

IMACE FOLLOW UP POSITION

on

The updated plan of the European Commission on Setting maximum levels for Mineral Oil Aromatic Hydrocarbons (MOAH) in foods

Brussels, 16 September 2024

In view of the evolution of the regulatory discussions on setting maximum levels for Mineral Oil Aromatic Hydrocarbons (MOAH) in foods, IMACE wishes to follow up by updating its [Position](#).

Precisely, we would like to stress the following points for the consideration of the European Commission in the upcoming discussions on developing this Regulation:

1. IMACE's Assessment of the three Options proposed by the European Commission

IMACE has the following views regarding three Options suggested by the European Commission:

Option 1:

Option 1 seems to be incomplete as “milk and dairy products and products containing dairy” do not have a clear ML and they remain under discussion.

We understand that this Option has been aborted by the EC.

Option 2:

- Advantages:

- Option 2 is straightforward and feasibly enforced.
- Butter would also correctly fall into the 2mg/kg limit.

- Disadvantages:

There is no classification of the MLs for the different categories of fats and oils nor the relevant timeframes. In particular, tropical oils (along with grapeseed, cottonseed, etc.) require having a higher ML and an appropriate timeframe in order to become compliant with the 2 mg/kg maximum level of MOAH.

Option 3:

- Advantages:

- We believe that the classification of the MLs for the different categories of fats and oils allows sufficient time to resolve the practicalities in removing and preventing MOAH in certain fats and oils.

- Disadvantages:

- **Calculation of MLs for compound foods**

In practice, it is extremely challenging to calculate the MLs of complex recipes. This is because the analytical results are not always reliable due to measurement uncertainties and lack of information on composition of the food. Ingredients often originate from different countries, they are tested in different labs, etc.

Consequently, **Option 3 would be feasible only if the MLs for compound foods are calculated at the highest MLs allowed for specific ingredients in the compound food** as per the example of the Regulation on 3-MCPD Esters and GE¹ (i.e. *“When the product is a mixture of different oils or fats of the same or of different botanical origins, the maximum level applies for the mixture. The oils and fats used as ingredient for the mixture shall comply with the maximum level established for the oil and fat in point 5.4.1”.*)

- **B2B ingredients and auto-controls**

We wish to reaffirm that in B2B, it may not be possible to share the exact compositional data of products due to legal Intellectual Property (IP) protections in place. Usually, the most that can be shared with a customer or obtained from a supplier is the actual calculated theoretical ML for a compound ingredient. Notably, manufacturers will not be able to provide full formulation details for products to authorities for them to calculate the theoretical max levels.

This leads to legal uncertainty for companies buying compound ingredients, as they must rely on a certificate of compliance stating a maximum limit. Furthermore, all analytical results obtained by official controls, exceeding the 2 mg/kg will require engagement of the Authorities with the manufacturer to get the formulation details.

¹ Regulation EU 2023.915 on maximum levels for certain contaminants in food and repealing Regulation EC No 1881.2006

Besides, the issue of auto-controls is overlooked in option 3. Recipes are (mostly) not available from suppliers to perform auto-controls as there are IP protections in place, as mentioned above. Therefore, there is a lack of clear criteria for inspections.

- **Unjustified discrimination of butter**

An additional great concern for IMACE under Option 3, is the fact **that butter is not classified under the category of "animal and vegetable fats"**. The MOAH ML for butter is calculated from the milk fat content of the product and the and the appropriate processing factor. We would like to highlight that there is no scientific justification to apply processing factors (i.e. Reverse Yield Factors) when leading to very high MOAH levels in certain end products.

The reverse yield factor^{2,3} for butter is 21.3 25.0 and the ML for milk is 0.5 ppm. Therefore, for the lower level of the reverse yield factor (i.e. 21.3) the ML for MOAH in butter would be $21.3 \times 0.5 = 10.7$. For the higher reverse yield factor (i.e. 25.0) the respective ML would be $25.0 \times 0.5 = 12.5$. **That would give an average of 11.6 mg/kg for butter.**

Consequently, there is no scientific substantiation to support such a special approach for butter. The 2023 EFSA Opinion⁴ clearly states that butter has similar levels of MOAH as in most vegetable oils and spreads. Based on the data in the EFSA report, a limit for butter of 2mg/kg should be feasible and correct. Although, EFSA's risk assessment demonstrates that butter may contain similar or even higher levels of MOAH compared to several vegetable oils (e.g. coconut oil, grapeseed, etc.) for which MLs are proposed in line with the levels found in those vegetable oils, a very high level is considered acceptable for butter.

