TEA & HERBAL INFUSIONS EUROPE

Formerly: European Tea Committee (ETC) and European Herbal Infusions Association (EHIA)

Hamburg, 17th January, 2024

THIE position on MOSH/MOAH

The position of the tea and herbal infusions industry regarding mineral oil hydrocarbons in tea and herbal and fruit infusion raw materials.

- Members of THIE take the concerns related to the presence of mineral oils in the food and drink supply chain very seriously and they have been investigating potential sources and approaches to mitigation at all stages of the supply chain.
- With regard to MOSH/MOAH analysis, there are major analytical problems for the product group tea (*Camellia sinensis*) and herbal and fruit infusion products, especially for the latter, LOQs of only 3-5 mg/kg can be achieved.
- In 2023, THIE participated in the stakeholder consultation of EFSA's Draft Scientific Opinion on the risk assessment of MOH in food and commented in detail on aspects relating to products represented by THIE.
- The grouping of lipophilic and lipophobic food matrices into the "coffee, cocoa, tea and infusions" group is surprising, especially in the case of MOSH/MOAH, as it does not allow a differentiated consideration of the exposure contribution despite completely different contents of MOSH/MOAH in the individual product groups. An unfavourable conclusion is the result.
- EFSA's CONTAM-Panel has stated that there is no analytical evidence for THIE's comments on the lack of transfer of MOH to the infusion.
- The National Associations, UKTIA (UK Tea & Infusions Association) and STEPI (Syndicat du Thé et de Plantes à Infusion), have each conducted an independent study to investigate the transfer of MOH in the infusion of tea and herbal and fruit infusion products.
- Result of both studies: **No transfer of MOH was observed into the brewed infusion.**

Sonninstrasse 28 · 20097 Hamburg · Germany · Tel.: +49 40 236016-21 · Fax: +49 40 236016-10/-11 · E-Mail: thie@wga-hh.de · http://www.thie-online.eu
Commerzbank AG · IBAN: DE67 2004 0000 0102 5881 00 · BIC: COBADEFFXXX

1. Background

Mineral oil hydrocarbons (MOH) generally consist of 10 to 50 carbon atoms. They can be divided into two main types, mineral oil saturated hydrocarbons (MOSH), which are long chain, partly branched hydrocarbons and mineral oil aromatic hydrocarbons (MOAH), which are aromatic hydrocarbons with 1-5 ring systems.

The existence of MOH in the food chain has been explored by EFSA and different national institutes for some years. At first, the transition from recycled paper was considered to be the main root cause for food contamination, but mineral oils proved to be ubiquitous in the environment and can be of man-made origin.

MOH are used either intentionally in production (food grade lubricants, rolling oils, wax and paraffin as technical additives, additives for plant protection agents etc.) or unintentionally in the production process (packaging material for raw materials from recycled paper, printing ink, cleaning products...). There are also natural sources of mineral oils (natural wax in fruit, biogenic wax, olefins in raw materials) or other known environmental contaminants (lubricants, exhaust emissions). As a consequence, MOH can be detected in agricultural produce, foodstuffs and other consumer goods.

2. Current situation

2.1. Legal situation

Currently, no legal maximum level exists for our product group. Some components of MOH are regulated according to the intended uses. Amongst these are:

- Materials in contact with food: Plastics (Regulation 10/2011)[1] and Rubbers (Order of 9/11/1994)[2]
- Foodstuffs: Additives (E 905): Regulation 231/2012[3]
- Pesticides (Regulation 1107/2009)[4]: for insecticides and acaricides

Within the EU a recommendation for European-wide monitoring of commodities was published in January 2017.[5] By means of this data collection a basis was to be created for the exposure and risk assessment which was carried out by the EFSA.

[1] Commission Regulation (EU) No 10/2011, on plastic materials and articles intended to come into contact with food, 14.01.2011; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010
[2] French decree, rubber materials and objects in contact with foodstuffs, products and beverages, 09.11.1994; https://www.legifrance.gouv.fr/loda/id/LEGITEXT000005617100
[3] Commission Regulation (EU) No 231/2012, laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council, 09.03.2012; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0231
[4] Commission Regulation (EU) No 1107/2009, concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, 21.10,2009; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107
[5] Commission 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, 16.01.2017; https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017H0084

There is currently a draft amendment to the German Commodities Ordinance (Bedarfsgegenständeverordnung)[6]. This German draft envisages to limit the transition (but not an already existing contamination) of MOAH to a foodstuff. In this case, a national regulation would restrict the single market in general and many different organisations have voiced their concerns on this draft. Although, the current draft (March 2017) does not include a limitation of MOSH.

