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Press Release and Statement by Papiertechnische Stiftung (PTS)

Mineral oil hydrocarbons in foodstuffs - contaminant legislation as useful regulatory approach to prevent contaminations

National mineral oil regulation became redundant by SC PAFF

The Standing Committee on Plants, Animals, Food and Feed (SC PAFF) of the European Commission has published maximum concentration levels for aromatic hydrocarbons (MOAH) in food for an EU-wide harmonized assessment of these food contaminants at the end of April 2022. This means that the regulation of MOAH as contaminants is de facto set. The regulation of MOAH from fcm paper containing recovered paper within a national mineral oil regulation, which is questionable in parts anyway, is now outdated and became redundant.

Background

Food must be safe. It must neither be injurious to health nor unfit for human consumption (Regulation 178/2002). A food is unfit for human consumption if, among other things, it has become unacceptable for human consumption for reasons of contamination.

Contaminant means any substance not intentionally added to food. It can be present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination (Regulation 315/93). By this enumeration the legislator already states:

Contaminants in food can have many and very complex causes. Packaging is only one possible cause among many.

Food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market. Furthermore, contaminant levels shall be kept as low as can reasonably be achieved by following good practices.

One group of contaminants that has been discussed for years are **mineral oil hydrocarbons** - often differentiated into saturated (Mineral Oil Saturated Hydrocarbons, **MOSH**) and aromatic (Mineral Oil Aromatic Hydrocarbons, **MOAH**). They can cause undesirable contamination of food and have many possible causes.

Monitoring of competent authorities to clarify the situation

The **EU Commission** had already stated in 2017 in its **Recommendation (EU) 2017/84** on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food, whereas "*mineral oil hydrocarbons can be present in food through environmental contamination, lubricants for machinery used during harvesting and food production, processing aids, food additives and food contact materials*".

Member States with the active involvement of food business operators as well as other interested parties such as NGOs, responded to the request to monitor these contaminants in food.

Many different product groups should be covered. The EU monitoring is now completed; the results will be considered during EFSA's evaluation and may lead to management action by the European Commission.

The **German Monitoring** also concluded in **2019** that only 2 out of 53 packaged foods had MOSH or MOAH detected above the proposed limits for migration from food contact materials made of paper, board or recovered paper, respectively. However, the comparison of the MOSH / MOAH distribution patterns of these 2 food samples showed that *the mineral oil input was less due to the packaging materials, but had other causes*. These other causes should also be regulated from a consumer protection point of view. In particular, vegetable edible oils and fats (including palm oil, coconut oil/fat) as frequent food ingredients should not be disregarded, according to the **2020 monitoring results**.

Sources and benchmark levels for mineral oil hydrocarbons - many tasks have been done

In cooperation between 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) and the Lebensmittelverband Deutschland e. V. (Food Federation Germany), benchmark levels for MOSH and MOAH have been derived since 2016 from more than 13,500 individual data for various product groups. The [data collection](#) is constantly being expanded. The data originate from monitoring by the companies as well as from investigations by the official food and feed safety surveillance and are comparable to a national monitoring in terms of significance. The benchmark levels based on the 90th percentile generally represent not less than achievable levels within the context of good manufacturing practice (GMP). With reference to MOAH, the maximum limits of quantification, LOQ_{max}, described in the [JRC Report](#) are considered as benchmark levels, (but) with reference to the overall fraction C₁₀ – C₅₀ (depending on the fat content of the matrix 0.5 mg/kg or 2 mg/kg, respectively).

In the spirit of the Contaminants Regulation 315/93, **levels have already been agreed upon between industry and competent authorities, as can reasonably be achieved by following good practices**. However, the levels are **recommendations and give guidance for practical use**. By definition they are not to be interpreted or used as threshold limit levels, as stated by the authors.

Legal certainty for food companies is given in case of compliance - at least on a German national level.

With the help of a [toolbox](#) published by Lebensmittelverband Deutschland e.V. (Food Federation Germany) in 2017 for preventing the transfer of undesired mineral oil hydrocarbons MOSH and MOAH into food, weak points in food production and processing can be identified systematically and on a company-specific basis - also considering food contact materials (FCM) as one of many possible entry pathways.

In **food investigations**, most recently initiated again by [Foodwatch](#) (December 2021), in Germany, France, the Netherlands, Austria and Belgium, products were also conspicuous due to their mineral oil residues. Some were offered at the point of sale in glass or plastic direct packaging - the entry paths of the contamination were thus again diverse and, as already in [the Foodwatch campaign on MOSH and MOAH in baby food](#) in metal cans in 2019, not to be

sought in the direct packaging of the final product. Foodwatch also demands to “(..) *establish immediately corresponding requirements for MOAH in the EU contaminants legislation for all food categories and not to allow any exceptions* (..).”

The argument that the **mineral oil analysis of foodstuffs** would lead to non-comparable and not legally reliable results can also be negated after years of Europe-wide development work, countless interlaboratory tests and today's expertise. Last but not least, the [JRC Guidelines on „Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials“](#) published in 2019 created the basis on European Level. The limits of determination or detection in foodstuffs are matrix- and especially fat content-dependent, but are in principle sufficiently sensitive and reliable. Unacceptable contamination of the food can be reliably detected.

Thus, uniform control of undesirable mineral oil contaminants in foodstuffs should now be possible throughout Europe. The functioning of the European internal market could also be ensured in this way.

