

EU Commission intends to regulate Mineral oils in food.

On 18 January DG SANTE organised an online Stakeholder Forum on mineral oil hydrocarbons.

At this occasion the Commission presented its intention to provide a regulatory follow up to the updated risk assessment by EFSA.

Aside the Commission, also laboratories and different stakeholders were presenting their views in relation to the planned legislation.



Veerle Vanheusden (DG SANTE E2 Food processing technologies and Novel foods) gave a clear overview of the recent mineral oil “history” with mainly the adoption of the SCoPAFF limits in April/October 2022 and the new EFSA risk assessment published in September 2023. (See FC updates [02/06/22 & 18/09/23](#)).

Within the regulatory framework on contaminants in food [Council Regulation (EEC) No 315/93 and Commission Regulation (EU) 2023/915], the Commission intends to adopt a Regulation on maximum levels (MLs) for MOAH in food, a Recommendation on the monitoring of MOHs in food and a Regulation on methods with specific sampling and analytical method requirements.

For the Regulation on the maximum MOAH levels, the

Commission is currently considering two options, setting

maximum levels for the relevant contributors to the exposure and for foods which may contain very high concentrations of MOAH, or maximum levels for all foods other than fresh or frozen fruits, vegetables, meat, offal, fish and seafood. As the EFSA opinion - due to a lack of toxicological information -, expressed a general concern in relation to MOAH with no distinction made between the 1-2 ring and the 3 or more ring fractions, the intended Regulation will also not make this difference.

Based on the ALARA principle (As low as reasonably achievable), the MLs will be set at values which are possible to reach.

The proposed maximum levels are the same as those adopted in the SCoPAFF (Dry foods 0,5 mg/kg, Fatty foods 1,0 mg/kg, Fats and oils 2,0 mg/kg) and for assessing compliance a measurement uncertainty will be taken in account as described in the Annex to Regulation (EC) No 333/2007 points D1.3 and D2. The analytical result minus the maximum uncertainty should remain below the ML.

For some commodities the available test data are however indicating a large portion of the products contain MOAH concentration well above the proposed MLs and for those product categories, the manufacturers are asked to come with information on the sources and with MOAH occurrence data for samples on which the best available practices have been used.

The Recommendation on MOSH will cover, the monitoring in food, the need to look into the sources of the contamination and to apply mitigation measures. The reason for this initiative - although the EFSA risk assessment concluded there is no health concern related to MOSH -, is the limited margin of safe exposure. In case MOSH would not be monitored any longer and levels would go up again, the EFSA conclusion might change.

The text will also include the recommendation to validate more sensitive analytical methods (Two dimensional GC ...) in order to make the difference between naturally occurring substances and the real MOHs.

Indicative levels will be set for different product groups, varying in the current draft from 1,5 mg/kg liquid infant and follow up formulae to 15 mg/kg for animal and vegetable oils and fats. In case the indicative levels are exceeded it will be recommended to look into the sources and to take measures. The text will clearly state, those indicative levels should not be used to remove products from the market.

The Regulation on the methods, will set as an amendment of Reg. (EC) No 333/2007 specific sampling and analytical method requirements for mineral oils (Minimum recovery of the MO in laboratory tests, within laboratory reproducibility of the outcome ...).



Aside the measures in the regulatory framework on contaminants, it is the intention to have also a follow up in the Food Contact Materials and food additives legislation.

All stakeholders are invited to share with the Commission services further comments (supported with data) by the 27 February.

In Q2 and Q3 the discussion will continue with the Member States and the adoption is expected in Q3-Q4 2024. In between the SCoPAFF statement remains valid.

In short also some statements from a few other presentations:

Rudiger Helling from the Saxon State Ministry, presented the German Benchmark initiative developed by the authorities together with industry, now containing (MOSH/MOAH) benchmark levels for 9 food categories. (See FC update 06/01/22 & 30/01/23) For some food categories, there is a mismatch between the suggested indicative levels by the Commission and the German Benchmark values.

The test results obtained by the Saxon authorities do confirm a significant drop in the MOH contamination but also indicate very high values can still occur in all categories. For this reason, an ongoing monitoring is necessary.

Lydia Richter from CVUA Stuttgart, presented a few contamination examples.