In October 2022, the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) published a statement describing a harmonised approach for dealing with findings of MOAH in food.[7] The SCoPAFF defines the following analytical limit of quantification (LOQ) adapted to specific fat contents as guideline values:

1. Dry foods with a low-fat content (≤ 4% fat/oil): 0,5 mg/kg
2. Foods with a higher fat content (> 4% fat/oil, ≤ 50% fat/oil): 1 mg/kg
3. Fat/oil or foods with > 50% fat/oil: 2 mg/kg

Following the EU statement on MOAH in food and as a consequence of EU Recommendation 2017/84, the Dutch Food Safety Authority (NVWA) is planning to carry out more stringent monitoring of MOAH.[8] On September 21st, NVWA has published a temporary enforcement policy for MOAH. Starting from January 1st, 2024, NVWA will enforce the withdrawal from the market of all those products with MOAH levels exceeding the guideline values listed in EU statement on MOAH in food. On this regard, NVWA is currently conducting monitoring of MOAHs in food and solicits companies engaged in the food trade to do the same, to eventually report non-compliant products.

The Dutch measure will be based on 2022 MS Joint statement on MOAH in food. Products may be considered unsafe and thereby withdrawn from the market if their sum of MOAHs exceed the guidance value after having applied a 50 % uncertainty over the measurement. Nevertheless, due to the more difficult analysis, especially for herbal and fruit infusions, which is described in section 2.2, we do not consider the Dutch enforcement policy to be appropriate for our products.

2.2. Analytical situation

As part of the activities to reduce MOH/MOH-analogues, our sector continues to conduct root cause analyses to identify and reduce the very low traces of MOH/MOH-analogues in our product category. It is striking that these analyses show traces of MOH/MOH-analogues, at all steps in the supply chain, including manufacture. This raises the suspicion that the analytics may be distorted by matrix effects and that natural substances in the plant may cause false positives for some products. The LOQ in food of 0.5 mg/kg may hence be much higher in tea/infusions due to matrix effects. Some accredited labs have consequently raised their LOQ to 5 mg/kg for some herbal and fruit infusion (HFI) products.

[6] BMEL Draft for the 22nd change of the German Commodities Ordinance, 06.11.2020; https://www.bmel.de/SharedDocs/Downloads/DE/_Verbraucherschutz/Produktsicherheit/MineraloelVO_Entwurf.html
[7] SCoPAFF, 19.10.2022; https://food.ec.europa.eu/system/files/2022-11/reg-com_toxic_20221019_sum.pdf
[8] NVWA, 09/2023; https://www.nvwa.nl/onderwerpen/contaminanten-in-levensmiddelen/moah-in-levensmiddelen

The reliability of analytical methods is extremely important when detecting possible contamination of food products with MOH. Methods for MOH analysis have been published, however, there is still a high variability of results between laboratories due to several analytical challenges. As MOSH/MOAH analysis is not a single substance analysis as is usually the case, but a sum analysis, it is particularly important to distinguish between the MOSH/MOAH signal (hump) and other interfering signals, the so called MOH-analogues. In the absence of well-established or even existing identification and differentiation possibilities within the hump, the purification/processing of the sample extract and the subsequent interpretation of the chromatogram based on extensive experience are of particular importance. So far, there is only one standardised method for oils and fats. For tea, herbs and spices, in-house methods are used, the suitability of which may be questionable.

Furthermore, plant material can contain large amounts of unsaturated hydrocarbons, especially Squalene (a Triterpene). These can overload the gas chromatograms to such an extent that even the MOSH fractions can no longer be detected reliably. While attempts have been made to achieve very low -LOQ it should be kept in mind that, the lower the quantification limit is, the higher the level of uncertainty.

In summary, it can be said that the actual analysis still has a very high error probability (preparation, measuring, interpretation) at the present time. In addition, due to the complicated matrices of our products, a clear statement/identification of whether the analytical signals are really MOH is not possible with certainty. Furthermore, almost all tested materials from raw-material to processed materials showed traces of MOH/MOH-analogues and absence/ “negative” results are very rare. This supports the suggestion of the existence of background levels of MOH/MOH-analogues in food supply chains.

3. Toxicology

According to the EFSA (Scientific Opinion on Mineral Oil Hydrocarbons in Food, 2012)[9] and the German BfR (2023)[10] MOSH and MOAH have different toxicological potential. The long chained MOSH hydrocarbons may accumulate in certain organs and could potentially cause damage to those organs. The BfR has given guidance values for tolerable transition of MOSH hydrocarbons from paper.

