

Evaluation of mineral oil hydrocarbons (MOH) in food

Explanatory notes on the EFSA opinion and the Joint Statement of the EU Member States in the SCoPAFF

I. Background

The occurrence of mineral oil hydrocarbons (MOH) in food has been a matter of concern for analytics, industry along the entire supply chain, monitoring and science for years. MOH and analogous compounds are found particularly in compounded, processed and packaged foods as a result of a complex input of mineral oil traces or mineral oil-based products and chemically similar compounds from very different sources at all stages of the process chains. According to current understanding, defined fractions of mineral oil hydrocarbons and chemically closely related substances with 10 to 50 carbon atoms are summarized as MOH, whereby a distinction is made between saturated mineral oil hydrocarbons (mineral oil saturated hydrocarbons = MOSH) and aromatic mineral oil hydrocarbons (mineral oil aromatic hydrocarbons = MOAH) with 1-7 ring systems.

Good Manufacturing Practices (GMP) have been analyzed and improved for several years in almost all affected areas of primary production as well as food and packaging production in order to reduce MOH inputs. This has been confirmed by relevant analysis results in the period from 2008/2009 to the present day, including data from industry, various product testers and food monitoring, and confirmed by the European Food Safety Authority and the EU Commission.

II. Risk assessment of MOSH and MOAH by EFSA (2023)

The risk assessment of MOH by the European Food Safety Authority (EFSA) was last carried out in 2012 and was updated in 2023. As a result, the focus in risk management is primarily, but not exclusively, on the issues of toxicology and consumer exposure to MOAH as well as the source-independent detection and assessment of MOAH findings. This takes account of the new, differentiated scientific assessments of MOSH and MOAH [1].

Saturated hydrocarbons (MOSH) in the chain length range between 10 and 46 carbon atoms are absorbed by the human body and can be detected in some organs and adipose tissue (n-C20 to n-C46). However, EFSA concludes that the current intake levels in the European population via food across all age and consumption groups does not cause concern and considers acute toxicity to be low.

From EFSA's point of view, the fraction with three or more aromatic rings is particularly relevant for the assessment of MOAH levels in food, as genotoxic and carcinogenic effects cannot be ruled out for certain, particularly less alkylated 3-7 ring systems. For a complete risk characterization, further data on the toxicity of the 3- and multiring MOAH contained in the MOAH fraction and on exposure to these, as well as in particular on the oral toxicity for MOAH with 1-2 rings, are required. In EFSA's view, the technical specifications of white oils and waxes should be supplemented with information on the content and composition of MOAH. EFSA also emphasizes the need to develop specific analytical methods to detect ≥ 3 -ring systems and make them available for routine use.

Additional information on the toxicity of MOSH and MOAH

For MOSH, EFSA does not see any adverse effects for humans in the current exposure range, but the saturated hydrocarbons can be detected in some organs and cause enlargement there.

A health-based guideline value (HBGV - e.g. TDI or TWI) for the safe consumption of substances cannot currently be derived for MOSH due to insufficient data. EFSA therefore uses a Margin of Exposure (MOE) of 1200 to the NOAEL (concentration without observed adverse effect) of 236 mg/kg bw derived from animal studies for the toxicological assessment. Based on the analytical data provided to EFSA and based on consumption data, EFSA considers exposure to be at or above the MOE for almost all population and age groups (with the exception of infants fed exclusively on infant formula) and therefore no cause for concern. However, EFSA also points to insufficient data and gaps in knowledge, including insufficient data on the long-term accumulation of MOSH.

For the toxicological evaluation of MOAH, a BMDL10 value of 0.49 mg/kg bw and day from a study on the carcinogenic effect of non-alkylated PAH (PAH 8) was used as a reference due to a lack of toxicological data. There are only few data on the proportion of 3-7 ring systems in the MOAH fraction. Accordingly, EFSA has worked with different scenarios (10% and 1%) of 3- and multi-ring MOAH in the total MOAH fraction. For the “worst case” scenario (10% 3- and multi-ring MOAH), the MOE was found to be < 10,000 for all population groups, both for average and high consumers, and thus a cause for concern. For the 1% scenario, exceeding or falling below the targeted MOE of 10,000 for most of the groups considered depends on whether a “lower bound” or “upper bound” estimate is used. A particularly critical exposure was found for the group of high consumers among young children.

According to the EFSA opinion, the main sources of exposure are cereals and cereal-based foods, vegetable and animal fats and oils as well as products adapted for infants and young children.

When considering the health risks, EFSA has highlighted the relationship to the various C fractions of MOSH and MOAH; due to a lack of sufficient toxicological data, the assessment is provisionally based on the total fraction $c_{10} - c_{50}$ with regard to potential health risks.

III. Risk management of MOAH in food

In April 2022, SCoPAFF (Standing Committee on Plants, Animals, Food and Feed) extended a statement on the presence of mineral oil aromatic hydrocarbons (MOAH) in infant and young child food, which had been in place since June 2020, to all foods for general consumption as part of a joint statement by all EU Member States [2]. Clarifications to the text were made at the SCoPAFF meeting in October 2022 [3]. Following the publication of the revised risk assessment by EFSA, this SCoPAFF statement was adapted in September 2023 with regard to the presentation of the reasons [4].

Starting in December 2023, the EU Commission has proposed various options for statutory maximum MOAH levels under European food contaminant legislation. It is currently planned to include maximum MOAH levels for certain foods, ingredients and raw materials in the EU Contaminants Regulation 2023/915 [5].

To explain these (initial) regulatory proposals, the responsible Commission services have provided a non-coordinated FAQ catalog on the “Draft regulatory measures for mineral oil hydrocarbons in food” (June 2024) [6].

In this FAQ of the EU Commission, the SCoPAFF recommendation is characterized as a basis for the case-by-case risk assessment of findings by the authorities of the member states, which should apply until adequate, specific maximum levels are set. In terms of harmonization, this is an agreement between the member states on the interpretation of Article 14 of the basic Regulation (EC) No. 178/2002 [7].

The agreement is intended to facilitate the task of assessing individual cases by the competent authorities. In Germany, food monitoring is the responsibility of the federal states and the enforcement authorities are generally located at municipal level.

Therefore these explanations agreed between the industry and the ALB serve as a transitional information basis and application aid until regulation becomes effective.

Objectives and content of the Joint Statement of the Member States in the SCoPAFF on MOAH in food

The aim of the SCoPAFF Joint Statement is to communicate a uniform assessment concept agreed between the Member States with EU-wide harmonized limits of determination for MOAH for different food groups depending on the fat content of the respective food. According to SCoPAFF, the procedure should be as follows: If quantifiable levels of MOAH are detected in food (including infant formula) by food monitoring, the affected products should be withdrawn from the market, if necessary by means of a recall (Article 14 of Regulation (EC) No 178/2002). This procedure is aimed at all foodstuffs in the form in which they are placed on the market, irrespective of the source of MOAH. This means, for example, that powdered foods are considered as such and should not be assessed in their prepared form for consumption.

The MOAH limits of quantification (LOQs) achievable throughout the EU according to the SCoPAFF statement (version of 19.10.2022) are C₁₀ - C₅₀ (total hump) for the total fraction:

- *0,5 mg/kg for dry foods with a low fat/oil content ($\leq 4\%$ fat/oil)*
- *1 mg/kg for foods with a higher fat/oil content ($> 4\%$ fat/oil, $\leq 50\%$ fat/oil)*
- *2 mg/kg for fats/oils or foods with $> 50\%$ fat/oil*

The basis for the classifications and limits of quantification was not specified in the Joint Statement, but is likely to be based on the JRC Technical Reports. Limits of quantification should be described in such a way that they are achievable for all official laboratories in the cross-section of EU Member States using the current JRC method (see IV.). This should enable a uniform approach, irrespective of the Member State in which the analysis is carried out.

The SCoPAFF protocol of 22.09.2023 leads to the following further conclusions:

- EFSA emphasizes the uncertainty regarding the consequences of long-term accumulation of MOSH in the human body.
- In recent years, minimization measures have been established by industry and individual member states (note: this includes the orientation value concept in Germany). These minimization measures will also be continued with regard to MOSH.
- For MOAH, the common monitoring approach until EU limit values are established means that measures based on Article 14 of Regulation (EU) 178/2002 must be examined in each individual case if the specified limits of determination are exceeded.
- An evaluation of EFSA data shows that 90-95% of foodstuffs remain below the limit of determination and therefore, including oils and fats, a maximum MOAH content of 2 mg/kg can predominantly be complied with. Only for a large part of the production of olive pomace oil and tropical fats and oils, e. g. coconut oil, would there be demonstrable problems with the 2 mg/kg MOAH limit.
- MOAH does not occur natively in agricultural source materials. Consequently, contamination must be avoided along the entire value chain during harvesting, transportation, storage and processing.

Scope of application of the Joint Statement of the Member States in the SCoPAFF on MOAH

The current version of the Joint Statement adopted by the EU Member States in the SCoPAFF concerns “all foods as sold”. In this respect, the individual case assessment to be carried out by the national food control authorities should be aimed at food in the form in which it is placed on the market and not, for example, at preliminary products or raw materials that are further processed.

The Protocol to the SCoPAFF Statement refers also to the possible consequences of MOAH findings through official controls. Assuming that in individual cases MOAH in food may result in classification as an unsafe food, market-related measures must be considered in accordance with Article 14 of the Basic Regulation (see III).

Food business operators in the supply chain must continue to apply their existing duties of care, self-checks and recognized good manufacturing practice. In concrete terms, this means that conspicuous findings of MOAH in raw materials must be investigated and remedied, even if the raw materials are not placed on the market as such and the subsequent steps in the process reduce the MOAH contamination.

IV. Application through monitoring, marketability and reporting obligations

The SCoPAFF statement states:

“If the quantified presence of MOAH, which are possible genotoxic carcinogens, in food including food for infants and young children is confirmed by an official control, the products concerned should be withdrawn and, if necessary, recalled from the market on the basis of Article 14 of the General Food Law (Regulation (EC) No 178/2002), to ensure a high level of human health protection. In this regard the Member States also stress the responsibilities of food business operators in accordance with Article 19 of the General Food Law.”

The Member States have agreed in this respect that the official assessment of foodstuffs containing MOAH at or above the limits of quantification described is to be considered as unsafe food within the meaning of Article 14 of the basic Regulation (EC) No 178/2002. Application of the assessment criteria of Article 14 may lead to withdrawal from the market and, if necessary, to a public recall.

In Germany, the enforcement authorities of the federal states are responsible for the implementation of official measures on MOAH under the SCoPAFF Statement, even though the Federal Ministry of Food and Agriculture represents Germany in SCoPAFF.

The LAV-Arbeitsgruppe „Lebensmittel- und Bedarfsgegenstände, Wein und Kosmetika“ (ALB) the responsible specialist departments of the federal states are involved in coordinating application issues. The ALB chair submitted the views of the federal states in a letter dated 22.12.2022 in response to inquiries from the Food Federation Germany [8]:

“The ALB welcomes the agreement of the Standing Committee on Plants, Animals, Food and Feed - Section for Novel Foods and Toxicological Safety of the Food Chain on the handling of foods with quantifiable levels of aromatic mineral oil hydrocarbons, as reached between the European Commission and the Member States at the meeting on 21 April 2022, including adjustments to the applicable limit of determination depending on the fat content of the foodstuffs as per the meeting minutes of 19 October 2022. April 2022 between the European Commission and the Member States, including the adjustments to the applicable limit of determination depending on the fat content of the foodstuffs in accordance with the meeting minutes of October 19, 2022. The food control authorities of the federal states will take the agreement reached in the SCoPAFF into account accordingly in the food law assessment of contamination of foodstuffs with aromatic mineral oil hydrocarbons.”

In the FAQ on the planned regulatory measures, the Commission clarifies that according to the provisions of Regulation (EC) No 333/2007 the measurement uncertainty must be stated and applied in conformity assessments, including in supply chains.

For Germany, it should be noted at this point that the monitoring authorities currently regularly take the measurement uncertainty into account when considering maximum levels, but - if there is no legal maximum level - do not take the measurement uncertainty into account in purely toxicological assessments with reference to Article 14 or the question of the detectability / determinability of a substance.

The measurement uncertainty of 20 % stated in the JRC Technical Report serves as an orientation value. In specific individual cases, the measurement uncertainty is laboratory-specific and also varies depending on the matrix (see DGF unit methods C-VI 22).

In addition, there are matrices for which the reference to the fat content to determine the minimum achievable LOQ is not helpful due to, for example, high levels of essential oils and other plant constituents (e.g. herbs, spices, tea). The reference to the sales form instead of the preparation always appears problematic with regard to the provisions of Article 14 if the analytically determined MOAH content in the ready-to-eat food is no longer reasonably to be expected (infusion of tea or coffee).

In this respect, the SCoPAFF statement should not be applied across the board, but rather requires a reasonable consideration of the individual case.

Measures based on Article 14 of Regulation (EC) No 178/2002 require a demonstration that the specific food is unfit for human consumption.

This requires a case-by-case assessment and individual risk assessment for the product concerned on the basis of existing scientific knowledge and the available data material, taking into account, among other things, the following:

- The usual destination and consumption pattern as well as the target consumer groups. The SCoPAFF statement can support the assessors in the sense of an expert opinion from the experts of the Member States and the EU Commission.
- In accordance with the JRC recommendation, a differentiating analysis using a two-dimensional technique must be carried out for positive MOAH findings and the result must be included in the risk assessment. Accordingly, if 3-7-ring systems are detected using GCxGC-TOF-MS and, if necessary, quantitative determination of these substances in accordance with the SCoPAFF Summary Report and the updated EFSA opinion, an assessment in accordance with Article 14(2)(a) of Regulation (EC) No 178/2002 must be examined.
- In the case of the binding EU maximum levels for MOAH, which are expected in the course of 2025 at the earliest, the measurement uncertainty must be taken into account when evaluating the results. In anticipation of the expected regulation, it may be appropriate for the authorities to include the measurement uncertainty in the assessment now as part of the necessary considerations in order to avoid undue hardship, particularly if, for example, the food to be assessed is only consumed rarely or in small quantities.
- If MOAH levels are detected during self-monitoring, the measurement uncertainty must not be deducted unilaterally from the result, but must be taken into account comprehensively and, if necessary, added to the result in order to demonstrate legal compliance with sufficient certainty. In the case of results that give particular reason to assume high health risks with regard to the EFSA opinion (e.g. disproportionately high MOAH findings and detection of 3-ring and multi-ring systems using GCxGC), it must be checked whether there is an obligation to notify the authorities and an obligation to recall.

Reporting obligations of laboratories according to LFGB § 44 paragraph 4a in Germany

For MOAH findings in foodstuffs in which the MOAH concentration is at or above the limit of determination, it must be checked in each individual case whether there is a reporting obligation for the responsible laboratory operator in accordance with Section 44 (4a) LFGB. This would be the case if an analysis carried out by the laboratory on a sample taken in Germany and tested in Germany gives reason to assume that the food could be subject to a marketing ban in accordance with Article 14 of Regulation (EC) No. 178/2002.

V. Sampling and analysis

According to the protocol to the SCoPAFF statement, analysis and sampling should be carried out in accordance with the provisions of Regulation (EC) No. 333/2007. The JRC Technical Report (on the LC-GC-FID method) should be consulted for the detection of MOAH. It contains instructions for

- Integration of total MOAH
- Indication of total MOAH, without the need to report the MOAH fractions
- Calculation of LOQ for total MOAH
- Consideration of measurement uncertainty

Many laboratories achieve lower LOQs in some cases. However, the limits of quantification specified in the SCoPAFF statement are relevant for the evaluation.

The Joint Research Center (JRC) has created the reference bases for MOAH analysis applicable in the EU [9]:

- JRC TECHNICAL REPORT
Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials In the frame of Commission Recommendation (EU) 2017/84 S. Bratinova, E. Hoekstra (Editors) 2019
- JRC TECHNICAL REPORT
Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials - In the frame of Commission Recommendation (EU) 2017/84, 2nd Edition S. Bratinova, P. Robouch, E. Hoekstra, 2023
- JRC TECHNICAL REPORT
Determination of MOSH and MOAH in edible oil Proficiency Test Report JRC FCM-22/01 Stefanka Bratinova, Piotr Robouch, Fernando Cordeiro, Giorgia Beldi, Chiara Senaldi, Lubomir Karasek and Eddo Hoekstra, 2023
- JRC TECHNICAL REPORT
Determination of MOAH in infant formula JRC IF 2022-05 – the ring trial validation study Bratinova S., Robouch P., Beldi G., Senaldi C., Karasek L., Gonçalves C., Valzacchi S., Garcia-Ruiz S., Hoekstra E., 2023

VI. Further information and references

Common MOH benchmark levels for food in Germany

The German benchmark levels for mineral oil hydrocarbons (MOH) are a good guide for the current range of different end consumer products as to how a product should be assessed against the background of standard good manufacturing practice [10].

The data basis for the common benchmark levels was compiled in a joint project lasting several years by the industry and the relevant monitoring authorities of the federal states and so-called benchmark levels were derived from this in a statistical procedure. These mark the findings for MOSH to be expected if good manufacturing practice is adhered to, which apply to at least 90% of foodstuffs. With regard to MOAH, the benchmark levels indicate that MOAH cannot be determined (n.b.) for at least 90% of the products in the product categories described. There is good agreement with the EFSA data from the updated opinion.

If the benchmark levels are exceeded, there is reason to examine possible factors influencing the product such as packaging, processing aids, ingredients and raw material provenance and to review good manufacturing practice.

The current and risk-oriented benchmark levels exist for the following product groups:

- Vegetable oils and fats
- Bread and biscuits, fine pastries, cereal products and cereal-based products, cereals, rice, pasta
- Confectionery, chocolate and cocoa-based confectionery
- Nuts, shell fruits, oilseeds, coconut, peanuts and dried fruit
- Desserts and ice cream, including those with fatty coatings, glazes and couvertures
- Meat, meat preparations and meat products
- Fish and fish products
- Milk and milk products including preparations thereof
- Vegan and vegetarian savory spreads, bread toppings, cold cuts and similar products as well as products derived from products of animal origin

Information from the BfR

The German Federal Institute for Risk Assessment (BfR) published an updated version of its advice on mineral oil components in foodstuffs with regard to the EFSA assessment:

- BfR-Mitteilung 35/2023 „Neue EFSA-Risikobewertung: Einige Mineralöl-Rückstände in Lebensmitteln bleiben gesundheitlich problematisch“ i. V. m. Fragen und Antworten zu Mineralölbestandteilen in Lebensmitteln und aktualisierte FAQs des BfR vom 31.7.2023 ([LINK](#))

References

- [1] EFSA: *Update of the risk assessment of mineral oil hydrocarbons in food* EFSA Panel on Contaminants in the Food Chain (CONTAM) 13.9.2023 ([LINK](#))
- [2] Standing Committee on Plants, Animals, Food and Feed Section (SCoPAFF) | *Novel Food and Toxicological Safety of the Food Chain*, 21.4.2022 ([LINK](#))
- [3] Standing Committee on Plants, Animals, Food and Feed Section (SCoPAFF) | *Novel Food and Toxicological Safety of the Food Chain*, 19.10.2022 ([LINK](#))
- [4] Standing Committee on Plants, Animals, Food and Feed Section (SCoPAFF) | *Novel Food and Toxicological Safety of the Food Chain*, 22.9.2023 ([LINK](#))
- [5] VERORDNUNG (EU) 2023/915 DER KOMMISSION vom 25. April 2023 über Höchstgehalte für bestimmte Kontaminanten in Lebensmitteln und zur Aufhebung der Verordnung (EG) Nr. 1881/2006 ([LINK](#))
- [6] FAQ der Kommission: FAQ document on the draft regulatory measures on mineral oil hydrocarbons (MOHs) in food (Juni 2024; liegt dem Lebensmittelverband vor)
- [7] Basisverordnung (EU) Nr. 178/2002 zur Festlegung der allgemeinen Grundsätze und Anforderungen des Lebensmittelrechts, zur Errichtung der Europäischen Behörde für Lebensmittelsicherheit und zur Festlegung von Verfahren zur Lebensmittelsicherheit ([LINK](#))
- [8] Brief ALB-Vorsitz | Geschäftsstelle der LAV-Arbeitsgruppe „Lebensmittel, Bedarfsgegenstände, Wein und Kosmetika“, 22.12.2022 (liegt dem Lebensmittelverband Deutschland e. V. vor)
- [9] JRC Technical Report: Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials - 2nd Edition, 2023, ISBN 978-92-68-01789-0 (online) ([LINK](#))
- [10] Gemeinsame Orientierungswerte für Mineralölkohlenwasserstoffe (MOH) in Lebensmitteln der LAV und Lebensmittelverband, Fassung 1/2024 ([LINK](#))

Länderarbeitsgemeinschaft Verbraucherschutz
Arbeitsgruppe Lebensmittel- und Bedarfsgegenstände,
Wein und Kosmetika (ALB)



LEBENSMITTELVERBAND
Deutschland

Imprint

Dr. Sieglinde Stähle
Lebensmittelverband Deutschland e. V.
Haus der Land- und Ernährungswirtschaft
Claire-Waldoff-Straße 7, 10117 Berlin
staehle@lebensmittelverband.de
www.lebensmittelverband.de

Dr. Rüdiger Helling
ALB-Vorsitz
Sächsisches Staatsministerium für Soziales und Gesellschaftlichen Zusammenhalt
Referat 22 Lebensmittel- und Futtermittelsicherheit
Albertstraße 10, 01097 Dresden
ruediger.helling@sms.sachsen.de | alb-vorsitz@sms.sachsen.de
www.sms.sachsen.de

Date: 28.10.2024