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COMMISSION RECOMMENDATION

of **XXX**

on the monitoring of mineral oil hydrocarbons in food (SANTE PLAN 2023-2727-Rev5).

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) 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).
- (2) In 2012 the European Food Safety Authority ('the Authority') adopted a Scientific Opinion on mineral oil hydrocarbons in food¹. 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 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.
- (3) 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) 2017/84² 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 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>.

² 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>).

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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.

- (4) 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.³
- (5) 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.
- (6) As data, which were obtained with sufficiently sensitive and reliable methods, are lacking for certain foods, the Authority recommended to improve the analytical methods for a better characterisation of MOSH and MOAH.
- (7) Taking into account the available occurrence data, maximum levels have been established for MOAH in various foods in Commission Regulation (EU) 2023/915⁴.
- (8) However, for some foods, insufficient occurrence data were available to allow to assess the need for possible maximum levels. Therefore, further occurrence data for MOAH should be collected and further mitigation measures should be applied for those foods.
- (9) Even though the Authority concluded that the current exposure to MOSH does not raise health concerns, the available margin for a safe exposure is limited. In case that the mitigation measures, which have been implemented following Recommendation (EU) 2017/84⁵, would be dropped, the exposure would increase again and the consumer exposure might no longer be within the safe range. Therefore the monitoring of the presence of MOSH in food and the application of mitigation measures against MOSH in food should be continued.

³ 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>.

⁴ 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>).

⁵ 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>).

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- (10) Because in processed and compound foods typically higher levels of contamination are observed, in comparison to raw agricultural commodities, the monitoring should include these foods.
- (11) Follow-up investigations towards the sources of contamination are required to allow the implementation of follow-up measures to avoid the occurrence of MOSH and MOAH in food. Such investigations are recommended when the maximum levels for MOAH in food are exceeded. For MOAH in foods for which no maximum level is established and for MOSH, in order to provide guidance for these investigations, it is appropriate to set indicative levels of concentrations of MOSH and MOAH in food. Those levels should not affect the possibility to place on the market any food, but investigations should be carried out, when the concentration of MOSH and MOAH in a foodstuff exceeds those levels.
- (12) For dried, diluted, processed and compound foods, for which no maximum level applies and for which no specific indicative level is recommended, the indicative levels should be calculated, taking into account the appropriate drying, dilution or processing factors, as well as the ingredient composition. When calculating the indicative levels for these foods on the basis of the indicative levels of the ingredients and the appropriate processing factor, indicative levels might be obtained that are not analytically achievable. In those case the recommended indicative level should be increased to the achievable limit of quantification.
- (13) In order to ensure that the samples are representative for the sampled lot and that the analytical results are reliable and comparable, Commission Regulation (EC) No 333/2007 should be followed,

HEREBY RECOMMENDS:

- 1. Member States, in collaboration with food business operators, should monitor during the years 2026, 2027, 2028 and 2029 the presence of MOSH and MOAH in food.
- 2. The monitoring of MOSH should include oilseeds, oil fruits, animal and vegetable based fats and oils, products based on or containing animal and vegetable fats and oils, tree nuts, tree nut based products, tree nut containing products, pulses, pulses based products, pulses containing products, cereal grains, cereal based products, cereal containing products, milk, dairy products, products containing dairy, cocoa beans, cocoa and chocolate products, confectionary other than cocoa and chocolate products, coffee, tea and herbal infusions, spices, dried herbs, food for infants and young children, food supplements, processed vegetables, processed products containing vegetables, processed fruits, processed products containing fruits, poultry meat, processed meat and offal, products containing meat and offal, processed fish and seafood, products containing fish and other seafood, processed eggs, processed products containing eggs.

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4. The monitoring of MOAH should include coffee, tea, herbal infusions, processed vegetables, processed products containing vegetables, processed fruits, processed products containing fruits, poultry meat, processed meat and offal, processed products containing meat and offal, processed fish and other seafood, processed products containing fish and other seafood, processed eggs, processed products containing eggs and cereal grains used for the production of beer or distillates.
5. The sampling procedures and the analyses should be performed in accordance with the requirements for sampling and analysis laid down in Regulation (EC) No 333/2007⁶. Member States, which use methods which cannot achieve the limits of quantification included in point C.3.3.1 of the Annex to Regulation (EC) No 333/2007, may submit results obtained with methods with higher limits of quantification. However, those Member States should take the necessary action to achieve the performance criteria for limits of quantification, or, where this is not possible due to endogenous interferences, a limit of quantification which is as close as possible to the required limit of quantification.

It is recommended to validate analysis methods for MOSH and MOAH in food on the basis of comprehensive gas chromatography (GC×GC), in order to distinguish the presence of MOSH and MOAH from other co-extracted and possibly interfering compounds.

