1 to 3.4.8.'

(2) entry 3.4.5 and the row above are replaced by the following:

'3.4.5	Muscle meat of the following fish:		The maximum level applies to the wet weight. Where fish are intended to be eaten whole, the maximum level applies to the whole fish. In case of dried, diluted, processed and/or compound food, Article 3(1) and (2) applies.
3.4.5.1	Species other than those listed under 3.4.5.2	0,10	
3.4.5.2	Anglerfish, monkfish and giant stargazer (*Lophius* species; *Kathetostoma giganteum*), flatfishes (*Pleuronectiformes* species), haddock (*Melanogrammus aeglefinus*), herring (*Clupea* species), ray (*Rajidae* species) and shark (all species).	0,50	
3.4.6	Crustaceans		The maximum level applies to the wet weight. The maximum level applies to muscle meat from appendages and abdomen, which means that the cephalothorax of crustaceans is excluded. In case of crabs and crab-like crustaceans (*Brachyura* and *Anomura*) the maximum level applies to the muscle meat from appendages. In case of dried, diluted, processed and/or compound food, Article 3(1) and (2) applies.
3.4.6.1	Crabs and crab-like crustaceans (*Brachyura and Anomura*), prawn and shrimps (all species).	0,10	
3.4.6.2	Crustaceans other than those listed under 3.4.6.1 and 3.4.6.3.	0,20	
3.4.6.3	Langoustine (*Nephrops norvegicus*) and rock lobster (*Jasus* species)	1,5	

3.4.7	Bivalve molluscs		The maximum level applies to the wet weight. In case of *Pecten maximus*, the maximum level applies to the adductor muscle and gonad only. In case of dried, diluted, processed and/or compound food, Article 3(1) and (2) applies.
3.4.7.1	Scallops	0,10	
3.4.7.2	Bivalve molluscs other than those listed under 3.4.7.1	0,50	
3.4.8	Cephalopods	0,050	The maximum level applies to the wet weight. The maximum level applies to the animal without viscera. In case of dried, diluted, processed and/or compound food, Article 3(1) and (2) applies.
		Total arsenic	The maximum level for total arsenic applies to the products listed in 3.4.9.
3.4.9	Salt	0,50’	