

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate E – Food and Feed Safety, Innovation E2 – Food processing technologies and novel foods

## Information document on the ongoing discussions in the EU on regulatory measures on mineral oil hydrocarbons in food.

- Mineral oil hydrocarbons (MOHs) are substances that may contaminate food in many ways: via harvesting or production processes (use of lubricants for machinery, drying processes, contact with exhaust fumes, processing aids, the use of anti-dusting agents, the use of nonstick agents, the use of hexane or mineral oils in extraction processes, etc...), the use of food or feed additives, migration from food contact materials (jute bags, recycled paper and cardboard, printing inks, waxes, etc...) or through environmental contamination.
- MOHs are distinguished between mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH).
- In 2023 EFSA updated its risk assessment on MOHs in food (<u>https://www.efsa.europa.eu/en/efsajournal/pub/8215</u>).
- MOSH accumulate in liver, spleen, adipose tissue. EFSA considers that, according to the present knowledge, the current exposure to MOSH does not raise concern for human health, for all age groups. However the consequences of long-term accumulation of MOSH for human health have not yet been investigated and thus remain uncertain.
- MOAH with 3 or more aromatic rings are associated with genotoxicity and carcinogenicity. EFSA concludes that, 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, concerns for human health cannot be excluded.
- In view of the several findings of MOAH in various foods and of the fact that the occurrence of MOAH in food is avoidable, the Member States agreed on a common enforcement approach for concentrations of MOAH above the limit of quantification; in June 2021 for formulae for infants and young children, and in April 2022 for all other foods (<u>https://food.ec.europa.eu/safety/chemical-safety/contaminants/catalogue\_en#MOH</u>).
- At the moment no EU limits are in place for MOSH in food, however certain Member States have established national benchmark levels and food business operators are recommended to monitor their production and to apply mitigation measures, where needed.
- The analyses for MOH in food are typically carried out by coupling liquid and gas chromatography with subsequent flame ionization detection (LC-GC-FID). However in cases where naturally occurring/ biogenic substances interfere with the analysis, a confirmatory analysis with two-dimensional gas chromatography (GCXGC) is needed to confirm the concentration of MOAH. The Joint Research Centre of the European Commission published a Guidance on sampling analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials (<u>https://op.europa.eu/en/publicationdetail/-/publication/97cb92c2-d29e-11ed-a05c-01aa75ed71a1</u>) (referred to hereafter as 'JRC Guidance').



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- When MOSH or MOAH are quantified in food, the food business operators should check all steps of the process, in order to identify the source(s) of the contamination and they should apply the necessary mitigation measures, to avoid further contamination of their production.
- Taking into account the 2023 updated EFSA risk assessment, discussions have been started with the EU Member States on the regulatory follow-up. It is the intention to establish in the EU legislation on contaminants in food maximum levels for MOAH. As an increase of the exposure to MOSH might also lead to health concerns, indicative levels for MOSH in food are under discussion. The indicative levels are values that, when exceeded, should trigger investigations towards the sources of the contamination and the application of mitigation measures.
- The adoption of the maximum levels and indicative levels is targeted fourth quarter of 2024/ first quarter of 2025.
- As the presence of MOAH in food is avoidable, food business operators are urged to already check their processes and ensure that the concentrations of MOSH and MOAH are below the limits of quantification, which are included in the JRC Guidance:
  - $\circ$  0.5 mg/kg for dry foods with a low fat/oil content (≤ 4% fat/oil)
  - $\circ$  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
- Further information on this topic can be found on: <u>https://food.ec.europa.eu/safety/chemical-safety/contaminants/catalogue\_en#MOH</u>