Länderarbeitsgemeinschaft Verbraucherschutz (*Consumer Protection Consortium of the Federal States*) / Arbeitsgruppe Lebensmittel- und Bedarfsgegenstände, Wein und Kosmetika ALB (*Working group on foodstuffs and consumer goods, wine and cosmetics*)

Lebensmittelverband Deutschland e. V. (Food Federation Germany)



Benchmark levels for mineral oil hydrocarbons (MOH) in foods

The representatives of the food control authorities of the federal states and the Food Federation Germany (until June 2019 BLL e. V.) as the leading association of the German food sector recommend the use of "benchmark levels" for contents of mineral oil hydrocarbons and their structural analogues. These benchmark levels were developed within the framework of a joint project based on current data as from June 2016.

The objective is to provide the food sector, consumers, consumer protection organizations and goods testers as well as the food control authorities with guidance on the level to which contamination with mineral oil-like hydrocarbons - MOH) can be expected, while taking into consideration and monitoring and mastering the previously familiar routes of entry.

In their derivation, the benchmark levels expressly take no account of any aspects of toxicology or exposure because the current status of scientific literature as well as the possible bioaccumulation of certain MOSH fractions does not permit health-based levels to be derived for the entirety of the mineral oil-like hydrocarbons in time. The European Food Safety Authority (EFSA) therefore assessed the exposure of the European population to MOSH and updated its risk assessment using the Margin of Exposure (MOE) approach. The EFSA concluded in 2023 that the current exposure of the European population does not raise concern. This is mainly due to the minimization efforts of industry and national projects such as the "Mineral Oil Benchmark Levels Project" (EFSA Update of the risk assessment of mineral oil hydrocarbons in food, 2023).

As contemplated by the resolution of the 13th consumer protection minister conference (VSMK) 2017, the benchmark levels can represent the starting point for further efforts aimed at minimization. The 15th VSMK welcomed the results of the joint project "as an essential part of a national minimization strategy and supports its continuation in order to develop guidance values for further relevant food product groups" (April 2019).

Phase-related actions, such as those in the BLL Toolbox for example, are recommended for the avoidance of recognized, specific contamination sources by adapting the good and state-of-the-art manufacturing and packaging practices (GMP), which can then be implemented in the process chains. Due to the diversity of sources, ubiquitous environmental influences, the complexity and variety of the process chains but also the use of approved processing aids, it becomes apparent that, even if an optimized good manufacturing and packaging practice is observed, it is not possible to avoid contents of mineral oil-like hydrocarbons in all cases.

Parameters for the concept:

- Independence from source
- Consideration of current data based on generally accepted analytical procedures
- Entire range of fractions C₁₀ C₅₀
- No consideration of exposure and toxicity
- Statistical consideration of the situation within a product group
- No legal or health-related assessment

The benchmark levels were drawn up by a "Project Group" comprising relevant representatives of the federal states and industry experts involved, with the latter being coordinated by the Food Federation Germany (until June 2019 BLL e. V.). The data collection is constantly being expanded product-specifically. Meanwhile more than 16,000 individual data records were collected in anonymized form and evaluated.

As a result, "Common MOH benchmark levels" are recommended for initial food categories, which have been confirmed in parallel approval processes by committees and finally confirmed by VSMK. After the first publication in April 2019 of three product categories, further categories were added in June 2020.

The MOH guidance values will undergo a decisive further development in August 2021 by extending the recommendations to include four new product categories. Important food groups of animal origin (meat, fish, milk) are now also described. The derivation based on the statistical principles of the project required special efforts in these areas as well as knowledge of good manufacturing practice.