The EU Standing Committee on Plants, Animals, Food and Feed (SC PAFF) shows: agreement at EU level was already done.

The Standing Committee on Plants, Animals, Food and Feed (**PAFF Committee**) plays a key role in ensuring that Union measures on food and feed safety, animal health and welfare as well as plant health are practical and effective.

It already commented in 2021 on the assessment of MOAH findings in infant formula. Recently, this opinion was updated as follows and the scope was broadened, as shown in the 21 April 2022 meeting [summary](#) (refer to SC PAFF [web page](#)):

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** - i.e. without consideration of fractions - in food are at or above the following maximum LOQs:

- 0.5 mg/kg for dry foods with a low fat/oil content ($\leq 4\%$ fat/oil)
- 1 mg/kg for foods with a higher fat/oil content ($> 4\%$ fat/oil)
- 2 mg/kg for fats/ oils

Furthermore, the Commission services requested the relevant competent authorities and food business operators to follow-up on the findings in certain foodstuffs which have been found to contain MOAH and to **perform investigations on the source of contamination**. Again, explicitly addressed are ingredients, food additives, food contact materials, lubricants and others. In addition, it is appropriate that Member States and food business operators perform controls on the presence of MOAH and take, if necessary, measures to prevent the occurrence of MOAH in food.

A de facto agreement on MOAH maximum levels in food in the EU has been achieved.

After the results of official monitoring, NGOs and industry cause analysis and years of effort to obtain scientific evidence, there can only be one answer:

It is necessary to fix the designated MOAH maximum levels within the contaminant legislation for setting maximum levels for certain contaminants in foodstuffs (Regulation No 1881/2006)

This regulatory approach was already favoured by experts at the beginning of the discussions - however, there was a lack of comparative benchmark levels in foodstuffs, among other things, according to which the possible contents in foodstuffs could be classified according to **good manufacturing practice**. With the finalization of the EU monitoring on mineral oil and the national benchmark levels, the European Commission should now have sufficient data to finalize this assessment and to set achievable levels.

A national German mineral oil regulation offers no added value for consumer protection

However, the German Bundesministerium für Ernährung und Landwirtschaft (BMEL) (Federal Ministry of Food and Agriculture (BMEL)) is currently continuing to vigorously pursue the [regulation](#) formulated in various versions since 2011 within the German Bedarfsgegenstände-Verordnung (BedGgstV) (German Consumer Goods Ordinance) - the so-called **German Mineral Oil Ordinance**. Here, only food contact materials with recovered paper content are addressed as a possible source for mineral oil transfer. Migration limits for MOAH C₁₆ to C₃₅ (not for higher molecular MOAH) with 0.5 mg/kg food and questionable limits for MOAH migration with 0.15 mg/kg simulant (usually poly(2,6-diphenyl-p-phenylene oxide / Tenax® - common practise is the specification of the migration as area reference per dm² and recalculation to mg/kg food in the given application) are named. These limits are supplemented by a mandatory requirement for the use of barriers against MOAH - not for other substances from the material.

The sole consideration of MOAH transfer via migration from recovered paper-FCM misses the goal of contaminant reduction in food. Other, perhaps the most important sources of contamination, are only addressed and recognized in a much lower priority.

A regulation within contaminant legislation also covered the potential source of transfer as addressed by the BMEL - the maximum concentrations of 0.5 mg/kg MOAH for dry foods communicated by SC PAFF regulates all MOAH sources. A national German regulation on mineral oil therefore offers no added value for consumer protection.

The national mineral oil regulation would also be difficult to enforce. Competent authorities can only check the mentioned migration limits if the unpacked foodstuff and any MOAH contamination already present are known prior to the packaging process. This surveillance cannot be ensured without elaborating on step-by-step consideration of the whole food supply chain and functions at best domestically, if at all. This would systematically discriminate against German products, since such a step-by-step based control by German competent authorities can only be implemented there.

Responsibility of the paper and packaging industry for environmental and consumer protection

Paper producers, paper and plastics converters, and the supplier industry show responsibility within the food value chain. Individual packaging solutions for the market were developed in research and development projects. The focus is on the selection of raw materials and additives, the packaging structure and the design of materials (e.g. adsorbents or barriers).

Various solutions show that **environmental protection and consumer protection** do not contradict each other. **Papiertechnische Stiftung (PTS)** provides support and consultancy with research and services on innovative packaging solutions for foodstuffs in order to ensure a design for safe, bio-based, recyclable products right from the development phase.

A regulation of maximum mineral oil levels via contaminant legislation ensures that foodstuffs are already considered safe before the packaging process - and remain safe and protected by sustainable, fiber-based packaging solutions.

About Papiertechnische Stiftung (PTS) | www.ptspaper.de

As an applied research and service institute based in Heidenau (near Dresden), Germany, we support the paper industry and companies in all sectors in the development and application of modern fiber-based solutions. We develop, optimize and test products and processes in the fields of paper production and converting, composite materials, finishing, packaging, corrugated board and smart services & products.

At AiF (Arbeitsgemeinschaft industrieller Forschungsvereinigungen "Otto von Guericke" e.V. <https://www.aif.de>), Zuse-Gemeinschaft (www.zuse-gemeinschaft.de) and Forschungsallianz DRESDEN-concept e.V. (dresden-concept.de) Papiertechnische Stiftung (PTS) is each a proud member and part of three networks dedicated to promoting applied research for small and medium-sized enterprises, with the aim of transferring findings from science into applicable technologies and setting the basis for innovation.



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