SANTE PLAN 2023/2345 Rev.2.

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 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 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).

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) 2017/84[4] Member States, with the active involvement of food business operators as well as manufacturers, processors and distributers 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, there 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.

(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 maximum levels for MOAH in food should be set on the basis of the 'As Low As Reasonably Achievable Principle'. Only for foods, for which it has been demonstrated that, according to the currently best available practices, no concentrations below the limit

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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.

of quantification can be achieved, maximum levels above this limit of 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) For dried, diluted, processed and compound foods the maximum levels should be calculated on the basis of Article 3 of Regulation (EU) 2023/915. Contaminations with MOAH that are introduced during the further processing of a product, shall not be taken into account for calculating the maximum level for the final product. Only the concentrations of MOAH in the initial ingredients and the concentration or dilution of the contaminants during the production process should be taken into account for calculating the maximum level of the final product. When calculating the maximum levels for compound products and considering a zero contribution for ingredients, for which no maximum level is established, maximum levels for the compound foods might be obtained that are not analytically achievable. Therefore for ingredients for which no maximum level is established, a concentration of 0,50, 1,0 or 2,0 mg/kg, depending on the fat content of the ingredient, should be taken into account for calculating the maximum level for the compound foods.

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

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

(12) 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.

(13) 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) To Article 3 the following point is added:

4. Contaminations with mineral oil aromatic hydrocarbons (MOAH) that are introduced during the further processing of a product, shall not be taken into account for calculating the maximum level for the final product. Only the concentrations of MOAH in the initial ingredients and the concentration or dilution of the contaminants during the production process should be taken into account for calculating the maximum level of a dried, diluted, processed or compound food. For the ingredients of compound foods, for which no maximum level for MOAH

has been established, the following concentrations shall be taken into account for calculating the maximum level for the compound food:

- 0,50 mg/kg for ingredients with a fat < 4% fat/oil content
- 1,0 mg/kg for ingredients with ≥ 4% and ≤ 50% fat/oil content
- 2,0 mg/kg for ingredients with > 50% fat/oil content

(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 points is added:

'(q) 1 January 2026 as regards the maximum levels for mineral oil aromatic hydrocarbons set out in section 5.5 of Annex I ;

(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 2026.

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

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ANNEX

to the

COMMISSION REGULATION (EU) No .../...

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

Proposed application date 01/01/2026 unless specified otherwise

ANNEX

In Section 5: Processing contaminants of the Annex to Regulation (EC) No 2023/915, subsection 5.5 Mineral Oil Aromatic Hydrocarbons is added:

Option 3

5.5	**Mineral Oil Aromatic Hydrocarbons (≥C10 to ≤C50)**	**Maximum levels (mg/kg)**	**Remarks**
5.5.1	**Oilseeds and oilfruits**	2,0	
5.5.2	**Animal and vegetable fats and oils other than those produced from cocoa beans and milk.**		
5.5.2.1	Maize, rapeseed, sunflower, soybean, linseed and olive oil other than olive pomace oil listed under 5.5.2.4.	2,0	
5.5.2.2	Oils and fats other than those listed in 5.5.2.1, 5.5.2.3 , 5.5.2.4, 5.5.2.5 and 5.5.8 and those produced from cocoa beans and milk.	4,0 from 01/01/2026 2,0 from 01/01/2028	
5.5.2.3	Blackcurrant seed, grapeseed, groundnut, sesame, argan, cottonseed and rice oil and coconut fat and oil.	6,0 from 01/01/2026 4,0 from 01/01/2028 2,0 from 01/01/2030	

5.5.2.4	Olive pomace oil	10,0 from 01/01/2026 5,0 from 01/01/2028 2,0 from 01/01/2030	
5.5.2.5	Marine oil and essential oil	10,0 from 01/01/2026 5,0 from 01/01/2030	
5.5.3	**Tree nuts**	2,0	
5.5.4	**Pulses**	0,50	
5.5.5	**Cereal grains**	0,50	The maximum level does not apply to cereals used for the production of beer or distillates, provided that the remaining cereal residue is not placed on the market for the final consumer as food. In case the remaining cereal residue is placed on the market for the final consumer as food, the maximum level applies, taking into account Article 3(1) and (2).
5.5.6	**Milk**	0,50	
5.5.7	**Cocoa beans**	2,0	
5.5.8	**Sugar**	0,50	
5.5.9	**Spices and dried herbs**	5,0	

5.5.10	**Infant formulae (3), follow-on formulae (3), young-child formulae (4), food for special medical purposes intended for infants and young children (3), baby food (3), processed cereal-based food for infants and young children (3) and drinks for infants and young children placed on the market and labelled as such.**		
5.5.10.1	Products with < 4% fat/oil content	0,50 mg/kg	
5.5.10.2	Products with ≥ 4% and ≤ 50% fat/oil content	1,0 mg/kg	
5.5.10.3	Products with > 50% fat/oil content	2,0 mg/kg	
5.5.11	**Food supplements**	10,0 from 01/01/2026 5,0 from 01/01/2030	

The footnotes correspond to the footnotes in the Annex to Regulation (EU) 2023/915.

For dried, diluted, processed and compound foods the maximum level shall be calculated in accordance with Article 3 of Regulation (EU) 2023/915. Contaminations with MOAH that are introduced during the further processing of a product, shall not be taken into account for calculating the

maximum level for the final product. Only the concentrations of MOAH in the initial ingredients and the concentration or dilution of the contaminants during the production process should be taken into account for calculating the maximum level of a dried, diluted, processed or compound food. For the ingredients of compound foods, for which no maximum level for MOAH has been established, the following concentrations shall be taken into account for calculating the maximum level for the compound food:

- 0,50 mg/kg for ingredients with a fat < 4% fat/oil content
- 1,0 mg/kg for ingredients with ≥ 4% and ≤ 50% fat/oil content
- 2,0 mg/kg for ingredients with > 50% fat/oil content