In July 2017, the Dutch National Institute for Public Health and the Environment (RIVM)[11] reviewed new toxicological data and consumption data. It concluded that dietary exposure to MOSH does not pose a risk to Dutch consumers. This report suggested the focus of further studies should be on MOAH.

The transition of MOH into the infusion is unlikely due to the lipophilic character of MOH as stated in the RIVM report, section 4. Even assuming that the measured values observed in tea and herbal infusions (dry products) are correct (noting the potential for false positives), in combination with a comparably high dilution, there are no concerns regarding the marketability

[9] Scientific Opinion on Mineral Oil Hydrocarbons in Food. EFSA Journal 2012; https://doi.org/10.2903/j.efsa.2012.2704
[10] BfR- Questions and answers on mineral oil components in foodstuffs, 2023; https://www.bfr.bund.de/cm/343/fragen-und-antworten-zu-mineraloelbestandteilen-in-lebensmitteln.pdf
[11] Mineral oils in food; a review of toxicological data and an assessment of the dietary exposure in the Netherlands, RIVM Letter report 2017-0182;

or the safety of our products. The risk assessment of contaminants should always be based on the total intake of the contaminant and the actual exposure of the consumer. Since we were able to show with the transfer studies that no transfer of MOH into the consumed infusion can be observed, there is also no health risk for MOH for tea and HFI products.

3.1. EFSA's Scientific Opinion

In March 2023, EFSA launched a public consultation on its Draft Scientific Opinion on the risk assessment of MOH in food. From the point of view of the tea and herbal infusions industry, the EFSA's Draft Scientific Opinion contained a number of aspects that required a more critical and differentiated consideration with regard to their significance and impending consequences for tea and HFI. Therefore, THIE participated in the stakeholder consultation and addressed these aspects, which were also adopted and addressed by FoodDrinkEurope.

The key comments from THIE are listed below:

- The grouping of lipophilic and lipophobic food matrices into the "coffee, cocoa, tea and infusions" group is unsuitable, especially in the case of MOSH/MOAH, as it does not allow a differentiated consideration of the exposure contribution despite completely different contents of MOSH/MOAH in the individual product groups. An erroneous conclusion is the result.
- The number of samples for tea and herbal infusions considered by EFSA is very small and does not allow reliable conclusions to be drawn for these products.
- The application of a dilution factor in order to be able to conclude from the dry product to the ready to drink beverage is not acceptable from a scientific point of view due to the fact transfer of MOSH/MOAH into water hardly occurs.

EFSA published its final risk assessment on MOH in food in the EFSA-Journal on 12th September, 2023. The EFSA publication will be used as a basis for the Commission to set maximum levels. EFSA concludes that dietary exposure to MOSH, in contrast to MOAH, is classified as toxicologically safe (NOAEL: 236 mg/kg bw per day). MOAH with 3 or more aromatic rings represent a potential hazard according to toxicological data.

The comments submitted by the tea and herbal infusion industry were noted and commented on by the responsible CONTAM Panel. Unfortunately, only a few points were taken into account in the final risk assessment. One of the main criticisms of the CONTAM panel was the lack of analytical evidence to demonstrate there is no transfer of mineral oils into the infusion. Even the reference to the work of Schulz et. al (2014)[12], which analytically proved there is no transfer of PAHs into the infusion, was not considered a valid point of argumentation, despite the chemical similarity of MOH to PAHs. In order to obtain scientific evidence for the transfer behaviour/rates of MOH/MOH analogues from tea and HFI products into the infusion, two independent studies were conducted specifically on these product groups.

[12] C. M. Schulz, H. Fritz & A. Ruthenschrör, 25.09.2014; Occurence of 15+1 EU priority polycyclic aromatic hydrocarbons (PAH) in various types of tea (Camellia sinensis) and herbal infusions

4. Studies on the transfer of MOH to the infusion

UKTIA (UK Tea & Infusions Association) and STEPI (Syndicat du Thé et de Plantes à Infusion) have independently conducted different transfer studies of MOH in infusions of tea (*Camellia sinensis*) and herbal and fruit infusions. The two studies are summarised in detail below.

4.1. UKTIA study on the transfer of MOH to the infusion

Between 2019 and 2021, UKTIA conducted a two phased project to establish transition rates in teas and herbal infusions. Aim of phase 1 of the project was to determine typical levels of mineral oils in tea and fruit & herbal infusions at point of import into the UK. The purpose of this was to identify whether there are issues with mineral oil contamination within the supply chain.

