Directorate-General for Health and Food Safety

Stakeholder forum on mineral oil hydrocarbons in food.

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Mineral Oil Hydrocarbons (MOHs)

- Introduction
- Recent history
- Risk assessment
- Regulatory follow up to the EFSA opinion
- Analytical aspects
- Mitigation measures

MOHs - Introduction

- Chemical compounds derived mainly from crude oil, but also produced synthetically from coal, natural gas and biomass.
  - MOSH: mineral oil saturated hydrocarbons
  - MOAH: mineral oil aromatic hydrocarbons
  - MOHs can be present in food via harvesting and production processes (e.g.drying processes, contact with exhaust fumes, lubricants for machinery, the use of anti-dusting agents, non-stick agents, the use of paraffin for hexane recuperation in extraction processes…), via contamination of food contact materials, food ingredients and food additives or via environmental contamination.
  - Most sources of MOHs in food are avoidable by following good practices

MOHs – Recent history

- 2012 EFSA opinion on MOHs in food
  - Exposure to MOSH and MOAH in food is of potential concern.
    - **MOSH** can accumulate in human tissue and may cause **adverse effects in the liver.**
    - **MOAH** may be **mutagenic and carcinogenic**
- Commission Recommendation (EU) 2017/84
    - Monitoring of food and food contact materials and application of mitigation measures
- 2019 and 2021 Foodwatch findings of MOAH in food
- 2020 EFSA rapid assessment on MOAH in infant and follow-on formulae
- 2020 mandate to EFSA for an update of its risk assessment on MOHs in food

MOHs – Recent history

- Statements of the SC PAFF on a common enforcement approach
  - 23 June 2020 - 21 April 2022 - 19 October 2022 (additional clarifications)
- Good practices exist to avoid MOAH in food, so no MOAH should be present in food at levels above the limit of quantification (LOQ).
- Enforcement action on the basis of Article 14 of GFL
  - Awaiting the establishment of maximum levels for MOAH in food
  - GFL (Regulation (EC) No 178/2002: food shall not be placed on the market if it is unsafe.
  - Member States can enforce quantities of MOAH above the LOQ because:
    - The MOAH fraction may contain genotoxic carcinogens.
    - The presence of MOAH in food is avoidable.

MOHs – Recent history

Joint statement of 21 April 2022 of the Member States regarding the presence of MOAH in food, including food for infants and young children + further clarifications of 19 October 2022

*In order to ensure a uniform enforcement approach throughout the EU, the Member States agreed to **withdraw and, if necessary, to recall products** from the market, when the **sum of the concentrations of MOAH** in food are **at or above** the following maximum **LOQs**:*

-0.5 mg/kg for dry foods with a low fat/oil content (≤ 4% fat/oil)

-1 mg/kg for foods with a higher fat/oil content (> 4% fat/oil, ≤50% fat/oil)

-2 mg/kg for fats/ oils or foods with >50% fat/oil

Analysis and sampling should be done according to the provisions of Regulation (EC) No 333/2007.

This statement replaces the statement of the he Standing Committee of 23 June 2021

MOHs – Risk assessment

- 2023 EFSA opinion on an update of the risk assessment of MOHs in food
  - The present dietary exposure to MOSH does not raise concern for human health for all age classes.
    - The margin for safe exposure is limited, so those conclusions might change if the mitigation measures would be dropped.
  - Genotoxicity and carcinogenicity are associated with MOAH with three or more aromatic rings.
  - For 1-2 ring MOAH some studies point towards adverse effects, but insufficient toxicological information is available for a conclusive risk assessment.
  - Based on two scenarios on three or more ring MOAH contents in the diet and lacking toxicological information on effects of 1 and 2 ring MOAH, a possible concern for human health was raised in relation to the presence of MOAH in food.

