concawe
ENVIRONMENTAL SCIENCE FOR THE EUROPEAN REFINING INDUSTRY

Vytenis Andriukaitis
Commissioner for Health and Food Safety
European Commission
Rue de la Loi 200
1049 Brussels

Your ref.:

Our ref.:

Brussels, 10 October, 2016

Concawe and EWF position on the ***4th version*** of the EU Commission Recommendation on ***the monitoring of mineral oil hydrocarbons in food and materials and articles intended to come into contact with food***

Concawe and EWF welcome the initiative of the EU Commission to monitor mineral hydrocarbons and materials and articles intended to come into contact with food.

This initiative is in line with our organisations' aim to ensure product safety and consumer protection.

Over the past years, Concawe and EWF have been actively involved in the "MOSH and MOAH" paradigm and gained significant insight about the complexity and confusion present in the public, supply chain and regulatory authorities around the topic of "mineral oil".

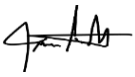
Due to the overlap of legislations that regulate the different uses given to petroleum products and considering their complexity in composition and toxicity, we wish to provide constructive comments on the EU Commission initiative on the monitoring of "mineral oil" in the food supply chain. Comments are intended to convey our learnings about this complex issue from a manufacturing point of view.

Our thoughts and arguments are presented as comments (in red and italics) to each the initiatives' paragraphs.

We again, welcome to the initiative and hope that our comments will be helpful in the interpretation of the collected data.

Yours sincerely,

On behalf of Concawe and EWF


Hans Ketelslegers
Science Executive, Health
Concawe

Juan Carlos Carrillo
Chair mineral oil & waxes task force
Concawe

Jan Woldhuis
Chairman
EWF

Boulevard du Souverain 165
B-1160 Brussels,
Belgium

T. +32.2.566.91.60
info@concawe.org
www.concawe.org

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COMMISSION RECOMMENDATION

of XXX

on the monitoring of mineral oil hydrocarbons in food and materials and articles intended to come into contact with food

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) Mineral oil hydrocarbons (MOH) comprise a diverse group of chemical compounds, derived mainly from crude oil but also produced synthetically from coal, natural gas and biomass. Food grade MOH products are treated in such a way that the content of mineral oil aromatic hydrocarbons (MOAH) is minimised. MOH can further be present in food through several sources: environmental contamination, lubricants for machinery used during harvesting and food production, processing aids, food additives and food packaging materials.

In the case of oils involved in food production and "food grade" MOH products, the strictest requirements for PAH are in place; the removal of these species is done to a level at which the refined product fulfils international legal specifications to consider it non-carcinogenic. Thus, refined petroleum products supported by Concawe and EWF which are used at different stages of food production, including food contact materials, are not carcinogenic[(1) (2)]! It should be pointed out that MOAH in itself is an unspecific term which may encompass all types of aromatics and will include predominantly highly alkylated 1-2 ring systems in the case of "food grade" products.

While it is true that refinement of mineral oil products diminish aromatic hydrocarbon levels, the refinement process is primarily designed to remove a specific family of aromatic substances (the 3-7 ring polycyclic aromatic compounds referred to as PAH; polycyclic aromatic hydrocarbons), which are the potentially carcinogenic species. The presence of MOAH in itself is not indicative of carcinogenic potential, toxicologists thus focus on PAH.

Unlike the 3-7 ring polycyclic aromatic compounds, which are known to be carcinogenic, highly alkylated 1-2 ring systems are not genotoxic and are not considered to be a concern for carcinogenicity. Hence, although these species are likely to contribute to the "MOAH" identified in MOH products, they, in and of themselves, do not pose a carcinogenic risk in the MOH products.

(1) Shubik P, Saffiotti U, Lijinsky W, Pietra G, Rappaport H, Toth B, Raha CR, Tomatis L, Feldman R, Ramahi H. (1962).Studies on the toxicity of petroleum waxes. Toxicology and Applied Pharmacology, 4, Supplement 1, 1-62

(2) Oser BL, Oser M, Carson S, Sternberg SS. (1965).Toxicologic studies of petrolatum in mice and rats. Toxicology and Applied Pharmacology, 7, 382-401

(2) The Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) concluded that the potential human health impact of groups of substances among the MOH vary widely. MOAH may act as genotoxic carcinogens, while some mineral oil saturated hydrocarbons (MOSH) can accumulate in human tissue and may cause adverse effects in the liver. As some MOAH are considered mutagenic and carcinogenic, it is important to organise monitoring of MOH to better understand the relative presence of MOSH and MOAH in food commodities that are major contributors to dietary exposure.

The MOSH and MOAH paradigm, is a generic terminology that is used to describe an analytical fraction and is an overall descriptor of hydrocarbons from variable petroleum, synthetic and in some cases even natural sources.