In total 33 samples were tested (17 teas and 16 HFIs). Tea samples consisted of black, decaffeinated and green teas whereas HFI samples were derived from the following raw materials: Apple, Chamomile, Cinnamon, Fennel, Ginger, Hibiscus, Lemon balm, Lemon Peel, Lemon Grass, Liquorish root, nettle, Peppermint, Rooibos, Rosehip, Spearmint and a Blended herbal/fruit infusion.

The lab chosen for this project was asked to retain half of the samples for the phase 2 of the project, to determine the transfer level into the infusion. Samples were sent to the lab directly by the contributing members in the same type of aluminium foil bags purchased by UKTIA to ensure all samples were provided in the same packaging. Each sample was analysed in duplicate for MOH (MOSH / MOAH and their analogues).

Summary of results phase 1

At the time of this project, no legally binding limits existed for the assessment of mineral oil residues in food. Since then, guidance values have been proposed at the April 2022 SCoPAFF meeting, therefore the results of the UKTIA phase 1 project have been compared against the LOQ of 0.5 mg/kg for dry foods with a low fat/oil content (≤ 4% fat/oil).

Key messages from the results of phase 1 were:

- Most detections relate to MOAH levels. Considering MOSH and POSH (polyolefin oligomeric hydrocarbons) are analytically similar they cannot be separated.
- There was good agreement between repeated analysis.
- For Tea:
  - ➔ MOAH was detected in both green and black samples, with 41.2% (7/17) samples exceeding the level of 0.5 mg/kg. Range: 2.5 to 14 mg/kg.
  - ➔ Highest levels were found in samples from Argentina (1) and Vietnam (1)
  - ➔ Most positives were detected in samples that had been machine harvested or harvested using shears (where information had been provided). This observation is consistent with the fact that HFI products such as rooibos and liquorice are also machine harvested/cut and show comparatively higher MOH concentrations (see below).

- ➔ Pattern of fractions suggested “mineral oil of technical quality”, for example lubricating oil, as a possible source of contamination.

- For Herbals:
  - ➔ 1 sample exceeded 0.5 mg/kg. This was for liquorice root, detection at 1.4 mg/kg.
  - ➔ There were issues with high LOQ for Lemon balm & Chamomile, due to matrix interference. As a result, the LOQs were set at 3 and 5 respectively for these herbals.
  - ➔ In addition, testing lab was only able to quantify most of the herbal infusion samples to a limit of 1 or 2 mg/kg
  - ➔ Highest levels MOSH/POSH were found in rooibos.
  - ➔ Pattern of fractions suggest food grade white oils* as a possible source of contamination or the source was inconclusive.

*Examples where food grade white oils are used: to lubricate food-handling equipment, polish stainless steel surfaces, and to clean and maintain knives. Food grade white oils also have a food additive application as E905a.

In order to transfer the phase 1 results into a meaningful context and estimate consumer exposure from a cup of tea or herbal infusion, the following was calculated:

For Tea: assuming 3 g per serving, the consumer exposure is likely to be

- 42 µg/serving at maximum level and 16.5 µg/serving on average for MOAH
- And it would be 231 µg/serving at maximum level and 46.2 µg/serving on average for MOSH/POSH

For Herbals: assuming 3 g per serving, the consumer exposure is likely to be

- Less than 6 µg/serving (based on LOQ) for MOAH
- And it would be 81 µg/serving at maximum level and 28.9 µg/serving on average for MOSH/POSH

UKTIA conclusions for phase 1

- It is encouraging that no strong trends can be found within results and what has been found is likely to be of food grade material.
- Above estimates are likely to be the worst-case scenario as raw materials are usually sold as blends.
- These calculations would assume 100% transfer rate from raw material into the brew. This is unlikely to be the case in reality, and some compounds in tea would not be water soluble. Therefore, the above consumer exposure is likely to be significantly overestimated.
- According to EFSA 2013 Opinion the estimated MOSH and MOAH exposures from food is 30 to 300 µg/kg bw/day and ≥ 6 to 60 µg/kg bw/day respectively.
- A 2nd phase infusion/transfer study would be beneficial as a confirmatory project.

Phase 2

The aim of this phase was to confirm minimal/or no transfer of mineral oil contamination to the brew.

Method/Experimental plan:

- 6 samples, with the higher levels of detection of mineral oils from phase 1, were selected for phase 2. These products were Black Tea, Green Tea (each from Argentina and China), Spearmint, Ginger, and Lemongrass.
- A Matcha sample was included in addition to the above (i.e. as a 7th sample) to represent a tea where the leaf is directly consumed.

The lab proposed that the 2nd phase should be conducted as a 'mini-infusion' approach, rather than making a standard brew volume for each sample and then concentrating this, as it was suspected the mineral oils would be concentrated on the surface of the sample. Using a mini-brew approach would better enable the whole sample to be analysed. A wet leaf analysis was also suggested as this would support the evaluation of whether the mini-brew approach was appropriate.