MOHs – Risk assessment

- 2023 EFSA opinion on an update of the risk assessment of MOHs in food
  - Recommendations to improve the analytical methods, to further investigate the sources of the contamination, to collect more toxicological, toxicokinetic and occurrence data.
  - Technical specifications of white mineral oils and waxes used as food additives and food packaging materials should be updated, with detailed information about the MOAH content and composition.

MOHs – Regulatory follow-up to the EFSA opinion

- 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 shall be kept **as low as can reasonably be achieved** by **following good practices at all the stages.**
    - In order to protect public health the Commission may where necessary establish the maximum tolerances for specific contaminants.
  - Commission Regulation (EU) 2023/915 (Former Regulation (EC) No 1881/2006)
    - Establishes maximum levels for certain contaminants in food.

➔ MLs can be established when evidence becomes available, which indicates a risk to human health

➔ MLs are established on the basis of occurrence data according to the ALARA principle, when using good practices.

MOHs – Regulatory follow-up to the EFSA opinion – CONTAM legislation

- Draft Regulation on maximum levels (MLs) for MOAH in food

  -SANTE PLAN 2023/2345

- Draft Recommendation on the monitoring of MOHs in food

  -Discussion paper

- Draft Regulation on methods for the sampling and analysis of MOHs in food.

  -SANTE PLAN 2023/2726

MOHs – Regulatory follow-up to the EFSA opinion

Draft Regulation on maximum levels (MLs) for MOAH in food.

- MOAH is mostly found in processed foods due to contaminations during the processing, transport and packaging.
- The concentrations of MOAH in fresh foods are low.
- Two options:
  - Option 1: MLs for the relevant contributors to the exposure and for foods that may contain very high concentrations of MOAH.

  Or
  - Option 2: MLs for all foods other than fresh or frozen fruits, vegetables, meat, offal, fish and seafood.

MOHs – Regulatory follow-up to the EFSA opinion

Draft Regulation on maximum levels (MLs) for MOAH in food.

- Option 1- proposal to set MLs for:
  - Animal and vegetable fats and oils, products based thereof and products containing animal **and vegetable** based fats and oils.
  - Coffee, coffee-based products and coffee containing products
  - Tea and herbal infusions
  - Food supplements
  - Infant formulae, follow-on formulae and young-child formulae
  - Drinks for infants and young children placed on the market and labelled as such
  - Baby food and processed cereal-based food for infants and young children
  - Food for special medical purposes intended for infants and young children
  - Cereal grains, cereal based products and cereal containing products
  - Pulses, pulses-based products and pulses containing products
  - Tree nuts, tree nut-based products and tree nuts containing products
  - Oilseeds, oilseed-based products and oilseed containing products
  - Oil fruits, oil fruits-based products and oil fruit containing products.
  - Cocoa beans, cocoa based products and cocoa containing products
  - Sugar containing products and confectionary
  - Spices and dried herbs

MOHs – Regulatory follow-up to the EFSA opinion

Draft Regulation on maximum levels (MLs) for MOAH in food.

- Option 1- proposal to set MLs for:
  - Milk and dairy products and products containing dairy (to be discussed)
  - Processed products containing fish and other seafood OR smoked and canned fish products (to be discussed)
  - Products containing or based on meat of terrestrial animals (to be discussed)
  - Composite foods (to be discussed)
  - Processed products containing fruit or vegetables (to be discussed)
  - Processed products containing eggs (to be discussed)

MOHs – Regulatory follow-up to the EFSA opinion

Draft Regulation on maximum levels (MLs) for MOAH in food.

- Option 2- proposal to set MLs for MLs for all foods other than fresh or frozen fruits, vegetables, meat, offal, fish and seafood

MOHs – Regulatory follow-up to the EFSA opinion

Draft Regulation on maximum levels (MLs) for MOAH in food.

- Implementation of the ALARA principle when using good practices:
  - 90-95% of the food contains concentrations of MOAH below the achievable limits of quantification (LOQs) in the JRC Guidance.
  - When using good practices concentrations of MOAH in food can be kept below the LOQ.
  - MLs for MOAH in food are proposed at the achievable LOQs (JRC Guidance)

MOHs – Regulatory follow-up to the EFSA opinion

Draft Regulation on maximum levels (MLs) for MOAH in food.

- Proposed MLs

5.5	Mineral Oil Aromatic Hydrocarbons (≥C10 to ≤C50)	Maximum levels (mg/kg)	Remarks
5.5.1.1	Products with a fat ≤ 4% fat/oil content	0,50 mg/kg	
5.5.1.2	Products with > 4% and ≤ 50% fat/oil content	1,0 mg/kg	
5.5.1.3	Products with > 50% fat/oil content	2,0 mg/kg	

- Decisions on compliance taking into account measurement uncertainty
  - Analytical result – MU should be ≤ ML
  - Points D.1.3. and D.2. of the Annex to Regulation (EC) No 333/2007.

MOHs – Regulatory follow-up to the EFSA opinion

Draft Regulation on maximum levels (MLs) for MOAH in food.

- For some commodities a large proportion of the products still contain concentrations of MOAH above the proposed MLs.
- Stakholders are invited to comment for which foods according to the currently best available practices the proposed MLs cannot be achieved yet. They should submit:
  - clear information on the sources of the contamination and why it cannot be mitigated within a year time.
  - occurrence data for MOAH for samples on which the best available practices have been used. No old samples will be taken into account from processes in which there was avoidable contamination.
  - a clear time plan for avoiding the contamination in the near future.

MOHs – Regulatory follow-up to the EFSA opinion

Draft Recommendation to

- Monitor MOSH in food, carry out investigations towards to sources of the contamination and to apply mitigation measures to avoid MOSH in food.
  - This recommendation would be supported by indicative levels: in case the indicative levels are exceeded, it is recommended to carry out investigations towards the sources of the contamination. Once the sources are identified, the appropriate mitigation measures should be applied. However an exceedance of the indicative level should not lead to a removal from the market of the concerned products.
- Validate more sensitive analytical methods and methods based on two-dimensional GC

MOHs – Regulatory follow-up to the EFSA opinion

Draft Recommendation – Indicative Levels

- Animal and vegetable oils and fats: **15 mg/kg**
- Coffee, tea, herbal infusions, food supplements, chocolate and confectionary, processed fish, processed seafood, offal, processed meat and processed offal products: **10 mg/kg**
- Eggs, grains, grain containing products, tree nuts, pulses, oilseeds, products containing tree nuts, pulses and oilseeds, composite products, dairy, dairy containing products, imitation dairy and imitation meat, seasonings, dry infant and dry follow-on formulae, cereal based foods for infants and young children and babyfood: **5.0 mg/kg**
- Liquid infant and follow-on formulae: **1.5 mg/kg.**

MOHs – Regulatory follow-up to the EFSA opinion

Draft Regulation on methods

- An amendment of Reg. (EC) No 333/2007 with specific sampling and analytical method requirements for MOHs.

Parameter	Criterion
Applicability	Foods 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 oxyde for the determination of mineral oil saturated hydrocarbons or when permorming 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 (intermediate precision)(RSD_R) Food with a fat content >= 4 %	≤ 20 %
LOQ Food with a fat content of < 4 %	≤ 0.50 mg/kg
LOQ Food with a fat content of 4 - 50%	≤ 1.0 mg/kg
LOQ Food with a fat content of > 50 %	≤ 2.0 mg/kg

MOHs – Regulatory follow-up to the EFSA opinion

Timelines

- 01/2024 stakeholder forum
- By **27 February 2024** further comments supported by data on:
  - occurrence of MOHs in food when using the best available practices
  - the sources of the contamination and available mitigation measures
  - achievable timelines for avoiding the contamination in the near future
- Q2/Q3 2024 continuation of the discussions with the Member States
- Q3-Q4 2024 vote
- In the meanwhile, the SC PAFF statement of 21 April 2022 remains valid

MOHs – Regulatory follow-up to the EFSA opinion – FCM and food additives legislation

- The DG SANTE teams on food contact materials and food additives will start discussions on the MOAH content of white mineral oils and waxes used as food additives and food packaging materials.