Because MOAH is catch all term, the best way to understand its relative presence in food and the risks associated with MOAH is to concentrate on those PAH carcinogenic species that are known to be present in less refined and contaminated mineral oils (e.g. used or poorly refined motor oils in jute bag batching). Industry is preparing a clear mapping of uses/sources which will allow evaluation of those sources which pose the risk for PAH, which is the "real" burden [(1)].

The concern about "accumulation" causing an adverse effect is linked to the "granuloma" observed in the liver of F344 rat. This effect is however unique to the F344 rat strain, because it is not observed in other rat strains, other animal species or even humans [(2)]. Therefore, the assumption that "some mineral oil saturated hydrocarbons (MOSH) can accumulate in human tissue and may cause adverse effects in the liver" is a direct extrapolation from the F344 rat findings, and is contrary to the opinion of human pathologists that clearly distinguish the F344 lesions from those observed in humans which do not result in the formation of granulomas, do not produce inflammation or other adverse effects and are considered incidental findings [(3)]. Although saturated hydrocarbons have long been observed in human tissues (saturated hydrocarbons have long been used as laxative agents), there are no direct reports indicating a specific health concern for these findings.

Following on the previous point, it is known that F344 rat also reacts adversely to n-alkanes, which is indicative that the F344 rat model is not adequate for risk assessment purposes. This is also supported by the fact that n-alkanes are not selectively retained in human livers [(4)]. N-alkanes are on the other hand ubiquitously retained in F344 rat livers.

Regarding focusing on MOSH presence in human; it is well known that hydrophilic substances like some hydrocarbons are preferably retained in tissues. The mere presence of hydrocarbons in the human body is in itself not indicative of "accumulation" a term that suggests that there is no reversibility or steady state and this presence has not been attributed to any clinical health outcome in humans. Furthermore, even if it were accumulation, that in itself is not a toxicological endpoint according to EFSA [(5)].

(1) CONCAWE 2014, MOCRINIS workshop September 2013. Report 2/14
(2) Fleming et al. 1998 (Regulatory Toxicology and Pharmacology, 27, 75-81); Smith et al., 1995(Drug Chem. Toxicol.; 18(1), 83-103
(3) Carlton et al. 2001 (Experimental and Toxicologic Pathology, 53, 247-255); Boinott et al. 1970 (Johns Hopkins Med J. 127(2):65-78; Dincsoy et al., 1982 (Am J Clin Pathol. 78(1):35-4; Wanless, 1985(Arch Pathol Lab Med. 109(3):283-6
(4) Barp et al., 2104(Food Chem Toxicol. 72:312-21)
(5) EFSA note for guidance food contact materials, Annex 4 to chapter 3.

(3) As migration from food packaging materials could contribute significantly to the total exposure, monitoring should include pre-packaged food, the packaging material and the presence of functional barriers. As migration is a continuous process, monitoring of pre-packaged food should focus on commodities that are closer to the date of minimum durability. Further possible sources of MOH arising from use of other food contact materials in the supply chain such as for storage, should also be investigated where relevant.

We support the initiative of monitoring in order to prioritize risk management measures. What we believe would be most efficient, is to first have a comprehensive mapping exercise of the food supply chain. This should also include imported raw materials, including foods that are subject for potential contamination by bulk transportation.

(4) To ensure reliability of the obtained analytical data, Member States should ensure the availability of suitable analytical equipment and gain sufficient experience in the analysis of MOH both in food and packaging material before submitting analytical results.

We support the development of a standardized analytical method that will be broadly applicable across industry, regulatory bodies and interested 3rd parties. Also, the disparity in types of matrices to be analysed may necessitate the need to consider including some flexibility to the established process of extracting MOSH or MOAH from various matrices; in other words, the applicability domain of the methodology should be evaluated according to the stage of the supply chain. The proposed monitoring should be supported by robust method validation and subsequent proficiency testing by involved laboratories.

(5) To ensure the uniform application of this recommendation, the European Union Reference Laboratory on Food Contact Material has made further guidance available to the Competent Authorities and other interested parties, which includes guidance on information that could be collected during investigations in the scope of this recommendation, sampling methods and analytical methods.

Guidance in this area is most welcomed.

HAS ADOPTED THIS RECOMMENDATION:

1. Member States should, with the active involvement of food business operators, manufacturers and distributers of food contact materials and other interested parties, perform monitoring of the presence of mineral oil hydrocarbons in food during 2017 and 2018. The monitoring should cover animal fat, bread and rolls (including fine bakery ware), breakfast cereals, confectionery (including chocolate and cocoa), fish meat, fish products (canned fish), grains for human consumption, ices and desserts, oilseeds, pasta, products derived from cereals, pulses, sausages, tree nuts, vegetable oils, as well as food contact packaging materials used for these products.

   Concawe mineral oil & waxes task force welcomes the opportunity to contribute to this exercise by undertaking an exposure mapping project that would investigate the potential sources of the hydrocarbons that are related to our industry. The scope of this project is to update the exposure assessment data base that was used by EFSA in the 2012 CONTAM report and thus, have more accurate assumptions about the exposure sources. Concawe invites downstream users to contribute to this exercise by providing input into the supply chain mapping and quantification.

