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Mineral oil aromatic hydrocarbons in food additives

Status: Commission internal procedures not yet launched

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

of XXX

amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 as regards the maximum presence of mineral oil aromatic hydrocarbons in food additives

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹, and in particular Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings², and in particular Article 7(5) thereof

Whereas:

- (1) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) The specifications for food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application from a Member State or an interested party.
- (3) Mineral oil hydrocarbons ('MOH') are chemical compounds containing 10 to about 50 carbon atoms, which are derived mainly from crude oil, but also produced

¹ OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>.

² OJ L 354, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1331/oj>.

³ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/231/oj>).

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, 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').

- (4) In 2012, the European Food Safety Authority ('the Authority') adopted a Scientific Opinion on mineral oil hydrocarbons in food⁴. 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.
- (5) Based on new scientific information and collection of occurrence data, the Authority concluded in its updated risk assessment in 2023⁵ 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.
- (6) To ensure a high level of human health protection, maximum levels for MOAH in certain foods were established in Commission Regulation (EU) 2023/915⁶.
- (7) Food additives can be also contaminated with MOAH either using contaminated raw material or during their production processes. Since there is very limited occurrence data available for food additives, it is more difficult to establish reasonably achievable maximum levels for MOAH in food additives. Therefore, in case that food is used as the raw material for production of food additive, such food must comply with the respective maximum level established in Commission Regulation (EU) 2023/915. Where occurrence data for a food additive is available, a maximum level for MOAH in that food additive can be established in the Annex to Regulation (EU) No 231/2012.
- (8) Based on available data on presence of MOAH in lecithins (E 322), a specific maximum level can be established for this food additive.
- (9) White and yellow beeswax (E 901), candelilla wax (E 902), carnauba wax (E 903), microcrystalline wax (E 905) and oxidised polyethylene wax (E 914) are authorised food additives that could contain MOAH. In order to ensure a high level of human health protection, a maximum level of 2,0 mg/kg for MOAH in the above-mentioned waxes authorised as food additives should be established, in order to avoid that the MLs for processed and compound foods, which are established in Annex I to

⁴ 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>.

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 2023; 21(9):8215, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.8215>.

⁶ 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>).

Regulation (EU) 2023/915, would be exceeded, when these food additives are used as an ingredient.

- (10) Given the deferred date of application of the maximum levels for MOAH in food in Commission Regulation (EU) 2023/915, the provisions laid down in this Regulation should apply from the same date as in Commission Regulation (EU) 2023/915, but in any case, after the entry into force of this Regulation.
- (11) The Annex to Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (12) 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 (EU) No 231/2012 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 xx xxxxxx 202x.

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

Done at Brussels,

*For the Commission
The President*

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ANNEX

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) The introductory part of the Annex is replaced by the following:

‘Ethylene oxide

Ethylene oxide may not be used for sterilising purposes in food additives.

No residue above 0,1 mg/kg, irrespective of its origin, of ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide ⁽¹⁾) shall be present in food additives listed in Annexes II and III to Regulation (EC) No 1333/2008, including mixtures of food additives.

Mineral oil aromatic hydrocarbons (MOAH)

In accordance with entry 5.5.12 of Annex I to Commission Regulation (EU) 2023/915*, if food is used as a source for producing a food additive, that food source shall comply with maximum level set out in Regulation (EU) 2023/915 and the maximum level for MOAH in the food additive produced from a food source shall be calculated on the basis of Article 3 of Regulation (EU) 2023/915.

However, if in addition to the maximum level for MOAH for food source set out in Regulation (EU) 2023/915, a specific maximum limit for MOAH for food additive is established in this Regulation, this maximum limit applies and not the maximum level calculated in accordance with Article 3 of Regulation (EU) 2023/915.

Aluminium lakes

Aluminium lakes for use in colours only where explicitly stated.

Definition	Aluminium lakes are prepared by reacting colours complying with the purity criteria set out in the appropriate specification monograph with alumina under aqueous conditions. The alumina is usually freshly prepared undried material made by reacting aluminium sulphate or chloride with sodium or calcium carbonate or bicarbonate or ammonia. Following lake formation, the product is filtered, washed with water and dried. Unreacted alumina may also be present in the finished product.
HCl insoluble matter	Not more than 0,5 %
NaOH insoluble matter	Not more than 0,5 %, for E 127 erythrosine only
Ether extractable matter	Not more than 0,2 % (under neutral conditions) Specific purity criteria for the corresponding colours are applicable.

* 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>).’;

A new entry at the end of the table is added for E 322 LECITHINS:

‘Mineral Oil Aromatic Hydrocarbons ($\geq C_{10}$ to $\leq C_{50}$)	Not more than 4,0 mg/kg’
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A new entry at the end of the table is added for E 901 BEESWAX, WHITE AND YELLOW:

‘Mineral Oil Aromatic Hydrocarbons ($\geq C_{10}$ to $\leq C_{50}$)	Not more than 2,0 mg/kg’
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A new entry at the end of the table is added for E 902 CANDELILLA WAX:

‘Mineral Oil Aromatic Hydrocarbons ($\geq C_{10}$ to $\leq C_{50}$)	Not more than 2,0 mg/kg’
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A new entry at the end of the table is added for E 903 CARNAUBA WAX:

‘Mineral Oil Aromatic Hydrocarbons ($\geq C_{10}$ to $\leq C_{50}$)	Not more than 2,0 mg/kg’
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A new entry at the end of the table is added for E 905 MICROCRYSTALLINE WAX:

‘Mineral Oil Aromatic Hydrocarbons ($\geq C_{10}$ to $\leq C_{50}$)	Not more than 2,0 mg/kg’
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A new entry at the end of the table is added for E 914 OXIDISED POLYETHYLENE WAX:

‘Mineral Oil Aromatic Hydrocarbons ($\geq C_{10}$ to $\leq C_{50}$)	Not more than 2,0 mg/kg’
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