MOHs - Analysis

- Analytical aspects
  - 2018 JRC Guidance on sampling, analysis and data reporting for the monitoring of MOHs in food and FCM
    - Outline of the analytical approach
    - Analytical method requirements
    - Reporting requirements
    - https://publications.jrc.ec.europa.eu/repository/handle/JRC115694
  - 2019 JRC roundtable workshop on the determination of MOAH in infant formula → analytical requirements for the determination of MOAH
    - https://ec.europa.eu/food/system/files/2020-01/cs_contaminants_catalogue_outcome-workshop-moah_en.pdf
  - 2022 updated SOP for the analysis of MOHs in infant formulae
    - Validated via a collaborative trial
    - https://joint-research-centre.ec.europa.eu/eurl-food-contact-materials/eurl-fcm-test-methods_en

MOHs - Analysis

- Analytical aspects
  - 2023 update of the JRC Guidance
    - Guidance on the integration of total MOAH
    - Guidance on the reporting of total MOAH, without a need to further report on the MOAH fractions
    - Guidance on the calculation of the LOQ for total MOAH
    - https://op.europa.eu/en/publication-detail/-/publication/97cb92c2-d29e-11ed-a05c-01aa75ed71a1/language-en
  - JRC report on the proficiency test for the determination of MOSH/ MOAH in edible oils
    - https://publications.jrc.ec.europa.eu/repository/handle/JRC133284
  - From January 2023 the EURL Processing Contaminants has taken over the work from JRC as regards the analysis of MOHs in Food
    - https://www.eurl-pc.eu/about
  - From January 2023 the JRC will remain the EURL for the analysis MOHs in food contact materials.

MOHs – Mitigation measures

- Actions to be taken by FBOs to avoid the presence of MOHs in food:
  - Monitoring of the production process to avoid the contamination of food at all stages of the transport and production, including through packaging.
    - Avoid contamination during drying processes and contact with exhaust fumes
    - Use of food grade/ MOH free lubricants.
    - Use of MOH free food contact materials or ensure that no transfer of MOAH to the food is possible
    - Use of MOH free ingredients and food additives.
    - Replacement of paraffin columns for hexane recuperation in extraction processes. Alternatives are refined or semi-refined plant-based oils of synthetic MOH free waxes.

    FoodDrinkEurope toolbox for preventing the transfer of undesired mineral oil hydrocarbons into food (https://www.fooddrinkeurope.eu/wp-content/uploads/publications_documents/Preventing_transfer_of_undesired_Mineral_Oil_Hydrocarbons_into_food_FoodDrinkEurope_BLL_Toolbox.pdf)
  - Analysis of the foods and food contact materials

Mineral Oil Hydrocarbons (MOHs)

- More information on MOHs in food:
  https://food.ec.europa.eu/safety/chemical-safety/contaminants/catalogue_en

- Questions?
  veerle.vanheusden@ec.europa.eu

Closing remarks

- Further written comments to be sent to veerle.vanheusden@ec.europa.eu by **27 February 2024** info on for which commodities the proposed MLs and ILs cannot be achieved yet, supported by the following information/ data:
  - Reasons why the ML/IL cannot be achieved yet? Why is this the case for a part of the production, while the majority of the production complies?
  - What are the sources of the contamination?
  - Which mitigation measures are already/ will be implemented?
  - A proposed timeline for complying with the proposed MLs
  - Raw occurrence data on samples on which good practices were used:
    - Analytical concentration of each sample
    - The LOQ for each sample
    - Information on the applied mitigation measures for the concerned batch.
    - Sampling year