

*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 11185-2018 Rev5.**

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

**of XXX**

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

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<sup>1</sup>, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006<sup>2</sup> of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs sets maximum levels for lead in a range of foodstuffs.
- (2) The Scientific Panel on Contaminants in the Food Chain (Contam Panel) of the European Food Safety Authority (EFSA) adopted an opinion on lead in food on 18 March 2010<sup>3</sup>. The Contam Panel identified developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults as potential critical adverse effects of lead on which to base the risk assessment. EFSA concluded that there was no evidence for a threshold for a number of critical endpoints including developmental neurotoxicity and adult nephrotoxicity. Therefore it would not be appropriate to derive a tolerable weekly intake and EFSA expressed a concern that there was potential at the current levels of exposure for lead to affect neurodevelopment in infants, children and the foetus of pregnant women.

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<sup>1</sup> OJ L 37, 13.2.1993, p. 1.

<sup>2</sup> 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).

<sup>3</sup> EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2010. Scientific Opinion on lead in food. EFSA Journal 2010;8(4):1570.

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- (3) The dietary exposure to lead in food should be reduced by lowering existing maximum levels and setting additional maximum levels for lead in relevant commodities at levels as low as reasonably achievable.
- (4) The conclusions made by EFSA were confirmed by the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (FAO/WHO) in 2010.<sup>4</sup>
- (5) Taking into account the most recent occurrence data at its 42<sup>nd</sup> session the Codex Alimentarius Commission (CAC42) lowered the Codex maximum level of 0.5 mg/kg for edible offal to a maximum level of 0.2 mg/kg for edible offal of cattle, 0.15 mg/kg for edible offal of pigs and 0.1 mg/kg for edible offal of poultry. Furthermore it lowered the maximum level for wine made from grapes from 0.2 mg/kg to 0.1 mg/kg and it established a maximum level for fortified/ liqueur wines made from grapes of 0.15 mg/kg. Both maximum levels apply to wine made from grapes harvested after the date of the adoption of the maximum level by CAC 42.
- (6) As for salt, maximum levels exist at national level in some EU countries and at the international level, it is appropriate to set a harmonized EU maximum level. Taking into account the most recent occurrence data at its 41<sup>th</sup> session the Codex Alimentarius Commission (CAC41) lowered the Codex maximum level lead in salt (excluding salt from marshes) from 2 mg/kg to 1 mg/kg.
- (7) It is necessary to amend the maximum levels for lead in wine and edible offal and to establish a maximum level for liqueur wine and salt, in order to take into account developments in Codex Alimentarius and the most recent European Union occurrence data.
- (8) Because wine and liqueur wine are commodities with a long shelf life and in line with the applicability of the Codex MLs, the new maximum levels should only apply to wine and liqueur wine produced from the 2021 fruit harvest onwards.
- (9) An evaluation of the most recent occurrence data shows that it would be appropriate to lower the MLs for certain foods for infants and young children.
- (10) For the main types of cultivated fungi an ML has been established, but not for wild fungi. In order to reduce the consumer exposure to lead, it would be appropriate to establish also an ML for wild fungi.
- (11) For spices currently no ML has been established. An ML for lead in spices would help to reduce the consumer exposure to lead and would facilitate an efficient enforcement of fraudulent practices such as the addition of lead chromate to curcuma. Therefore taking into account the EU occurrence data, an ML for lead in spices should be established.

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<sup>4</sup> Evaluation of Certain Food Additives and Contaminants. Seventy-third report of the joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960.

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- (12) Given that lead is a weak indirect genotoxic carcinogen, and consequently its presence is a higher risk for public health, products not complying with the new maximum levels for lead and placed on the market before the date of application should only be allowed to remain on the market for a limited period of time of 6 months.
- (13) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (14) 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 other than wine listed in the Annex to this Regulation that were lawfully placed on the market before 1 January 2022, may continue to be marketed until 30 June 2022.

#### *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*.

It shall be applicable on 1 January 2022. .

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

Done at Brussels,