6. Further investigation of the causes of the contamination should be carried out when the maximum levels for MOAH in food included in the Annex to Regulation (EU) 2023/915 or the following indicative levels are exceeded:

For MOSH:

- a) Olive pomace oil, grapeseed oil, blackcurrant seed oil, cottonseed oil, cereal germ oil, safflower oil, essential oil, oil produced from fishery products and algae and products derived from fats and oils⁷ listed under a): 50,0 mg/kg.
- b) Animal and vegetable fats and oils other than those listed under points a) or c) and products derived from fats and oils⁸ listed under b): 30 mg/kg
- c) Linseed oil, maize oil, rapeseed oil, sunflower oil, soybean oil, cocoa butter, spices, dried herbs, tea (dried products), herbal infusions (dried products), food supplements, products derived from fats and oils⁸ listed under c): 15 mg/kg

⁶ Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down methods of sampling and analysis for the control of levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29, ELI: <http://data.europa.eu/eli/reg/2007/333/oj>).

⁷ Products derived from fats and oils are defined as products containing more than 80% of fats and oils.

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- d) Cocoa beans, cocoa and chocolate products other than cocoa butter, confectionary other than cocoa and chocolate products, processed meat and offal, processed fish and other seafood and processed eggs: 10 mg/kg
- e) Oilseeds, oil fruits, tree nuts, pulses, cereal grains, cereal based foods⁸, milk, dairy, coffee beans, eggs, dry infant and dry follow-on formulae, cereal based foods for infants and young children and baby food, processed vegetables, processed fruits: 5,0 mg/kg
- f) Liquid infant and follow-on formulae, drinks for infants and young children placed on the market and labelled as such: 1,0 mg/kg.

For MOAH

- a) Coffee beans, instant coffee (dried products), cereal grains 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: 1,0 mg/kg. To other cereal grains the maximum level established in the Annex to Regulation (EU) 2023/915 applies.
- b) Processed vegetables, processed fruits, processed meat and offal, processed fish and other seafood, processed eggs: 2,0 mg/kg.
- c) Tea (dried products) and herbal infusions (dried products) other than instant tea and herbal infusions and other than tea and herbal infusions that are used as an ingredient in food: 5,0 mg/kg
- d) Essential oils: 10 mg/kg

Where no specific indicative level is recommended in this point for dried, diluted, processed and compound foods (i.e. composed of more than one ingredient) the following aspects should be taken into account when applying the indicative levels set out in this point:

- a) Changes of the concentration of the contaminant caused by drying or dilution processes;
- b) Changes of the concentration caused by processing;
- c) The relative proportions of the ingredients in the product;
- d) The analytical limit of quantification.

When calculating the applicable indicative level for MOSH in accordance with this point and in case this indicative level would be below the achievable limit of quantification of

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Products derived from cereals are defined as products containing more than 80% of cereal products, excluding cereal germ oils.

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- 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 recommended indicative level should 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.

In case that the concentrations of MOSH in processed poultry meat originate from the use of paraffin as an adjuvant in intramuscular vaccines, these concentrations of MOSH are considered to be unavoidable for the time being, due to the lacking availability of MOSH free vaccines.

The indicative levels should not affect the possibility of placing products on the market.

7. Where MOSH and MOAH are detected in food in concentrations above the indicative levels or the maximum levels established in the Annex to Regulation (EU) 2023/915, food business operators should carry out further investigations in order to determine the possible source or sources of contamination. For these investigations it is recommended to retain samples of the ingredients for further analysis. The investigations should, wherever possible, cover the systems operated by the food business operator that could affect or control contamination (e.g. production and processing methods, Hazard Analysis and Critical Control Points (HACCP) or similar systems or measures implemented to prevent such presence). The food business operators should implement the necessary measures to avoid the contamination of food with MOSH and MOAH.
8. Where following the investigations MOSH and MOAH are detected in or originate from food contact materials, Member States in collaboration with food business operators should collect data on the food contact material (e.g. type and composition of the packaging material, presence of functional barrier, shelf life of the packaged food) and carry out further investigations in the establishments of the manufacturers, processors and distributors of food contact materials, (e.g. production and processing methods of food contact material, and documentation required under Commission Regulation (EC) No 2023/2006⁹ on good manufacturing practices).

⁹ Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384, 29.12.2006, p. 75, ELI: <http://data.europa.eu/eli/reg/2006/2023/oj>).

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9. Member States and food business operators should provide the monitoring data to the Authority on a regular basis, together with the information and in the electronic reporting format as set out by the Authority, for compilation into one database. When reporting data for poultry meat, processed poultry meat or products containing poultry meat, where possible, the type of poultry (for example laying hens, broiler chickens or other specific poultry types) and the part of the poultry (leg, breast meat or wing) that was sampled, should be reported.