From the point of view of the project group, the following information and notes are important (September 2023):

- The benchmark levels were derived in accordance with statistical principles based on the 90th percentile of current data on product groups for which it had already been possible to achieve and demonstrate a successful reduction of the contamination with MOH in the past. The benchmark levels based on the 90th percentile generally represent not less than achievable levels within the context of good manufacturing practice (GMP).
- The "MOSH levels" refer to the entirety of the analysable mineral oil-like hydrocarbons in a product (MOSH including the MOSH analogues such as POSH or MORE [=mineral oil refinery products]) irrespective of the sources of contamination, e.g. packaging materials or technical processing aids.
- With reference to MOAH, the maximum limits of quantification, LOQ_{max}, as described in the JRC report (2023)¹ are considered as "benchmark levels" with reference to the overall fraction C₁₀ C₅₀.: These are in line with the recommendations of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) of the European Commission on MOAH in food (see SCoPAFF Statement of April 21, 2022, October 19, 2022 and September 22, 2023).
- The data basis goes back to 2016 and, depending on the data source, consists of integrated (total hump) and summed values of the individual fractions for MOSH and MOAH. According to current developments at JRC, new data from the integration of the hump in the C_{10} to C_{50} range are exclusively taken into account.
- For the analytical verification of compliance with the guidance values, the Technical Report published by the European Reference Laboratory JRC (Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials, (2nd Edition, 2023) and other product-specific guidelines of the JRC) serves as a methodological reference.
- A future project objective is to provide benchmark levels for additional product groups as well. The project group is continuously working on the collecting, compiling and evaluation of further data records.

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MOH BENCHMARK LEVELS

LAV and Food Federation Germany jointly recommend the use of "benchmark levels" for the occurrence, regardless of source, of mineral oil hydrocarbons and their analogues (MOH as the sum of MOSH (including MOSH analogues) and MOAH) in foodstuffs as uniformly applicable, approved principles for assessment.

The "benchmark levels" are statistically derived and are based on plausible, comparable data collected by the German Food Association and the Federal States as part of a joint project from June 2016. The data was collected according to agreed specifications for analysis and recording, independent of the potential sources of entry. The "benchmark levels" have been derived from the extensive data pool with a sufficient data basis for certain food groups in a pragmatic statistical process (generally based on the 90th percentile of a distribution). The benchmark levels derived in this way are not based on toxicological or exposure assessments and do not represent a criterion for demonstration of conformity with food legislation. They reproduce the current state-of-the-art, taking into account the various routes of entry for mineral oil hydrocarbons and their analogues (cf. BLL Toolbox Concept, December 2017).

Consequently, the levels are recommendations and give guidance for practical use. By definition they are not to be interpreted or used as threshold limit levels. The levels apply to end consumer products and products on the market and represent the state-of-the-art for good agricultural, manufacturing and packaging practice for the respective process chains at the current point in time.

Examination of adherence to the benchmark levels uses in particular the current guideline¹ of the European Reference Laboratory which serves as a methodological framework and also includes the minimum limits of quantification (LOQ_{max}) to be achieved, the general analytical conditions and the notes on further characterization for difficult samples and matrices using additional analytical methods, such as GC-MS, LC-GC-FID/MS or GCxGC-FID/MS, the need for which, however, has to be determined in each individual case. In addition, the JRC guidelines on mineral oils in infant formula^{2, 3}, in muesli⁴ and in fats and oils⁵ must be observed.

DEFINITION "MOH Benchmark Levels"

"The levels provide guidance on the content, regardless of source, of mineral oil-like hydrocarbons (MOH as the sum of MOSH and MOSH analogues (such as POSH, PAO, MORE) and as MOAH) in foodstuffs of a specific group that can be expected with high statistical probability as the result of a good technical manufacturing practice at the various process stages and due to ubiquitous influences.

If benchmark levels are exceeded, this may indicate possible sources of contamination along a supply chain, which may be avoidable by adopting good practice within the manufacturing and packaging process and may also provide a reason to instigate research into the causes. Further assessment of a product must take into account:

- the composition, type and duration of the packaging and shelf-life,
- information on the raw material situation, on processing methods and food contact materials at all stages as well as
- the intended purpose and the usual quantities consumed."

