

FRENCH REPUBLIC

Concawe comments on the French national restriction “Order specifying the substances contained in mineral oils prohibited for use on packaging and for printed matter distributed to the public” (2022/0004/F - S00E)

6th April 2022

Concawe welcomes the possibility to provide comments on Notification 2022/0004/F introduced by France on the TRIS database.

1. General comment

We would like to point out that as a national restriction this order would create a de-facto non-trade barrier to the common EU market. It is our position that when general measures to protect the European consumers and environment are implemented, these should be taken at the European Community level rather than by individual Member States. Furthermore, from our perspective, the proposed order would be conflicting harmonized EU Regulations already intended to protect human health on the Community level, such as the REACH regulation (EC) No 1907/2006 and the framework regulation (EC) No 1935/2004 on food contact materials.

That being said, we would like to take the liberty to share a number of specific comments to the detailed approach and detailed wording in the draft accompanying this notification:

2. Specific comments

- a. **Subject:** “Substances affected by the ban on the use of mineral oil on packaging and printing matter distributed to the public”

We believe that this statement can be based on applying chemically incorrect wording. The mineral oils used in printing inks are UVCBs and registered as such in line with the requirements of the EU REACH regulation. As will be repeated later when discussing the wording of Article 2, the MOSH and MOAH chemical identities defined in this Article are not substances in the sense of REACH. Essentially, they are analytical fractions containing up to thousands of chemical structures that are not and cannot analytically be identified on a substance level. Our suggestion for a correct wording would be:
Subject: “The analytical fraction of printing inks prohibited by the ban on the use of mineral oil on packaging and printing matter distributed to the public”

- b. **Notice:** “...to mineral oils containing substances that disrupt the recycling of waste or limit the use of recycled materials because of the risks they pose to human health. This Order specifies the substances thus concerned on the basis of the opinion of the ANSES of 8 March 2017”

Both Codes referred to in this section refer to two issues that are claimed to be connected with mineral oil:

- 1) Disruption of recycling of waste
- 2) Limit the use of recycled materials because of the risk they pose to human health.

In our view, both reasons are factually incorrect:

1) To the best of our knowledge, there are no publicly available reports that would suggest that mineral oil would disrupt the recycling of waste in different ways than for instance a similar product/article containing vegetable oils or resins.

2) With respect the risk posed by mineral oils to human health, this risk is well studied and found to be very limited. In fact, as the quote below shows, the most recent scientific review article from 2019 by independent researchers concludes that the potential for health risks when exposed to MOSH and MOAH originating from mineral oil are very low:

“... indicates a low risk for adverse hepatic lesions that may arise from the retention of MOSH in the liver. With respect to MOAH, at present there is no indication of any carcinogenic effects in animals dermally or orally exposed to highly refined mineral oils and waxes. Such products are used not only in cosmetics but also in medicinal products and as additives in food contact materials. The safety of these mineral oil-containing products is thus indirectly documented by their prevalent and long-term use, with a simultaneous lack of clinical and epidemiological evidence for adverse health effects.”

Reference: Pirow R, Blume A, Hellwig N, Herzler, M, Huhse B, Hutzler C, Pfaff K, Thierse H-J, Tewes T, Vieth B and Luch A 2019: Mineral oil in food, cosmetic products, and in products regulated by other legislations. Crit Rev Toxicol. 49(9):742-789.

- c. **Introduction**, reference to “the opinion of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) of 8 March 2017”
We believe that it would be scientifically preferable to include the most recent peer reviewed data, such as the reference above (Pirow et al., 2019), when drafting legislation.
- d. **Article 2:** Regarding the descriptions and definitions used, we have several remarks and suggestions for possible improvements. They are listed below by referring in italic font to the pertinent sentences or sections of the proposed Order.
- i. “For the purposes of Articles D. 543-45-1 and D. 543-213 of the Environmental Code, the substances concerned by the ban on the use of mineral oils are:”
As pointed out earlier, the use of the word “substances” can be considered to be imprecise in the current context. Better would be:
“For the purposes of Articles D. 543-45-1 and D. 543-213 of the Environmental Code, the analytical fractions concerned by the ban on the use of mineral oils are:”

