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COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) 2023/915 as regards maximum levels of mineral oil aromatic hydrocarbons in food

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) 2023/915 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 food[1], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EU) 2023/915[2] 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 food[3]. The Authority concluded that the potential human health impact of groups of substances among the MOH vary widely. MOAH may act as genotoxic carcinogens, while some 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) 2017/84[4], 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

[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).

[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).

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 the new occurrence data collected following Recommendation (EU) 2017/84 and new scientific information, the Authority adopted an updated risk assessment of mineral oil hydrocarbons in food on 12 July 2023.[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 MOAH with 1 and 2 aromatic rings, and to the presence of MOAH with 3- or more aromatic rings in the diet, the exposure to total MOAH is a possible risk for human health.

(7) Maximum levels for MOAH in food should therefore be set to ensure a high level of human health protection. Those maximum levels should apply regardless of the source of the contamination, which means that they should apply to contaminations that were originally 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.

(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' 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, in order to ensure that food business operators make continued efforts to identify and implement mitigation measures to reduce the contamination, clear timelines should be set for further lowering the maximum levels.

(9) 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 such dry tea and herbal infusions, unless they are used as an ingredient in food.

(10) In accordance with Article 3(1) of Regulation (EU) 2023/915, the maximum levels established in the Annex I 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 below the limit of quantification. In those cases, the applicable maximum level should be increased to the achievable limit of quantification. 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 in accordance with Article 3 of Regulation

[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.

(EU) 2023/915 should not apply unless the tea or herbal infusions are used as an ingredient in food.

(11) Since this Regulation lays down specific maximum levels applicable as of 1 January 2030 for processed and compound foods, in which ingredients were used for which a maximum level is set, this increase of the applicable maximum level to the limit of quantification should only apply until 31 December 2029.

(12) Regulation (EU) 2023/915 should therefore be amended accordingly.

(13) A reasonable period should be provided to allow food business operators to adapt to the maximum levels set out in this Regulation.

(14) 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 the maximum level should be allowed to remain on the market until their date of minimum durability or use-by date.

(15) A reasonable period should be provided to allow for the food business operators to adapt to the maximum levels set out in this Regulation.

(16) 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

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

(1) in Article 3, the following paragraphs are added:

‘4. Until 31 December 2029, for mineral oil aromatic hydrocarbons (‘MOAH’), when calculating the applicable maximum level in accordance with this Article, the following rules apply:

a) in case the maximum level calculated in accordance with this Article is below the limit of quantification of 0,50 mg/kg for foods with a declared fat/oil content or, in absence of a declared fat/oil content, with a fat/oil content as determined by the competent authority of less than 4%, the maximum level shall be increased to 0,50 mg/kg;
b) in case the maximum level calculated in accordance with this Article is below the limit of quantification of 1,0 mg/kg for foods with a declared fat/oil content or, in absence of a declared fat/oil content, with a fat/oil content as determined by the competent authority of between 4% and 50%, the maximum level shall be increased to 1,0 mg/kg;
c) in case the maximum level calculated in accordance with this Article is below the limit of quantification of 2,0 mg/kg for foods with a declared fat/oil content or, in absence of a declared fat/oil content, with a fat/oil content as determined by the competent authority of more than 50%, the maximum level shall be increased to 2,0 mg/kg;

5. For MOAH in tea and herbal infusions other than instant tea or instant herbal infusions, no maximum level shall be calculated in accordance with this article, 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 (u) may remain on the market until their date of minimum durability or use-by date:’;

(b) the following point is added:

‘(u) 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.

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 from 1 January 2027.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN