

Mineral oil hydrocarbons (MOHs) are chemical compounds mainly derived from crude petroleum oil which can end up in food during harvesting and production processes, with mineral oil aromatic hydrocarbon (MOAH) being of concern to human health

Veerle Vanheusden

Mineral oil hydrocarbons (MOH) are chemical compounds derived mainly from crude oil, but also produced synthetically from coal, natural gas and biomass.

There are two main categories of MOHs:

MOSH: mineral oil saturated hydrocarbons

MOAH: mineral oil aromatic hydrocarbons

MOHs can end up in food during harvesting and production steps, such as during drying processes; contact with exhaust fumes and asphalt; via leaking of machinery lubricants; or from mineral oil containing anti-dusting agents or non-stick agents. They can also enter food via contaminated extraction solvents; from contamination during the recuperation process for extraction solvents; via contaminated food ingredients, food additives or food contact materials; and through environmental contamination.

Most sources of MOHs in food are avoidable by following good practices at all stages of production.

Recent history

The first EU risk assessment of MOHs in food was carried out in 2012 by the European Food Safety Authority (EFSA), which concluded that exposure to MOSH and MOAH in food was of potential concern.

EFSA said MOSH could accumulate in human tissue and could cause adverse effects in the liver, and that MOAH may be mutagenic and carcinogenic.

At that time, there was insufficient occurrence data to set maximum levels for MOHs in food so the European Commission (EC) issued a recommendation in 2017 to collect further occurrence data. In 2020, the EC mandated EFSA to update its risk assessment of MOHs in food.

In 2019 and 2021, NGO Foodwatch carried out a survey of various foods and



MOHs update

found a wide range of concentrations of MOAH in food products, including in infant and follow-on formula.

Following these findings, EU member states agreed that pending the establishment of maximum levels (MLs) for MOAH in food, a common enforcement approach was appropriate.

EU member states agreed that good practices existed to avoid the presence of MOAH in food so that no MOAH should be present in food at levels above the limit of quantification (LOQ) – the lowest concentration of a substance that can be reliably detected and quantified with known accuracy and precision.

While awaiting the establishment of MLs for MOAH in food, EU member states agreed that enforcement action should be made on the basis of Article 14 of the General Food Law (GFL), which states that food should not be placed on the market if it is unsafe.

In a 21 April 2022 joint statement on the presence of MOAH in food, including food for infants and young children, EU member states said that in order to ensure a uniform enforcement approach throughout the EU, they agreed to withdraw and, if necessary, recall products from the market when the sum of the concentrations of MOAH in food were at or above, the following maximum LOQs:

- 0.5mg/kg for dry foods with a low fat/oil content ($\leq 4\%$ fat/oil)
- 1mg/kg for foods with a higher fat/oil content ($>4\%$ fat/oil, $\leq 50\%$ fat/oil)
- 2mg/kg for fats/oils or foods with $>50\%$ fat/oil

Risk assessment of MOHs in food

In 2023, EFSA issued an update on its risk assessment of MOHs in food. It concluded that current dietary exposure to MOSH does not raise a concern for human health. However, because MOSH accumulates in various organs in the body, the margin for safe exposure is very limited and its conclusion might change if mitigation measures are dropped.

ESFA concluded that 3-7 ring MOAHs contained genotoxic carcinogens.

For 1-2 ring MOAH, while some studies pointed towards mutagenic and carcinogenic effects, there was insufficient high quality toxicological information available to allow a conclusive risk assessment.

Taking into account these factors, ESFA concluded that the occurrence of total MOAH in food was of concern for human health.

In its 2023 EFSA opinion, ESFA made various recommendations to collect further data such as improving analytical methods, further investigating the sources

STANDARDS, TESTING & ANALYSIS



The European Commission intends to set maximum levels for MOAH in foods that are relevant contributors to MOAH exposure including oilseeds, animal fats and vegetable oils

► of the contamination, and collecting more toxicological, toxicokinetic and occurrence data.

It also recommended establishing a specification for MOAH in food additives and food contact materials.

Contaminant levels

The 2023 ESFA opinion concluded that MOAH in food was of concern for human health risks, mandating the EC to establish maximum levels for MOAH in food.

