

FoodDrinkEurope members' experiences and views with mineral oil hydrocarbons in food

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Virtual stakeholder forum on mineral oil hydrocarbons in food
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Context

- **Safety is our shared priority:** together with the agri-food supply chain, we remain fully committed to mitigating the presence of mineral oil hydrocarbons (MOH) in food, building on over ten years of extensive collaboration
- The **FoodDrinkEurope/BLL toolbox** enables FBOs to reduce preventable contamination with MOH as to the greatest extent as technically possible.
- The food industry has made remarkable progress, but **not all routes of entry are known** yet and those which are known, particularly upstream and in origin countries, are not always manageable.



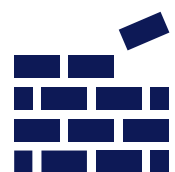
Key Messages

1. We fully support **further efforts** to investigate the sources of MOH and take necessary measures to mitigate their presence in food.
2. We **welcome the objectives of this initiative**: to guarantee high level of protection to consumers and to eliminate current legal uncertainties.
3. However, we have serious concerns about the **significant economic and other impacts** like food waste of the proposed risk management measures.
4. We strongly encourage the Commission to **engage with a broad range of stakeholders**, including those outside of the EU, to fully understand the impact of maximum levels on farmers and producing industries.

Continuous progress and engagement of industry



*“The efforts of the authorities and the industry in recent years have been quite successful in this respect. According to EFSA's new data, **the daily intake of mineral oil components in all population groups has roughly halved since 2012**” (BfR, 2023)*



*“Two types of data providers were identified in the final data set of 7,840 samples: European countries and food associations. **The data provided by food associations corresponded to 33,295 analytical results (3,413 samples, 43.5%)** while data from European countries referred to 39,827 analytical results (4,427 samples, 56.5%)” (EFSA, 2023)*

- Extensive collaboration to identify possible sources of MOAH and implement preventive measures throughout the supply and manufacturing chain
- Support to JRC on the development of the SOP and the improvement of a validated analytical methodology through production of reference materials for infant and follow-on formula products
- Data collection and submission to EFSA based on reliable test results for our complex matrices

SNE members are aware of their responsibility to the safety of the vulnerable population and have been prepared for the setting of MLs on MOAH. Since 2020, the sector implemented the currently proposed MLs as action limits.

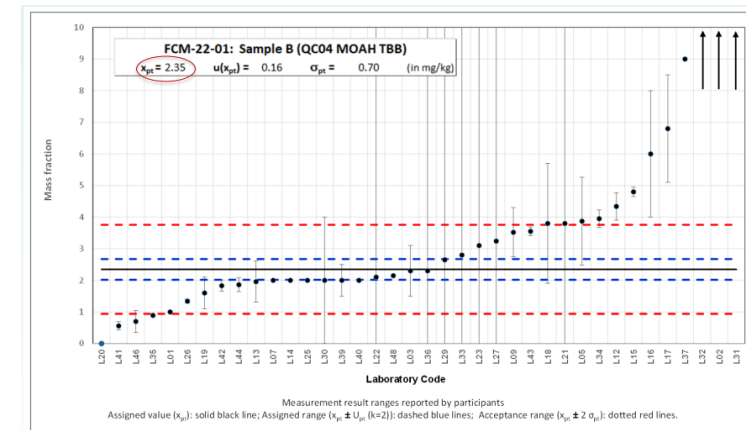
Other initiatives from other sectors will be presented at the Forum later today

....but some significant challenges remain on the way forward

Stakeholders in the chain continue to work in reducing the presence of MOH in foods

- Our members, in collaboration with other partners of the agri-food chain, have done a lot of progress over the last years. However, huge difficulties remain, such as:
 - Analytical challenges have not been fully resolved yet, e.g.:
 - lack of harmonized, robust methods for all food matrices
 - considerable differences among laboratories
 - interferences could result in overestimation (false positives)
 - for some commodities, LOQ differs from the JRC report
 - limited availability of capable laboratories in EU and Third Countries
 - time of analysis and test results
 - Difficulties with the upstream supply chain, in particular those originating in third countries.

