SANTE PLAN 2023 1241 Rev3.

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) 2023/915 as regards maximum levels for 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) No 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. In addition, anthropogenic activity has also contributed to increase the levels of arsenic in the environment through industrial emissions (mining, smelting of non-ferrous metals and burning of fossil fuels) as well as with the use of arsenic as part of 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 Scientific Panel on Contaminants in the Food Chain ('the CONTAM Panel') of the European Food Safety Authority ('the Authority') adopted an opinion on arsenic in food[3]. In that opinion, the CONTAM Panel concluded that the

[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] 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.

provisional tolerable weekly intake (PTWI) of 15 µg/kg body weight (b.w.), established by the Joint FAO/WHO Expert Committee on Food Additives ('JECFA') was no longer appropriate, as data had shown that inorganic arsenic causes cancer of the lung, of the urinary bladder and the skin, and that a range of adverse effects had been reported at exposures lower than those reviewed by the JECFA.

(4) The CONTAM Panel identified a range of 'benchmark dose lower confidence limit' ($BMDL_{01}$) values between 0,3 and 8 µg/kg b.w. per day for cancers of the lung, skin and bladder, as well as skin lesions. In its scientific opinion, the CONTAM Panel concluded that the estimated dietary exposures to inorganic arsenic for average and high level consumers in Europe are within the range of the BMDL01 values identified, and that therefore the possibility of a risk to some consumers cannot be excluded.

(5) The scientific opinion identified high consumers of rice in Europe, such as certain ethnic groups and children under three years of age, as most subjected to inorganic arsenic dietary exposure. Dietary exposure to inorganic arsenic for children under three years old, including from rice-based foods, was estimated to be about 2 to 3-fold that of adults.

(6) In its scientific report of 2014[4] on the dietary exposure to inorganic arsenic in the European population, the Authority identified grain-based products as the main contributor to the exposure, and rice, milk and dairy products as important contributors. However, the heterogeneity of the food consumption data, the conversion of total arsenic to inorganic arsenic and the treatment of left censored data represented significant uncertainties in the exposure assessment.

(7) In light of that information, Commission Regulation (EU) 2015/1006[5] set maximum levels for the presence of inorganic arsenic only in rice and rice-based products and in accordance with Commission Recommendation (EU) 2015/1381[6], Member States were called upon to monitor, during 2016, 2017 and 2018, the presence of arsenic in foods, preferably by determining the content of inorganic and total arsenic and, if possible, other relevant arsenic species, in a wide variety of foods.

(8) In its scientific report of 2021[7], the Authority assessed the chronic dietary exposure to inorganic arsenic, taking into account the most recent occurrence data for inorganic arsenic in food. It concluded that across the different age classes, the main contributors to the dietary exposure to inorganic arsenic were rice, rice-based products, grains and

4 Scientific report of EFSA on the dietary exposure to inorganic arsenic in the European population, EFSA Journal 2014; 12(3): 3597, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3597.

5 Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs (OJ L 161, 26.6.2015, p. 14).

6 Commission Recommendation (EU) 2015/1381 of 10 August 2015 on the monitoring of arsenic in food (OJ L213, 12.8.2015, p. 9).

7 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.

grain-based products not containing rice and drinking water. The Authority has further concluded that particular foodstuffs indicated for the young population (e.g. cereal-based food for infants and young children and biscuits, rusks and cookies for children, infant formulae, follow-on formulae, foods for special medical purposes intended for infants and young children and young child formulae, baby foods and fruit juices) made a relevant contribution in the dietary exposure to inorganic arsenic in this population group. In the adult population, food groups such as 'fish and other seafood' were also apparent sources of inorganic arsenic exposure in certain countries.

(9) On 28 November 2023, the CONTAM Panel of the Authority adopted its scientific opinion on an update of the risk assessment on inorganic arsenic in food.[8] It concluded that epidemiological studies show that the chronic intake of inorganic arsenic via the diet and/or drinking water is associated with increased risk of several adverse outcomes including cancers of the skin, bladder and lung. The CONTAM Panel used the $BMDL_{05}$ of 0.06 µg /kg b.w. per day obtained from a study on skin cancer as a reference point. Inorganic arsenic is a genotoxic carcinogen with additional epigenetic effects and the CONTAM Panel applied a margin of exposure (MOE) approach for the risk characterisation. In adults, the MOEs are low (range between 2 and 0.4 for mean consumers and be-tween 0.9 and 0.2 at the 95th percentile exposure, respectively) and as such raise a health concern despite the uncertainties. It is therefore appropriate to establish new maximum levels for commodities contributing to exposure to arsenic.

(10) By means of Regulation (EU) 2023/915 maximum levels were established or lowered various foods of non-animal origin and foods for infants and young children.

(11) For fish and other seafood data are available to allow also the establishment of maximum levels for inorganic arsenic in fish and other seafood. 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, foodstuffs that were lawfully placed on the market before the date of application of this Regulation should be allowed to remain on the market.

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

The Annex to Regulation (EU) 2023/915 is amended in accordance with the Annex to this Regulation.

[8] 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.

Article 2

Foodstuffs that were lawfully placed on the market before the entry into force of this Regulation 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.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.