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SANTE PLAN 2023/2345 Rev.7.

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

of XXX

amending Regulation (EU) 2013/915 as regards maximum levels of mineral oil aromatic hydrocarbons in food.

(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 (EU) 2023/915² sets maximum levels for certain contaminants in foodstuffs.
- (2) Mineral oil hydrocarbons (MOH) are chemical compounds containing 10 to about 50 carbon atoms, which are derived mainly from crude oil, but also produced synthetically from coal, natural gas and biomass. MOH can contaminate food in many ways, such as lubricants for machinery used during harvesting and food production, processing aids like release agents or dust binders, food or feed additives, food contact materials or environmental contamination. MOH are divided into two main types: mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH).
- (3) In 2012 the European Food Safety Authority ('the Authority') adopted a Scientific Opinion on mineral oil hydrocarbons in food³. The authority concluded that the

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>).

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potential human health impact of groups of substances among the MOH vary widely. MOAH may act as genotoxic carcinogens, while some mineral oil saturated hydrocarbons (MOSH) can accumulate in human tissue and may cause adverse effects in the liver. Therefore the exposure to MOSH and MOAH from food is of potential concern.

- (4) In order to better understand the relative presence of MOSH and MOAH in food commodities that are major contributors to dietary exposure, by means of Commission Recommendation (EU) 2017/84⁴ Member States, with the active involvement of food business operators as well as manufacturers, processors and distributors of food contact materials and other interested parties, were recommended to perform monitoring of the presence of MOH in food and food contact materials. Furthermore it was recommended that, where MOH are detected in food, investigations should be carried out, in order to determine the sources of the contamination and measures should be implemented to prevent the occurrence of MOH in food.
- (5) Taking into account these new occurrence data and also the availability of new scientific information, the Authority adopted on 12 July 2023 an update of the risk assessment of mineral oil hydrocarbons in food.⁵
- (6) The Authority concluded that MOSH may accumulate in various organs, but that the present dietary exposure to MOSH does not raise a concern for human health for all age classes. As regards MOAH it concluded that MOAH with 3- or more aromatic rings may be associated with genotoxicity and carcinogenicity. Due to a lack of toxicological information on the effects of 1 and 2 ring MOAH, and to the presence of 3-or more ring MOAH in the diet, the exposure to total MOAH is a possible concern for human health.
- (7) Maximum levels for MOAH in food should therefore be set, to ensure a high level of human health protection. These maximum levels should apply regardless of the source of the contamination, which means that they will apply to contaminations that were present in raw materials or ingredients or that occurred during the production process, transport and packaging. This includes also contaminations of foods due to the use of authorised but contaminated food additives and food contact materials.

³ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on mineral oil hydrocarbons in food. EFSA Journal 2012;10(6):2704, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2704>.

⁴ Commission recommendation (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food (OJ L 312, 17.1.2017, p. 95, ELI: <http://data.europa.eu/eli/reco/2017/84/oj>).

⁵ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on an update of the risk assessment of mineral oil hydrocarbons in food. EFSA Journal EFSA Journal 2023;21(9):8215, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.8215>.

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- (8) From the occurrence data and investigations towards the sources of the contamination of food with MOAH, it has become clear that in most foods the occurrence of quantifiable concentrations of MOAH can be prevented. Therefore, in accordance with the 'As Low As Reasonably Achievable' (ALARA) principle, maximum levels should where possible be set at the limit of quantification. However, for foods for which it has been demonstrated that concentrations below the limit of quantification cannot be achieved, even when applying good practices, maximum levels above the limit of quantification should be established. For those foods, further investigations should be carried out in order to identify mitigation measures, which should allow to reduce the contamination, and clear timelines should be set for further lowering the maximum levels.
- (9) In accordance with Article 3(1) of Regulation (EU) 2023/915 the maximum levels established in the Annex to that Regulation also apply to dried, diluted, processed and compound foods, taking into account the appropriate processing factor. When applying Article 3(1) of Regulation (EU) 2023/915 for calculating the applicable maximum levels for MOAH, maximum levels might be obtained that are not analytically achievable. In those cases the applicable maximum level should be increased to the achievable limit of quantification.
- (10) As studies have demonstrated that the transfer of MOAH from dry tea and dry herbal infusions other than instant tea or instant herbal infusions to the brewed beverage is limited, no maximum level should apply to dry tea and dry herbal infusions other than instant tea or instant herbal infusions, unless they are used as an ingredient in food. Also for dry tea and dry herbal infusions other than instant tea or instant herbal infusions, in which spices or dried herbs are used, the maximum level that is calculated on the basis of Article 3 of Regulation (EU) 2023/915, should not apply, unless the tea or herbal infusions are used as an ingredient in food.
- (11) Regulation (EU) 2023/915 should therefore be amended accordingly.
- (12) A reasonable period should be provided, to allow for the food business operators to adapt to the maximum levels set out in this Regulation.
- (13) Taking into account that certain foodstuffs covered by this Regulation have a long shelf life or may be processed into products with such 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 until their date of minimum durability of use-by date.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2023/915 is amended as follows:

(1) To Article 3 the following points are added:

4. For mineral oil aromatic hydrocarbons (MOAH), when calculating the applicable maximum level in accordance with this article and in case this maximum level would be below the achievable limit of quantification of
 - 0,50 mg/kg for foods with a < 4% fat/oil content
 - 1,0 mg/kg for foods with $\geq 4\%$ and $\leq 50\%$ fat/oil content
 - 2,0 mg/kg for foods with $> 50\%$ fat/oil content.

the applicable maximum level shall be increased to:

- 0,50 mg/kg for foods with a < 4% fat/oil content
- 1,0 mg/kg for foods with $\geq 4\%$ and $\leq 50\%$ fat/oil content
- 2,0 mg/kg for foods with $> 50\%$ fat/oil content.

The fat/oil content refers to the declared fat/oil content or, in absence of a declared fat/oil content, to the fat/oil content as determined by the competent authority. The provisions of this point shall apply until 31 December 2029.

5. For MOAH in tea and herbal infusions other than instant tea or instant herbal infusions, no maximum level, which is calculated in accordance with article 3 of this Regulation, shall be applicable, unless the tea or herbal infusion is used as an ingredient in food.

(2) 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) 1 January 2027 as regards the maximum levels for mineral oil aromatic hydrocarbons set out in section 5.5 of Annex I, or in case a specific application date is listed in section 5.5 until that date;

(3) Annex I is amended in accordance with the Annex to this Regulation.

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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*.

It shall apply 1 January 2027.

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

Draft