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WORKING DOCUMENT

Establishment of the maximum limit for MOAH in the food additive specifications

1 Background

1.1 Information on MOH, MOAH and MOSH

Mineral oil hydrocarbons (MOH) are a diverse group of chemical compounds mainly derived from petroleum distillation and refining.

They are divided into two main categories based on their chemical structure:

Mineral oil saturated hydrocarbons (**MOSH**)

Mineral oil aromatic hydrocarbons (**MOAH**)

Both groups contain a wide range of substances which cannot be isolated individually.

Mineral oil hydrocarbons can enter food in many ways - through environmental contamination, use of lubricants for machinery, release agents, processing aids, food or feed additives and migration from food contact materials.

The potential human health impact of MOH varies widely. MOSH, which are known to accumulate in the liver and lymphoid system, do not present a public health risk at current levels of dietary exposure. Certain components that can be present in the MOAH fraction are genotoxic substances that can damage DNA in cells and may cause cancer. For substances such as these, a safe level cannot be established (<https://www.efsa.europa.eu/en/infographics/mineral-oil-hydrocarbons-food>).

1.2 Statements of the Standing Committee

At the Standing Committee meeting of **21 April 2022** (see https://food.ec.europa.eu/system/files/2022-07/reg-com_toxic_20220421_sum.pdf) the follow-up to the 2021 Foodwatch report on Mineral Oil Hydrocarbons (MOHs) in food was discussed and a joint statement by the Member States on the presence of MOAH in food was drafted. The statement was prepared, in view of the toxicity of certain fractions of MOAH, as an interim measure pending the finalisation of the EFSA opinion (2023) on MOH and the establishment of Maximum Levels. The statement also refers to food additives, in particular to microcrystalline wax (E 905).

At the Standing Committee of **19 October 2022** further clarifications on the joint statement on MOAH was provided (https://food.ec.europa.eu/system/files/2022-11/reg-com_toxic_20221019_sum.pdf).

1.3 EFSA scientific opinion

On **13 September 2023**, EFSA published the opinion “Update of the risk assessment of mineral oil hydrocarbons in food” (<https://www.efsa.europa.eu/en/plain-language-summary/update-risk-assessment-mineral-oil-hydrocarbons-moh-food>; <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8215>) with the following findings:

- The present dietary exposure to MOSH does not raise concern for human health for all age classes.
- The margin for safe exposure to MOSH 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.
- 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.

2 Regulatory follow-up to the EFSA opinion

DG SANTE launched a discussion on the regulatory follow-up in the relevant sectors (i.e. contaminants, food additives and food contact materials).

2.1 Establishment of the maximum levels for MOAH in food

On 18 January 2024, DG SANTE organised the stakeholder forum on mineral oil hydrocarbons in food, where the intended follow-up in the contaminant legislation was presented. This included (1) the Draft Regulation on maximum levels (MLs) for MOAH in food, (2) Draft Recommendation on the monitoring of MOHs in food and (3) Draft Regulation on methods for the sampling and analysis of MOHs in food.

DG SANTE proposed the following maximum levels (MLs) for MOAH in food:

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	

The stakeholders were invited to comment for which foods according to the currently best available practices the proposed MLs cannot be achieved yet. The comments should be supported by the appropriate data.

DG SANTE informed that the discussion with Member States will continue in Q2/Q3 2024 with the intention to prepare a draft for vote before the end of 2024. In the meanwhile, the statement of the Standing Committee of 21 April 2022 remains valid.

For more information, see enclosed the presentation ‘1. DG SANTE presentation stakeholder forum MOHs.pdf’.

2.2 Establishment of the maximum limit for MOAH in the food additive specifications

The follow-up to the EFSA opinion as regards the food additive legislation was discussed with Member States at the meetings of the Working Group on Additives on 14-15 November 2023 and 23-24 January 2024. It was considered appropriate that the work follows the timelines and approach taken for the establishment of the MLs for MOAH in food. The preferred approach is the establishment of a general limit for MOAH for all food additives in Regulation (EU) No 231/2021 (to be noted: i.e. a similar approach to the establishment of the maximum limit for ethylene oxide by Regulation (EU) 2022/1396).

Therefore, it is proposed to establish **a maximum limit of 2.0 mg/kg for Mineral Oil Aromatic Hydrocarbons for all food additives.**

3 Targeted stakeholders' consultation on the establishment of the maximum limit for MOAH in food additive specifications

The stakeholders are invited to comment on the proposal to establish the limit of 2.0 mg/kg for MOAH for all food additives.

The comments should be supported by data on:

- Reasons why the proposed ML cannot be achieved?
- What are the sources of the contamination?
- Which mitigation measures are already/ will be implemented?
- A proposed timeline for complying with the proposed ML
- 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.

Comments shall be sent to jiri.sochor@ec.europa.eu and SANTE-E2-Additives@ec.europa.eu **by 15 March 2024 cob at the latest.**