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SANTE 10384-2018 Rev0.

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

of XXX

amending Regulation (EU) 1881/2006 as regards maximum levels of inorganic arsenic in certain foods.

(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 (EC) No 1881/2006² sets maximum levels for inorganic arsenic in a range of foodstuffs.
- (2) The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority ('the Authority') adopted an opinion on arsenic in food³ on 12 October 2009. In this opinion, CONTAM Panel concluded that the provisional tolerable weekly intake (PTWI) of 15 µg/kg body weight established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is no longer appropriate as data had shown that inorganic arsenic causes cancer of the lung and urinary bladder in addition to skin, and that a range of adverse effects had been reported at exposures lower than those reviewed by the JECFA.
- (3) CONTAM Panel identified a range of benchmark dose lower confidence limit (BMDL01) values between 0,3 and 8 µg/kg b.w. per day for cancers of the lung, skin

¹ OJ L 37, 13.2.1993, p. 1.

² Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

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>.

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and bladder, as well as skin lesions. The scientific opinion 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 there is little or no margin of exposure and the possibility of a risk to some consumers cannot be excluded.

- (4) The scientific opinion identified high consumers of rice in Europe, such as certain ethnic groups, and children under three years of age as the most exposed to inorganic arsenic dietary exposure. Dietary exposure to inorganic arsenic for children under three years old, including from rice-based foods, is in general estimated to be about 2 to 3-fold that of adults.
- (5) Since the analysis of inorganic arsenic is reliable for rice and rice based products, maximum levels for inorganic arsenic have been set for rice and rice based products under Regulation (EU) 2015/1006.⁴
- (6) In its 2014 report⁵ 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 also rice, milk and dairy products as important contributors. The heterogeneity of the food consumption data, the conversion of total arsenic to inorganic arsenic and the treatment of left censored data represented important uncertainties in the exposure assessment.
- (7) Therefore, the Commission considered that immediate maximum levels for commodities other than rice were not appropriate at the time. However, it adopted Commission Recommendation (EU) 2015/1381/EU⁶, which called on Member States to monitor during 2016, 2017 and 2018 the presence of arsenic, 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 2021 Scientific Report⁷ the Authority assessed the chronic dietary exposure to inorganic arsenic, taking into account the most recent occurrence data of 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 grain-based products not containing rice’ and ‘Drinking water’. Particular foodstuffs indicated for the young population (e.g. ‘Cereal-based food for infants and young children’ and ‘Biscuits, rusks and cookies for children’) made a relevant

⁴ 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).

⁵ 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>.

⁶ Commission Recommendation (EU) 2015/1381 of 10 August 2015 on the monitoring of arsenic in food OJ L213, 12.8.2015, p. 213.

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.2014.3597>.

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contribution in the dietary exposure to inorganic arsenic in this population group. In the adult population, food groups such as ‘Vegetables and vegetable products’ and ‘Fish and other seafood’ were also apparent sources of inorganic arsenic in certain countries. The mean and 95th percentile exposure lie within the range of the BMDL01 values identified in the 2009 opinion. It is therefore appropriate to establish new maximum levels for commodities contributing to the exposure and **to lower existing maximum levels**, where feasible

- (9) **The Codex Alimentarius sets a maximum level of 0.1 mg/kg for total arsenic in salt⁸. It is appropriate to set the same maximum level in the Union legislation.**
- (10) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (11) Because certain products have a long shelf-life, a transitional measure should be foreseen in order to ensure that products lawfully placed on the market before the application date, can remain on the market for a limited period of time.
- (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

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

Foodstuffs that were lawfully placed on the market before the entry into force may remain on the market until [*publication office please introduce the date 6 months after entry into force*].

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.

⁸ Codex General Standard for Contaminants and Toxin in Foods and Feeds – GSCTFF (CODEX STAN 193-1995).

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