- ii. *The definitions of*
 “(1) Mineral oil aromatic hydrocarbons (MOAH) consisting of 1 to 7 aromatic cycles;
 (2) Mineral oil saturated hydrocarbons (MOSH) consisting of 16 to 35 carbon atoms.”
 Our proposal would be to rephrase these definitions as indicated below:
 (1) Mineral oil aromatic hydrocarbons (MOAH) consisting of 1 to 7 aromatic rings;
 (2) Mineral oil saturated hydrocarbons (MOSH) consisting of hydrocarbon chains of 16 to 35 carbon atoms”
- iii. *“The ban on the use of mineral oils applies to”*
 To bring this sentence in line with a consequent chemical nomenclature we would suggest adding “to printing inks containing” so that it becomes:
 “The ban on the use of mineral oils applies to printing inks containing.”
- iv. the next two paragraphs where limits for MOAH and MOSH are defined:

We note that no analytical method with which to compare whether actual samples exceed the proposed limits has been specified. The only point of reference might be the guidance published in 2019 by the Joint Research Center. It is very questionable whether this method will succeed in reaching the required sensitivity to establish compliance with the 1 part per billion (ppb) established for MOAH. In general, without a clearly established and validated analytical method, systematic enforcement activities will be difficult if not impossible to organize. And this will doubtlessly lead to significant legal uncertainty for virtually all actors in the supply chain.

We also propose that for consistency reasons, some of the inaccurate chemical nomenclature should be changed in line with the suggestions made earlier in the section covering the definitions of MOAH and MOSH.

3. Scientific comments

Over the last 10 years, CONCAWE has significantly invested in the better scientific understanding and stakeholder communication on the MOSH MOAH topic.

Below we list a number links to relevant information on the CONCAWE website:

<https://www.concawe.eu/wp-content/uploads/2018/06/Mocrinis-II.pdf>

<https://www.concawe.eu/event/mocrinis-ii-workshop/>

The latest status of the scientific understanding regarding the MOSH and MOAH terminology and the limitations of its relevance in understanding the safety of mineral oils is the subject of two papers that are currently going through the process of publication in peer reviewed journals:

- 1) Isola AL, Carrillo JC, Lemaire P, Niemelä H, Steneholm A 2022 Lack of adversity of MOSH retained in tissues: Analysis of adversity and implications for regulatory assessment. Manuscript (submitted for publication).

This paper thoroughly assesses the consequences of the tissue retention of a diffuse fraction of mostly highly branched and alkylated cycloalkanes. An adversity framework is was utilized to support an in-depth weight of evidence analysis. The key conclusion of this analysis is that the mere presence of “MOSH” in human tissues does not translate into identification of specific hazards and hence should not be considered adverse.

- 2) Carrillo JC, Kamelia L, Romanuka J, Kral O, Isola A, Niemelä H and Steneholm A 2021 Comparison of PAC and MOAH for understanding the carcinogenic and developmental toxicity potential of mineral oils. Manuscript (submitted for publication).

This paper advocates that the term “MOAH” is far too broad to be a determinant of toxicity of mineral oils. From all the aromatic constituents covered by this concept, from the highly alkylated 1 to 7 membered aromatic ring systems to naked or little alkylated 5 to 7 membered ring constituents with a characteristic “bay or fjord region”, the latter correlate with a toxicological concern. Therefore, an indiscriminate regulatory focus on a “MOAH” or aromatic content alone to establish the safety of mineral oil and petroleum compounds intentionally used in consumer products, will lead to the unnecessary ban of perfectly safe products.

In summary, we believe that in view of the current absence of reliable and robust analytical methodologies supporting enforcement and the expected update of the 2012 EFSA risk assessment of mineral hydrocarbons in food, the present restriction proposal would create chaos and legal uncertainty in the food packaging and related supply chains. We therefore believe that in its present form, the impact of this Order on the consumer and environmental safety for the European citizens will be very limited.