2. Food sampling should be performed in accordance with the provisions laid down in Commission Regulation (EC) No 333/2007. Sampling should include a proportionate number of pre-packaged food commodities. Sampling of food contact materials should

follow best practices appropriate for the specific materials or articles as explained in the guidance document published on the website of the European Union Reference Laboratory for Food Contact Materials.

3. Where MOHs are detected, Member States should carry out further investigations in the establishments of the food business operators and manufacturers and distributers of food contact materials with a view of determining the possible source. Where MOHs are detected in food, the investigations should cover the systems operated by the food business operator that could affect or control contamination (e.g. production and processing methods, Hazard Analysis and Critical Control Points (HACCP) or similar system, measures implemented to prevent such presence).Where MOHs are detected in food contact materials, these investigations should cover the packaging material (e.g. type and composition of the packaging material, shelf life of the packaged food) and the systems operated by the manufacturers and distributers of food contact materials (e.g. production and processing methods of packaging material, measures to prevent such presence) as indicated in the relevant guidance.

We support the proposal of trying to trace back sources of MOH in food to ensure that only food contact approved materials are used. It is important however, to recognize that when a food sample is analysed, the levels of hydrocarbons detected is a summation of all the sources contributing to that particular hydrocarbon profile from food sample. Therefore it is difficult, if not impossible, to distinguish between intentional and non-intentional uses. What we propose is that the tracing back to potential sources of hydrocarbon detected in foods is done step by step considering each stage of the supply chain.

Extrapolation of results from one type of food has a limited value even if the MOH profile and supply chain is of a similar nature. In other words, the same hydrocarbon profile in a sample may be the result of totally different hydrocarbon containing products and articles and production lines.

Unequivocally pin-pointing to a particular source solely based on a MOH profile will almost certainly oversimplify the complex issues in the supply chain. Hydrocarbons detected in food samples do not necessarily have the same profile as the hydrocarbon containing product that are placed on the market for different uses and applications. Factors that affect changes of an analytical profile include but are not limited to: selective migration, evaporation and fractionation through processing and storage of both food and packaging materials.

For the assessment of MOAH within the food production chain there are "open" and "closed" systems. The latter are those processing steps where the uses of petroleum products is intentional and controlled where incidental contaminations can be traced back allowing to hazard characterize the types of MOAH found. In an open system, such as in harvesting, the origin of MOAH may not always be traced back to a single source such that the type of MOAH may indeed contain hazardous PAH from unknown origin, but detected MOAH may not even be mineral oil related as several substances like carbon black and resins may contribute to the overall MOAH level. MOAH methodology can't distinguish between MOAH from open or closed systems, thus systematic mapping is of pivotal importance to interpret results.

4. The samples should be analysed as marketed. The analysis should preferentially be performed following guidance of the European Union Reference Laboratory for Food Contact Materials. For pre-packaged food, the level of mineral oil hydrocarbons should be determined both in the food and in the food packaging materials.
Particular attention should be paid to the analysis of MOSH and MOAH in foods and food contact materials and to the interpretation of the analytical results to ensure that the generated data are reliable and comparable. Member States which intend to analyse the presence of MOSH and MOAH in foods and food contact materials may

request, if appropriate and needed, the technical assistance of the European Union Reference Laboratory for Food Contact Materials.

We support the idea of a step-wise approach as indicated in this paragraph and we've stated before.

The development of a method based on the analysis of MOAH by extraction should refocus on a DMSO extraction step; because it is well know that the potentially carcinogenic PAH/PAC species can be selectively extracted by this solvent. All industry standards, including biological tests that measure mutagenic activity, do include a DMSO extraction step.

To conclude on the presence of MOAH without a validation via MS may lead to false conclusions about the structure of these species.

5. To ensure uniform application of this recommendation and generate reliable and comparable results, the guidance developed by of the European Union Reference Laboratory for Food Contact Materials should be followed.

6. Member States, food business operators, manufacturers and distributers of food contact materials and other interested parties should provide to EFSA the monitoring data expressed on whole weight basis with the information and in the electronic reporting format as set out by EFSA for compilation into one database. Monitoring data should preferably be provided by 1 October 2017 and subsequently by 1 October 2018. The last results should be provided by 28 February 2019. Available occurrence data from preceding years that have not yet been provided should be transmitted according to the same modalities at the earliest opportunity.

Concawe's exposure mapping exercise is expected to be finished by Q2 of 2017. Furthermore, a MOCRINIS 2 is planned for the same timeline which will allow communication of our results to stakeholders.

Done at Brussels,

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

[1] EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Mineral Oil Hydrocarbons in Food. EFSA Journal 2012;10(6):2704. [185 pp.] doi:10.2903/j.efsa.2012.2704.