JRC (2022), n=38 laboratories, edible oils



RSD > 60%, range 0,56 – 9 ppm (spiked at 2 ppm)

Industry interlab study on vegetable oils:

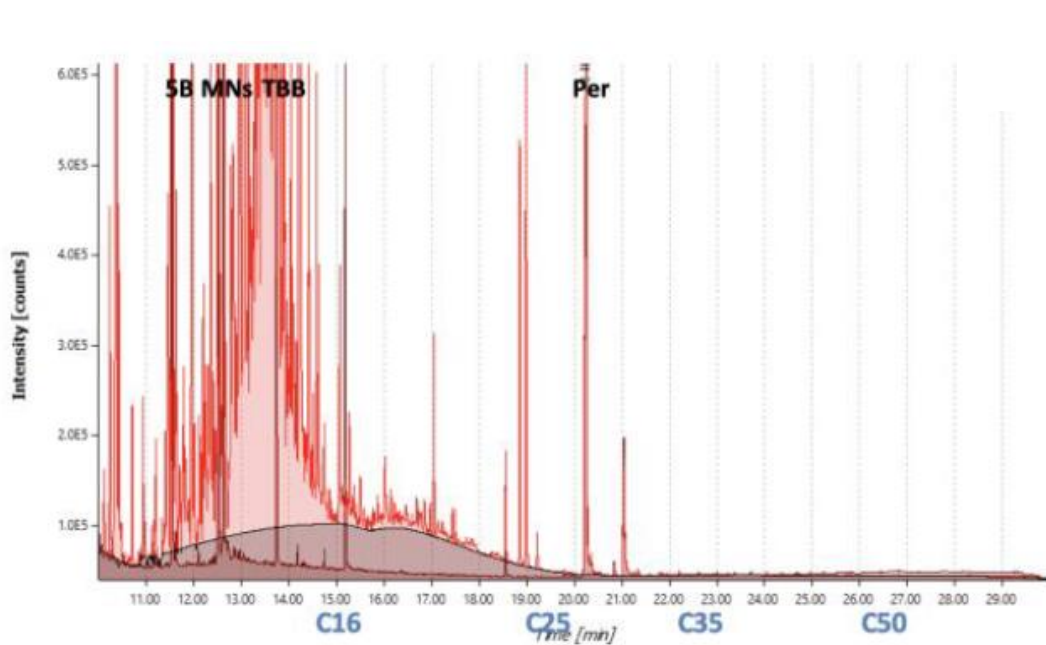
→ *Interlab variability comparable to JRC report*

→ *Only 24% of the laboratories (n = 25) show an acceptable "z" score for MOAH analysis (assigned value 2.1 ppm)*

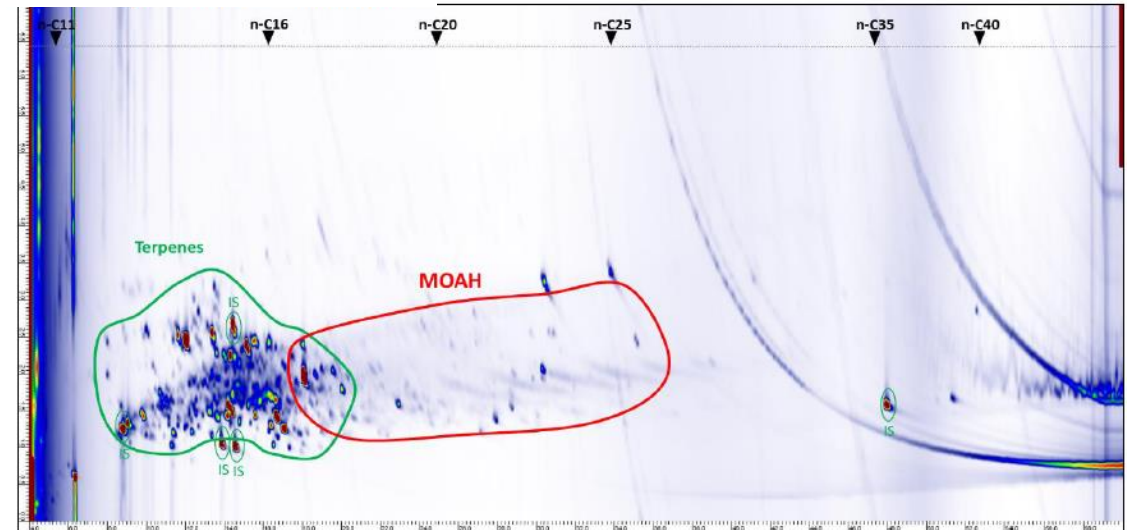
Any exceedance of MOAH limits must be confirmed by GC x GC MS / FID

Example: mint oil

LC-GC-FID



GC X GC plot with peak identification (confirmation)



- **Terpenes:** Aromatic Sesquiterpenes (n-C12-17 [x], between c- and 2-line [y])
- **MOAH** cloud probably from gaseous phase migration or from another source (mainly monoaromatics; located at n-C16-25 [x-axis], between 1- and 3-line [y-axis])

