

**Advice 19-2017 of the Scientific Committee of the FASFC on action thresholds for mineral oil hydrocarbons in food****Background & Terms of reference**

Mineral oil hydrocarbons (MOH), including mineral oil saturated (MOSH) and/or aromatic (MOAH) hydrocarbons, are found in various food products. They can enter the food mainly through 3 different routes: (i) as a contaminant via e.g. environment or lubricants used in equipment or machinery, (ii) as an additive or technical auxiliary, with MOH consciously added to food or agricultural raw material, or (iii) as a residue via the migration from materials and objects that come into contact with foodstuffs.

By means of the current analytical methods, it is possible to separate and quantify the MOSH and MOAH fraction in food but particular care should be taken to prevent interference with similar components present in the food. Since MOH are complex mixtures, it is nevertheless difficult or even impossible to fully characterize the MOH detected in food. Minimal detection and/or quantification limits reported for MOSH and MOAH vary between 0.1 and 10 mg/kg food. It is mostly difficult to identify the source of MOH contamination. MOSH and MOAH levels detected in food can vary strongly with MOSH levels being mostly higher than the MOAH levels. Mineral oil products that are not food grade (i.e. 'technical grade' MOH), contain around 15 to 35% MOAH.

While MOAH are possibly carcinogenic and mutagenic, MOSH are not mutagenic nor carcinogenic. However, it has been shown that MOSH tend to accumulate in different human organs. In rats, exposure to MOSH leads to the formation of granulomas in the liver, of which the relevance to humans is still unclear.

Given the potential public health risks linked to the presence of MOSH and MOAH in food as well as the absence of legal limits, the Scientific Committee has been asked to propose action thresholds in order to provide the FASFC with a scientific basis with a view to preserving safety of the food chain.

**Methodology**

The opinion is based on information available in the scientific literature combined with expert opinion.

Determination of action thresholds relies on the methodology described in the document "Inventory of actions and action limits and proposal of harmonization in the framework of official controls - Part 1 Action limits for chemical contaminants" (FAVV, 2017).

**Results**

In view of protecting public health, an action threshold for a chemical contaminant generally corresponds to the maximum content of this contaminant that a food can contain when it is consumed in large quantities, without exceeding the acceptable daily intake. However, there are still several uncertainties regarding the toxicity of both MOSH and MOAH that hamper the determination of an acceptable daily intake.

Given that the acceptable daily intake (ADI) values proposed in the past for MOSH were withdrawn, in this opinion an 'acceptable' daily intake of MOSH is derived from a margin of exposure or MOE and a toxicological dose-response reference point. For non-genotoxic contaminants it is generally assumed that a MOE above 100 gives little reason for concern for public health. As a toxicological dose-response reference point, a NOAEL ('no observed adverse effect level') of 19 mg/kg body weight per day is considered, originating from a subchronic exposure study with Fischer rats and the formation of granulomas in the liver as critical effect (EFSA, 2012a). Based on a comparison between the 'acceptable' daily intake obtained as such and the consumption values at the 97.5<sup>th</sup> percentile (P97.5) of adults (18 - 64 years) and children (3 - 9 years) for different food product groups, the following action thresholds are proposed for the MOSH fraction (C<sub>16</sub>-C<sub>35</sub>):

<b>Proposed action thresholds for MOSH (C<sub>16</sub>-C<sub>35</sub>) in different food products (mg/kg) (*):</b>	
Milk and dairy products	<b>5</b>
Fruit and fruit products	<b>10</b>
Composite food (including frozen products)	
Grains and grain-based products	<b>15</b>
Vegetables and vegetable products	<b>20</b>
Starchy roots and tubers	
Snacks, desserts, and other foods	
Meat and meat products	<b>30</b>
Sugar and confectionary	
Fish and fish products	<b>60</b>
Herbs, spices and condiments	<b>70</b>
Animal and vegetable fats and oils	<b>100</b>
Legumes, nuts and oilseeds	<b>150</b>
Eggs and egg products	

(\*) edible parts

With respect to MOAH, there are still too many gaps regarding toxicity. Therefore it is currently not possible for the Scientific Committee to evaluate the risk of presence of the MOAH fraction in food at a certain level (action threshold). Given the carcinogenic potential of certain components in this fraction, it is however recommended to limit the exposure to MOAH as far as possible. Following the example of Germany, the analytical detection limit of 0.5 mg/kg food could accordingly be considered as a possible action threshold for the MOAH fraction (C<sub>16</sub>-C<sub>35</sub>).

### **Conclusions**

Potential risks related to the presence of MOSH and/or MOAH in food are mainly from a chronic nature. Based on available information and possible risks linked to ingestion, action thresholds between 5 and 150 mg/kg are proposed for the MOSH fraction (C<sub>16</sub>-C<sub>35</sub>), depending on the food type. The toxicity data of MOAH on the other hand, are too limited for proposing an action threshold. It is nevertheless recommended to limit the presence of MOAH in food as far as possible.

Main uncertainties associated with the risk characterization and thus the determination of action thresholds, concern toxicity and composition of the mineral oil hydrocarbon mixtures (MOSH / MOAH) that can be found in foods. In addition to uncertainties associated with the determination of action thresholds, the importance of the correct interpretation of (complex) chromatographic analytical results is emphasized.

The full text is available on this website in dutch and in french.