COMMISSION RECOMMENDATION

of XXX

on the monitoring of mineral oil hydrocarbons in food (SANTE PLAN 2023-2727-Rev0).

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 food[1]. The authority concluded that 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) 2017/84[2] 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

[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).

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) The Authority identified for the analysis of MOSH and MOAH in food various challenges as regards the sensitivity and the specificity of the analytical methods and the analytical capability of the laboratories and it recommended to further improve the analytical methods and analytical capability for MOSH and MOAH in food. Therefore recommendations should be made to improve the sensitivity and specificity of the analytical methods.

(7) 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.

(8) Taking into account the available occurrence data, maximum levels have been established for MOAH in various foods in Commission Regulation (EU) 2023/915[4].

(9) 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 for those foods.

(10) 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) 2017/84[5], 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

[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).

presence of MOSH in food and the application of mitigation measures against MOSH in food should be continued.

(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. In order to provide guidance in this regard, 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 the indicative levels should be calculated, taking into account the appropriate drying, dilution or processing factors, as well as the ingredient composition, in line with the approach laid down in Article 3 of Regulation (EU) 2023/915. Contaminations with MOSH and MOAH that are introduced during the further processing of a product, shall not be taken into account for calculating the indicative level for the final product. Only the concentrations of MOSH and 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 indicative level of the final product. When calculating the indicative levels for compound products and considering a zero contribution for ingredients, for which no indicative level is established, indicative levels for the compound foods might be obtained that are not analytically achievable. Therefore for ingredients for which no indicative level is established, a concentration of 0,50, 1,0 or 2,0 mg/kg, depending on the fat content of the ingredients, should be taken into account for calculating the indicative level for compound foods.

(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 based products, cocoa containing products, sugar, sugar based products, sugar containing products, confectionary, coffee beans, 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.

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 333/2007[6].

5. The analyses should be carried out in accordance with Article 34 of Regulation (EU) 2017/625 of the European Parliament and the Council[7] using a method of analysis that has been proven to generate reliable results.

The limits of quantification of the analytical methods should be below or at:

a) 0,50 mg/kg for MOSH and MOAH in products with < 4% fat/oil content

b) 1,0 mg/kg for MOSH and MOAH in products with > 4% and ≤ 50% fat/oil content.

c) 2,0 mg/kg for MOSH and MOAH in products with > 50% fat/oil content

Member States which use methods which cannot achieve these limits of quantification may submit results obtained with methods with higher limits of quantification. However, those Member States should take the necessary action to achieve the target limits of quantification as soon as possible.

It is recommended to validate analysis methods for MOSH and MOAH in food on the basis of two-dimensional gas chromatography, in order to distinguish the presence of

[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] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj).

MOSH and MOAH from biogenic substances, which might interfere with the analysis in certain types of food.

6. Further investigation of the causes of the contamination should be carried out when the following indicative levels are exceeded:

For MOSH:

a) Animal and vegetable oils and fats, spices, dried herbs, tea, herbal infusions and food supplements: 15 mg/kg

b) Cocoa beans, cocoa based products and cocoa containing products other than cocoa butter, sugar, sugar based products, sugar containing products, confectionary, processed meat and offal, processed fish and other seafood and processed eggs: 10 mg/kg

c) Oilseeds, oil fruits, tree nuts, pulses, cereal grains, milk, 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

d) Liquid infant and follow-on formulae, drinks for infants and young children placed on the market and labelled as such: 0,50 mg/kg.

For MOAH

a) Coffee beans, 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 under 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 and herbal infusions: 5,0 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 shall 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.

Contaminations with MOSH and MOAH that are introduced during the further processing of a product, shall not be taken into account for calculating the indicative

level for the final product. Only the concentrations of MOSH and 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 indicative level of a dried, diluted, processed or compound food. For the ingredients of compound foods, for which no indicative level for MOSH or MOAH has been established, the following concentrations shall be taken into account for calculating the indicative 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

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.

7. Where MOSH and MOAH are detected in food in concentrations above the indicative levels, Member States should carry out further investigations in the food business establishments in order to determine the possible source or sources. 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 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, to establish the systems operated by the businesses concerned (e.g. production and processing methods of food contact material, and documentation required under Commission Regulation (EC) No 2023/2006[8] on good manufacturing practices) as indicated in the guidance.

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

[8] 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).

meat, where possible, the type of poultry (laying hens or broiler chickens) and the part of the poultry (leg, breast meat or wing) that was sampled, should be reported.