In this test set up:

- 5 g of tea was brewed in 100 ml of boiling water for 5 min.
- Tea leaves were filtered and dried from Friday to Monday in a drying oven at 100 °C
- Both, the brew and the dried leaves were analysed for mineral oils.

A separate method was used for Matcha powder analysis as the complete mineral oil content would be consumed.

UKTIA conclusions from Phase 2

- There were no detectable levels of MOAH or MOSH/POSH in prepared tea or herbal infusions despite using 4x more concentrated ratio of tea/herbal infusion to water.
- In general, the level of MOAH and MOSH/POSH in the dried leaves after infusion is at a similar level to that of the respective raw material, taking into account variability between methods and the moisture content of the raw materials was not standardised before analysis.
- Where large differences do exist between the mineral oil level in the raw material versus the dried leaf portion, this may indicate non-homogenous distribution of MO on the leaf material.

4.2. STEPI study on the transfer of MOH to the infusion

Between 2022 and 2023, STEPI carried out a study to analyse MOAH rates in teas and herbal infusions.

The first step of the project was to determine levels of MOAH in teas and infusions purchased on the French market and to confirm minimal/or no transfer of mineral oil contamination to the brew. 10 pre-selected references were tested (Black Tea, Green Tea, Mint, Lemon verbena,

Chamomile, Matcha, Maté and Rooibos). According to the sample, products were sold in bulk and in bags.

For each reference, the lab used for this project studied:

- the raw product (as sold).
- the remaining preparation once the product has been infused.
- the infusion prepared according to the preparation conditions indicated on packaging for each product by the manufacturer.

Each analysis has been performed twice to ensure reproducibility of results given the analytical problems that still persist.

Thresholds have been proposed at the April 2022 SCoPAFF meeting; therefore, results were compared against the LOQ of 0.5 mg/kg for dry foods with a low fat/oil content (≤ 4% fat/oil).

Conclusions of the first step

- Variability of results obtained for the same sample
- Results on the raw product: disparity on MOAH contamination levels observed in the different products.
- Analytical problems identified for Chamomile (insufficient detection limit on raw product)
- No detection in the remaining preparation once the product has been infused and, in the prepared infusion.

STEPI has decided to carry out a new phase of analyses to clarify the initial results, and to understand the transfer of MOAH and verify they are found in the remaining preparation once the product has been infused. The samples selected were those for which the level of MOAH found in phase 1 was the highest (Black Tea from China, Spearmint from UE).

For each reference, the lab used for this project studied:

- The raw product (as sold).
- The remaining preparation dried after infusion.

Conclusion of the second step

- The MOAH level in the dried leaf after infusion is similar to that of the raw material.
- Considering the results obtained in the dried mixture, it is very unlikely that MOAH will transfer into the infusion, the product consumed by the consumer.

In conclusion, according to the study, in the products tested, similar contents were detected in the dried leaves or in the wet leaves after infusion and in the products tested. MOAH was not detected in the infusion ready to be consumed, after infusion, according to the preparation conditions recommended by manufacturers for consumers.

4.3. Comparison of the two studies

When comparing the studies conducted by UKTIA and STEPI, there are some similarities as well as several differences between the two studies. In terms of similarities both studies gained results obtained from the plant material samples as well as from the infusions; several different plant materials covering both teas and herbal/fruit infusions were included; there were two steps/phases in the respective studies to confirm if there are MOH transfer to the infusions and each analysis were performed twice to ensure reproducibility.

In terms of differences, one project used raw materials obtained from origins whilst the other used samples from the retail market; one project used the same sample batch/blend for both phases and one study gained results from highly concentrated infusions (i.e. 4x concentrated compared to the preparation instructions for consumers) whilst the other gained results from infusions prepared according to the preparation conditions suggested by manufacturers.

Regardless of the above, both studies led to the same conclusion. There are no detectable levels of MOH transferred into teas and herbal/fruit infusions. Furthermore, the studies showed clearly that certain plant materials (e.g. Chamomile) can cause matrix interferences which can significantly hamper the analysis and affect the detection limit.

5. Final statement of the tea and herbal infusions industry

Tea (*Camellia sinensis*) and herbal and fruit infusions are not consumed directly but only the infusion, which in turn is heavily diluted. The two studies referred to show conclusively that **no transfer of MOH into the infusion was observed** when tea and HFI products are infused. After brewing, tea and HFI do **not contribute to consumer exposure** from MOH/MOH-analogues and therefore **do not pose any risk to the consumer**.