Under the EU regulatory framework on contaminants in food (Council Regulation EEC No 315/93), food containing a contaminant in an amount which is unacceptable from the public health viewpoint shall not be placed on the market. Contaminant levels have to be kept as low as can reasonably be achieved (the ALARA principle) by following good practices at all production stages.

In order to protect public health, the EC may, where necessary, establish maximum levels for certain contaminants in certain foods. These maximum levels are then established under Commission Regulation (EU) 2023/915. These maximum levels should be established in accordance with the ALARA principle.

Draft regulations

There are currently three EU regulations following up on the 2023 EFSA opinion.

- A draft regulation on maximum levels (MLs) for MOAH in food.
 - A draft recommendation on the monitoring of MOHs in food.
 - A draft regulation on methods for the sampling and analysis of MOHs in food.
- The EC intends to set MLs for foods

that are relevant contributors to MOAH exposure and for foods that may contain very high concentrations of MOAH.

MOAH is mostly found in processed foods due to contamination during processing, transport and packaging. Concentrations are low in fresh foods, which will not be included in the scope of the draft regulation.

Commodities and basic ingredients in which MLs will be set are: oilseeds and oil fruits; animal and vegetable fats and oils; tree nuts; pulses; cereal grains; milk; cocoa beans; sugar; spices and dried herbs.

For dried, diluted, processed and compound foods, the ML will be calculated in accordance with Article 3 of Regulation (EU) 2023/915. This means that the maximum level for the final product is calculated based on the MLs for the ingredients and ingredient composition, taking into account concentration or dilution factors.

For compound foods, the maximum level for the final product may be unrealistically low and impossible to achieve analytically due to some ingredients not having an ML (resulting in a zero ML).

In this case, provisions have been added where if there is no maximum level for MOAH, the following concentrations should be taken into account for calculating the maximum level for the compound food:

- 0.5g/kg for ingredients with a fat <4% fat/oil content
- 1.0mg/kg for ingredients with ≥4% and ≤50% fat/oil content
- 2.0 mg/kg for ingredients with >50% fat/oil content.

This is to ensure that the calculated amount for the final food is analytically achievable.

For establishing MLs for MOAH in food under the ALARA principle, it can be seen that 90-95% of all food contain MOAH concentrations below the achievable limits of quantification (LOQs).

This means that when good practices are used, concentrations of MOAH in food can be kept below the LOQ.

Therefore, the initially discussed MLs for MOAH were proposed at achievable LOQs, ie 0.5-2.0mg/kg depending on the fat content of the product.

An important point to note is that when deciding on the compliance of a product, the measurement uncertainty should be taken into account. This is to be entirely sure that when a product is said to be non-compliant, it really is non-compliant.

Those conducting analyses need to deduct the measurement uncertainty from the analytical result. Only when the result of that subtraction is above the ML should a product be non-compliant.

Analytical result: MU should be ≤ ML

EU stakeholders from the food industry were consulted at the start of this year on the ML at the limit of quantification (LOQ).

They submitted comments and occurrence data which showed that for many foods, the bulk of production complied with an ML at the LOQ. However, for some products, the bulk of production did not yet comply with an ML of 0.50-2.0mg/kg. For a limited number of products, the LOQ of 0.50-2.0mg/kg could not be achieved due to endogenous interfering substances.

Following on from the stakeholders' comments and data, a revised draft proposal has been drawn up in accordance with the ALARA principle.

This version contains MLs at the LOQ for those commodities in which this is achievable.

For certain commodities for which an ML at the LOQ is not yet achievable, a time plan is included which starts with higher MLs, to be reduced over time to the LOQ in order to give food business operators more time to implement the appropriate mitigation measures.

For products for which a LOQ above 2.0 mg/kg is not achievable, due to endogenous interfering substances, a higher ML is proposed.

Furthermore, EU member states are discussing transitional measures for products placed on the market before the application date. They are also discussing what would be the appropriate application date of the MLs.

Timeline

In mid-2024, the EC published a frequently asked questions document answering general stakeholder comments and questions. For the remainder of 2024, discussions with member states will continue on the proposed MLs and transitional measures.

Between the first and third quarter of 2025, stakeholders will be informed on how their comments on specific MLs were taken into account.

The EU proposal will also be notified to the World Trade Organization (WTO) so that third countries can comment on its proposal.