Examining 10 butter samples, one was found to be additionally MOSH contaminated by the wrapping paper. In a second study, out of 17 samples of hemp seed oil one was MOAH contaminated (including 4 and 5 ring PAC) due to a diesel-powered hot air generator for drying the oil seeds. In the last presented case, it was found the storing of fresh apples at local farmers markets, in a not appropriate way in newspapers, is also leading to not compliant MOAH levels, unless the apples are peeled.

Richard Stadler (FoodDrinkEurope) stated how food safety is not negotiable and how - also well recognised by the Commission - the FDE/BLL Toolbox initiative has been an excellent aid to mitigate the contamination. FDE is however very concerned about the measure the Commission is intending. There will be disproportionate economic and other impacts and the analytical challenges remain.

Examples were given. When assessing the MOAH level, there can be strong interferences with naturally occurring substances (terpenes) and for MOSH in case for instance a product is packed in a polyethylene pouch, no distinction can be made with POSH.

In the following discussion, Veerle Vanheusden stated there is no need for an impact assessment as the MLs are set at levels which can be reached and the stakeholders are now given the possibility to comment. A transitional period is according to the Commission also not necessary as the monitoring recommendation is dating from 2017. All this should not be new to the sectors.

Suzy Summer from FoodWatch, came basically with the rather positive message, in the latest test results from 2021, 7 out of the 8 tested products were not contaminated and this proves it can be done. (See FC update 06/01/22) In their NGO role they insisted on no exceptions, no exemptions and no delays.

Many more interventions were covering the specific issues certain sectors have: vegetable oil and fats, cacao, coffee, tea and herbal infusions, spices, oils, margarines, the bakery ingredients and the traders in various products. Not easy to monitor all upstream farmers worldwide, the jute bags ...

All this means the food supply chain can expect further control by the authorities, with for the carton sector no doubt ongoing questions from the market.
On demand we can share the presentations at this forum and also more available background.

Testing conditions for cartons

The ECMA Food Safety Committee is currently discussing appropriate testing conditions for long term storage at room temperature. Customers are often requiring testing according to approaches included in the Plastics Regulation 10/2011, but for a number of materials and substances used in the carton sector - such as the acrylates - this is not appropriate.

From the Plastics Regulation the wording in Annex V Section 2.1.4 "Specific conditions for contact times above 30 days at Room temperature and below", is well known:



(e) For storage at room temperature the testing conditions can be reduced (from 10 days at 60°C) to 10 days at 40 °C if it is shown by scientific evidence that the migration of the respective substance in the polymer has reached equilibration under this test condition.”

In the same Annex V the Section 2.1.3 “Conditions of contact when using food simulants” is however also stating that:

- (i) If it is found that carrying out the tests under the combination of contact conditions specified in the Tables causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.*
- (ii) If the material or article during its intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment.*

This wording from the Plastics Regulation and also what is included in the EuPIA Guidance on migration test methods for evaluation of substances in printing inks and varnishes for food contact materials (version 03/05/23) within the paragraphs 4.2.2 “Migration conditions” and 4.4 “Justified deviations from the recommended methods” <https://www.eupia.org/key-topics/food-contact-materials/migration-testing/> and in the FEICA Migration testing of adhesives intended for food contact materials (version 10/05/23) within the section “Accelerated tests at elevated temperature” <https://www.feica.eu/information-center> will be taken in account for developing an own ECMA statement on this matter.

Allergens

Initiated and discussed in the FFI Quality Managers Committee, the ECMA Food Safety Committee was in its December meeting also covering the issue of allergens. It has been reported how printing powders can be wheat based and how this needs to be declared in order to allow the food manufacturers to communicate on their packaging on the presence of the allergen. BRC/FSSC certified companies have probably gone through this, as allergens became a serious issue in recent updates.

Some background on allergen management is included in the ECMA GMP Guidance 2.1 in the FSSC 22000 Part, paragraph 3.6 Additional Requirements.

ECMA Food Safety documents

The most important documents are again easily accessible from the members only part of the ECMA website within the section GMP 2.1:

As the Checklist and the Food Contact Status Declaration are dating from 2015 and 2017 it has been agreed to review both in 2024. Any comments for improvement are of course most welcome !

Downloads

- [Checklist to use with customers](#) (Word)
- [Supplier questionnaire](#) (Excel)
- [Food contact status declaration](#) (Word)