Moreover, this was also proposed in the initial discussion document shared by the EC in January 2024: *"Butter: In the cleaned EFSA data set the concentrations of MOAH in butter were below the LOQ. In the 2022-2023 non-cleaned data set suddenly the P95 is 8 mg/kg. The recent samples originate are all from one Member State. 3 on 51 samples show very high concentrations of MOAH (8, 10 and 14 mg/kg) and these samples drive the P95. However, 47/51 of these samples comply with an ML of 2.0 mg/kg and the P90 of 2.3 mg/kg confirms the achievability of an ML of 2.0 mg/kg for butter. Therefore, an ML of 2.0 mg/kg is proposed for butter."*

² EFSA. 2019. The raw primary commodity (RPC) model: strengthening EFSA's capacity to assess dietary exposure at different levels of the food chain, from raw primary commodities to foods as consumed

³ EFSA. 2019. Annex A to the technical report on the raw primary commodity (RPC) model - Input data

Table 1: Summary of comparison of the three EC Options, as presented so far

Option	Advantages	Disadvantages
Option 1	-	-Milk and dairy products and products containing dairy do not have a clear ML
Option 2	- The most straightforward Option and feasible to apply for enforcement	-There is no classification of the MLs for the different categories of fats and oils
Option 3	-The classification of the MLs for the different categories of fats and oils is a positive element	- In practice, it is very challenging to apply Option 3 as it is highly complicated to calculate the MLs of complex recipes. It must be considered that the composition of most compound foods is frequently protected by Intellectual Property rights. This causes a practical obstacle when it comes to B2B compound ingredients as well as at auto-control level. - Butter has an unjustified exemption, as it being granted a high ML that leads to unfair competition with many other food products having to comply with lower limits.

2. Setting a maximum concrete value rather than the LOQ level

IMACE wishes to reiterate that a maximum level for MOAH needs to **be set based on the ALARA principle and not on the LOQ**.

The LOQ refers to the technical ability of an analytical method and depends on commercial analytical laboratories that determine what is an acceptable level based on their competence and is not defined, as appropriate, by the competent authority on the basis of scientific evidence demonstrating at which max levels safe consumption is guaranteed.

In order to provide legal certainty and in line with Recital 2 of Regulation (EU) 2023/915⁴, a maximum level for MOAH needs to be set based on the ALARA (as low as reasonably

⁴ [COMMISSION REGULATION \(EU\) 2023/915](#) of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006

achievable) principle and not on LOQ. A **concrete maximum value is required without reference to the LOQ in recitals or respective articles of the regulation.**

3. Monitoring Recommendation of mineral oil saturated hydrocarbons (MOSH) in food

At this stage, we wish to reemphasise that EFSA⁵ has not identified a risk related to MOSH presence in foods thus, as per our initial Position, **we are of the opinion that a Monitoring Recommendation Guidance is unnecessary.** The industry is already carrying out the relevant regular controls with no need for further guidance. Our sector is committed in continuing to engage with our suppliers to steer the reduction of MOSH in the ingredients. In addition, we are bound to continuous engagement with our customers.

Should the European Commission proceed with such monitoring recommendation, IMACE stands firm **that specific limits in the guidance should not be set.** Any level (even if intended as a guidance) may be used as an action limit by Member State's Competent Authorities and lead to unnecessary, costly recalls without any robust scientific justification.

Furthermore, the FAQ document shared by the EC in June 2024 notes that *"however, in case very high concentrations of MOSH would be quantified in food, Member States can always take enforcement action against MOSH in food on the basis of Art. 14 of the Regulation (EC) No 178/2002 following a case-by case risk assessment"*. Firstly, the statement *"very high concentrations"* is vague and unclear creating further uncertainty to all food business operators. Besides, as there is no scientific evidence to demonstrate that MOSH is an issue for human health, we request that this point is removed from the FAQ document.

4. Regulation on setting maximum levels for MOAH for emulsifiers

Until now, we have been reassured by the European Commission that the discussions on MOAH in food additives are ongoing and there are internal efforts to coordinate the proposals.

We wish to repeat that the two Regulations (i.e. on foods and food additives) **should be aligned concerning both timelines and ML values.**

⁵ EFSA Opinion on Update of the risk assessment of mineral oil hydrocarbons in food. September 2023.