A vote on the proposal will be scheduled at the WTO Standing Committee on Plants, Animals, Food and Feed and if a favourable vote is reached, the regulatory procedure for scrutiny by the European Parliament and Council will be launched and adoption procedures will take place. These procedures will take about four months, meaning that the targeted entry for the regulation to come into force is the end of 2025.

It is very important to note that in the period before the application date of maximum levels, the ESFA statement of members states (21 April 2022) on the enforcement of quantities of MOAH above the LOQ will remain valid. Member states will need to keep enforcing levels of MOAH in food above the limit of quantification.

Monitoring

Alongside the draft regulation on maximum levels (MLs) for MOAH in food, there is also a draft regulation under discussion which focuses on the gathering of MOH occurrence data, the carrying out of investigations towards the sources of contamination, and on the application of MOH mitigation measures.

There are also recommendations to develop more sensitive analytical methods.

The monitoring recommendation establishes indicative levels (ILs) for MOHs in food. These are levels that, once exceeded, should result in an investigation into the sources of the contamination and the application of mitigation measures to avoid future contaminations.

ILs should not be used as a threshold for removing products from the market' and ILs for MOH in food are proposed between 0.50-15mg/kg, depending on the commodity.

ILs for MOAH in food are proposed for some commodities from which beverages are prepared. As MOAH only transfers to

Parameter	Criterion
Applicability	Food specified in Regulation (EC) No 915/2023
Specificity	Free from matrix or spectral interferences
Recovery	80-110% (The recovery can be lower than 80%, when applying a sample preparation with aluminium oxide for the determination of mineral oil saturated hydrocarbons or when performing a sample preparation with epoxidation for the analysis of mineral oil aromatic hydrocarbons)
Within-laboratory reproducibility (intermediate precision) (RSDR) Food with a fat content <4%	≤15%
Within-laboratory reproducibility (RSDR) Food with a fat content ≥4%	≤20%
LOQ Food with a fat content of <4%	≤0.50mg/kg
LOQ Food with a fat content of 4-50%	≤1.0mg/kg
LOQ Food with a fat content of >50%	≤2.0mg/kg

Table 1: Proposed analytical method requirements for MOHs

Source: Veerle Vanheusden, European Commission, OFI International 2024

to beverages to a limited extent, no MLs were established for these commodities: coffee beans, tea and herbal infusions, 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.

Because contaminations can occur in certain processed foods, but occurrence data is lacking to establish MLs at this stage, ILs are also proposed for processed vegetables, processed fruits, processed meat and offal, processed fish and other seafood, and processed eggs.

Sampling and analysis

The third piece of legislation to tackle MOHs is a draft regulation on methods to sample and analyse MOAH in food.

This will be an amendment to Regulation (EC) No 333/2007, with specific sampling and analytical method requirements for MOHs.

Some specific requirements for MOHs are added to the regulation – these are precautions to be taken to avoid contamination during the sampling and analysis procedures.

There are also specific analytical method requirements for MOHs in food. (see Table 1, above).

Discussions are also ongoing to establish specifications for MOAH in food additives and food contact materials, with the DG SANTE teams on food contact materials and food additives due to start discussions on the MOAH content of white mineral oils and waxes used as food additives and food packaging materials.

Mitigation measures

It is very important that food business operators take action to avoid the presence of MOHs in food. They should:

- Monitor the production process to avoid the contamination of food at all stages of production and transport, including through packaging.
- They should check their drying processes and avoid contact with asphalt, burning fumes, and exhaust fumes of machinery.
- Use food grade lubricants.
- Use MOH-free food contact materials or ensure that no transfer of MOH to the food is possible by using MOH-free jute bags or MOH-free wrappers.
- Use MOH-free ingredients and food additives.
- Use MOH-free hexane and replace paraffin columns for hexane recuperation in extraction processes. Alternatives are refined or semi-refined plant-based oils or synthetic MOH-free waxes.

FoodDrinkEurope has published a toolbox which operators can use to prevent the transfer of undesired mineral oil hydrocarbons into food.

Finally, it is very important that food business operators check their final food and food contact materials for unexpected sources of contamination during their process.

This article is based on a presentation made by Veerle Vanheusden, Policy officer – Unit E2 – Food processing and novel food, Directorate General Health and Food Safety, European Commission, at OFI International 2024 on 9-11 September