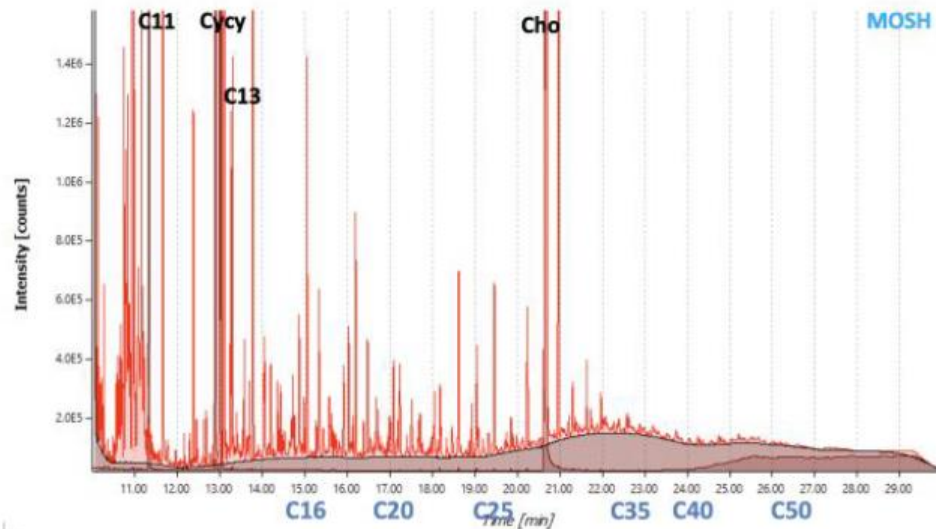
Confirmed MOAH ?

Natural aromatic sesquiterpenes (C12-C17)
MOAH «cloud» mainly monoaromatics

Indicative limits for MOSH may be exceeded due to interferences

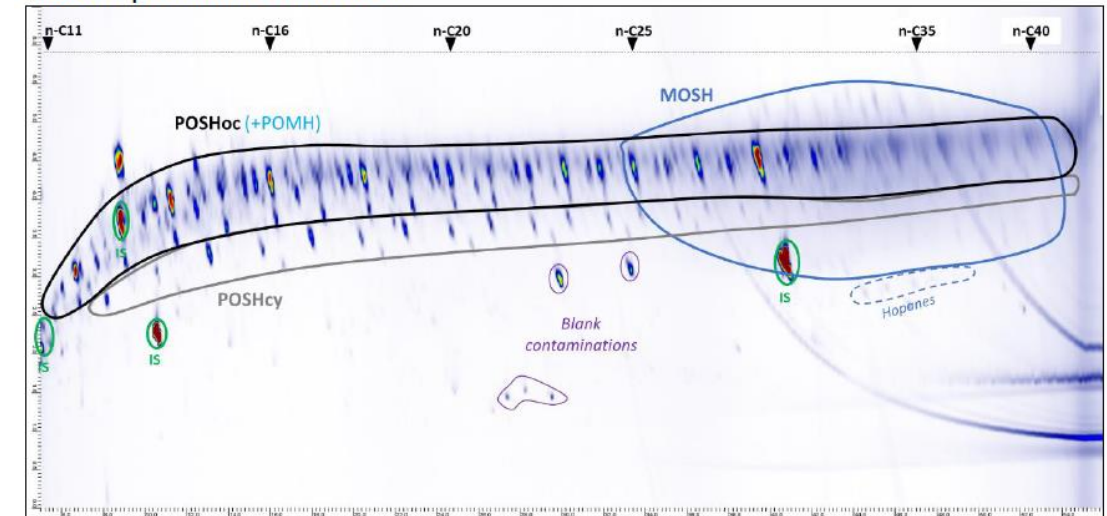
Example: product packed in polyethylene pouch

LC-GC-FID: MOSH (total) = 5.7 mg/kg



GCxGC-FID: MOSH & POSH; POSH ~ 75%

GCxGC plot with identification:



The JRC method for MOSH accounts for MOSH and other saturated hydrocarbon fractions (NOT originating from mineral oils)

We support further action but have big concerns about the MLs for MOAH in food being considered

- Maximum Levels (MLs) for MOAH in foods provides industry and enforcement authorities with legal clarity and a harmonized approach across EU.
- However, the proposed MLs for MOAH do not consider any differentiation and toxicity among MOAH substances.
- Certain assumptions remain unclear e.g. on which basis the specific fat/oil (%) content ranges were decided for setting the MLs for MOAH.
- MLs for certain products are not feasible based on best practices, and/or do not consider the contribution of the product as consumed to the overall exposure (*see sector comments*).
- MLs are suggested also for food groups with no evidence of frequent contamination or that are not major contributors to the exposure.

