

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

SANTE 2021-10382 Rev1.

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

of XXX

amending Regulation (EU) No 1881/2006 as regards maximum levels of mercury in fish other than shark and swordfish and in salt.

(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 certain contaminants including mercury in foodstuffs.
- (2) The Scientific Panel on contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) adopted an opinion on mercury and methylmercury in food³ on 22 November 2012. In this opinion, EFSA's CONTAM Panel established a tolerable weekly intake (TWI) for inorganic mercury of 4 µg/kg b.w. and for methylmercury of 1.3 µg/kg b.w. (both expressed as mercury) and concluded that the 95th percentile dietary exposure is close to or above the TWI for all age groups. High fish consumers, which might include pregnant women, may exceed the TWI by up to approximately six-fold. Unborn children constitute the most vulnerable group. The opinion concluded that exposure to methylmercury above the TWI is of concern, but advised to take into account the beneficial effects of fish consumption, if measures to reduce methylmercury exposure were considered.

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 the risk for public health related to the presence of mercury and methylmercury in food. EFSA Journal 2012;10(12):2985.

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- (3) The Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) of EFSA adopted an opinion on the health benefits of seafood consumption in relation to the health risks associated with exposure to methylmercury⁴ on 27 June 2014. In this opinion, the NDA Panel reviewed the role of seafood in European diets and evaluated the beneficial effects of seafood consumption in relation to health outcomes, including the effects of seafood consumption during pregnancy on functional outcomes of children's neurodevelopment and the effects of seafood consumption on cardiovascular disease risk in adults. The NDA Panel concluded that consumption of about 1-2 servings of seafood per week and up to 3-4 servings per week during pregnancy has been associated with better functional outcomes of neurodevelopment in children compared to no consumption of seafood.
- (4) On 19 December 2014, the EFSA Scientific Committee adopted a statement on the benefits of fish/seafood consumption compared to the risks of methylmercury in fish/seafood.⁵ The conclusions of this statement are that to achieve the benefits of fish consumption associated with 1 – 4 fish servings per week and to protect against neurodevelopmental toxicity of methylmercury, the consumption of fish/seafood species with a high content of mercury should be limited.
- (5) Taking into account the outcome of EFSA's scientific opinions and statement, maximum levels for mercury should be reviewed in view of further reducing the dietary exposure to mercury in food.
- (6) The maximum levels in Regulation (EC) No 1881/2006 for certain fish species should therefore be amended accordingly and an maximum level for salt should be set.
- (7) Eventhough the occurrence data indicate that the current maximum level of 1.0 mg/kg for shark and swordfish does not cover the mercury present in shark and swordfish on the European market, in view of the health concerns related to mercury and in view of the lacking knowledge on the effectiveness of consumption advice in reducing the mercury exposure, at this stage it is not appropriate to increase the maximum level for mercury in shark and swordfish. Therefore it should be maintained at the current level, pending a further data collection and scientific assessment.
- (8) In the Codex General Standard for Contaminants and Toxin in Foods and Feeds – GSCTFF (CODEX STAN 193-1995) a maximum level of 0.1 mg/kg is established for mercury in salt. This maximum level should be implemented in EU legislation.
- (9) Because salt is a commodity, which is consumed in small volumes and which has a long shelf-life, a transitional measure should be foreseen in order to ensure that products

⁴ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on health benefits of seafood (fish and shellfish) consumption in relation to health risks associated with exposure to methylmercury. EFSA Journal 2014;12(7):3761.

⁵ EFSA Scientific Committee, 2015. Scientific Opinion on statement on the benefits of fish/seafood consumption compared to the risks of methylmercury in fish/seafood. EFSA Journal 2015;13(1):3982.

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lawfully placed on the market before the application date, can remain on the market until the end of their shelf life.

- (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

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

Article 2

Foodstuffs listed in part 3.3.5 of the Annex that were lawfully placed on the market before the entry into force 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.