¹ JRC Technical Report: Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials, 2019, ISBN 978-92-76-00172-0; LINK

² JRC Technical Report: Mineral oil in infant formulas - guidelines for integrating chromatograms, 2022, ISBN 978-92-76-53278-1; LINK

³ JRC Technical Report: Determination of MOAH in infant formula, 2023, ISBN 978-92-68-01815-6; LINK

⁴ JRC Technical Report: Determination of MOSH and MOAH in muesli and paperboard, 2021, ISBN 978-92-76-40589-4; LINK

⁵ JRC Technical Report: Determination of MOSH and MOAH in edible oil, 2023, ISBN 978-92-68-02137-8; LINK

LAV and Lebensmittelverband: Common MOH-Benchmark levels (Last update: September 2022)				
No.	Product group Food category (consumer products) ⁶	MOSH and analogues [mg/kg] C ₁₀ -C ₅₀	MOAH [mg/kg] C ₁₀₋ C ₅₀	Notes on the application Notes on the food groups covered/on products not covered and delimitations/on justifications or other special features (see footnotes, if applicable) MOH orientation values are always to be applied in conjunction with the definition described.
1	Vegetable oils and fats (such as rapeseed oil, sunflower oil, soya oil, linseed oil, olive oil and margarines) (excluding oils/fats of tropical plants)	13	n.q. ⁷	not for use with oils/fats obtained from tropical plants (e.g. coconut oil) ⁸
2	Bread and biscuits, fine pastries, cereal products and cereal-based products, cereals, rice, pasta	6	n.q. ⁹	not to raw commodities or raw doughs
3	Confectionery (sugar confectionery except chewing gum), chocolate and cocoa-based confectionery	9	n.q. ^{7/9}	
4	Nuts, Shell fruits, oilseeds, coconut, peanuts and dried fruit, including mixtures thereof	4	n.q. ^{7/9}	
5а	Desserts (ready-to-eat) and ice cream (except category 5b)	4	n.q. ^{7/9}	
5b	Ice cream with fat-based coatings, glazes and couvertures (whether or not in pieces on / in ice cream, on / in wafers)	10	n.q. ^{7/9}	
6	Meat, meat preparations and meat products (including sausages)	9	n.q. ^{7/9}	not for firm raw sausages with cheese, with cheese or pepper coatings; not for meat preparations in oil-based marinades
7	Fish and fish products (including canned fish in aqueous infusion/own juice)	4	n.q. ^{7/9}	not for canned fish and fish products in oil or oil-based sauces and dips; not for crustaceans and molluscs and products thereof
8	Milk and milk products (such as cream, butter, yoghurt, cheese) including preparations thereof	22 mg/kg milk fat	n.q. ^{7/9}	assessment is made in all milk products and preparations in relation to the milk fat content ¹⁰ ; not for mixed spreadable fat products
9a	Vegan and vegetarian savory spreads, toppings, cold cuts and similar products (meat, fish and sausage substitutes)	5	n.q. ^{7/9}	not for plant based alternatives for milk, cheese and dairy
9b	Vegan and vegetarian pan products with leanings towards products of animal origin, such as ground meat and ground meat products, burger patties, breaded products	11	n.q. ^{7/9}	expected total MOALI hump (C C.)

n.q. - not quantifiable, i.e. contents < limit of quantification (here: LOQ_{max} in mg/kg as integrated total MOAH hump (C_{10} - C_{50}) in accordance with the JRC Guidance on sampling, analysis and data reporting for monitoring of mineral oil hydrocarbons in food and food contact materials, 2^{nd} Edition, valid as of 2023) and product specific JRC reports

⁶ If there are guiding principles for the respective product categories in the German Food Codex (Leitsätze des Deutschen Lebensmittelbuchs), the guiding principles form the basis for the designations and properties.

⁷ LOQ_{max} for total MOAH hump (cf. JRC Technical Report¹) for fats/oils is equivalent to 2 mg/kg

⁸ Deferred due to insufficient data

⁹ LOQ_{max} for total MOAH hump (cf. JRC Technical Report¹) for low-fat foods < 4% fat is equivalent to 0.5 mg/kg; > 4% fat is equivalent to 1 mg/kg

¹⁰ Based on the type and scope of the stage control carried out by Institut Kirchhoff Berlin on behalf of the Milchindustrie-Verband in 2017, a linear concentration from the raw milk can be assumed with a high degree of probability. No process-related contamination was detected in the samples tested.