A clear scope is critical to provide legal certainty for food business operators

- MOH can enter the food chain in many ways, such as environmental contamination or during different stages of production.
- MOAH is not a processing contaminant (not formed during the manufacture of products like acrylamide) and therefore **must be mitigated at source**.
- Food business operators must keep potential entry points under control with appropriate measures (*see FoodDrinkEurope/BLL Toolbox*). For some commodities, the possibilities to mitigate MOAH any further during the final processing steps are limited.
- The scope of the current proposals for MLs for MOAH is unclear and may lead to misinterpretation by stakeholders and regulators with the risk of creating issues.
- A **comprehensive impact assessment** across all stages of the supply chain is necessary and should be made to develop a proposal that all actors in the chain can deliver.

To make MLs for MOAH workable, some important conditions must be considered

- Continued work by JRC and the Commission is needed as it must establish **robust methods of analysis** (including Confirmation and Characterization) for MOAH in foods, that are demonstrated to be repeatable and reproducible, and are made available for public access.
 - ❖ IYC specific comment: as the method is not validated < 1 mg/kg, results are not reproducible.
- Until robust methods are available, clear rules for **measurement uncertainty** need to be included in the MOAH sampling and analysis regulation.
- **MLs for MOAH should be set based on the ALARA* principle** and not on the limit of quantification (LOQ).
- **Early awareness should be raised** about draft risk management measures to Third Countries.
- A reasonable **transition period is critical** and should be provided to allow supply chains to adapt and minimize the environmental/economic impact.

Monitoring MOSH

- EFSA has concluded that there is no concern for health for the overall population.
- Monitoring can help to better understand the root causes for contamination and minimize any risks to food safety.
- However, there are still issues with the analytical methods and definition of MOSH.
- *“As compared to the 2012 EFSA SO (EFSA CONTAM Panel, 2012), it seems there is a decrease in MOSH levels across the different food commodities, which, at least partially, could be explained by the different measures introduced by industry since 2012” (EFSA, 2023)*
 - MOSH Levels went down in recent years
 - We would like to get more clarity on the general approach followed for establishing Indicative Levels
- Foremost, Indicative Levels should not be understood as MLs, and an exceedance should not lead to a removal from the market of the concerned products.

Conclusions and way forward

- **Safety remains our top priority.** We remain fully committed to investigating the sources of MOH in food and mitigating their presence to ALARA.
- We are very concerned about the **disproportionate economic and other impacts** that the proposed risk management measures will trigger.
- There are still **analytical challenges** that call for the inclusion of Confirmation and Characterization and of the measurement uncertainty, which is critical to address.
- A **clear scope** must be provided to ensure legal certainty for food business operators.
- We request careful consideration of the points raised we have raised to develop workable MLs for MOAH and achieve a legal framework for a more effective implementation.
- We look forward to **being consulted and collaboration to develop a proposal** that guarantees a high level of consumer protection and can be implemented by all stakeholders.
- Specific comments from some of our sectors will follow to further contribute to this process.





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Further comments on the proposed analysis of MOH

- JRC guidelines recommend sample pre-treatments but do not specify how this will apply to each of the different product categories. Given there are studies indicating that the application of these treatments are matrix dependent and can impact analyte recoveries, we fear that an inappropriate application (or lack of) sample pre-treatment could impact results.
- The recommended method (LC-GC-FID) is suitable for quantitation purposes, but it does not specify a characterization method (GCxGC MS / FID) to identify non-mineral oil interferences which could result in overestimation. The future Regulation should include the need of Characterization and Confirmation of MOAH fraction in suspect results using a validated GC×GC-MS method.
- The Measurement Uncertainty should be considered to account for the natural product interferences that are observed in complex matrices. Furthermore, matrices not validated by the JRC method will be problematic for most labs with significant measurement uncertainty.
- Performance criteria given in the JRC guidance document as well as in the draft implementing regulation need to be critically assessed to confirm they can be achieved by most laboratories in EU and Third Countries.
- The time for analysis of MOH (sometimes up to three weeks) remains a challenge.

Further comments on sampling of MOH

- The sampling precautions for mineral free sampling conditions (tools and sampling materials) are not clarified as the lists indicates that personal care products need to be excluded during sampling which raises the following questions:
 - how is this to be achieved?
 - how are products that could be potential contaminants be determined?
 - how would they be excluded during sampling?
- How are recommended containers (PET, aluminium, glass) ensured to be mineral free?
- The recommended cleaning procedures given in JRC guidelines (hexane rinse, annealing) will not apply to all container types and may not be practical in all situations (e.g. hexane carries its own Health and Safety risks if not suitably controlled).