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FAQ document on the draft regulatory measures on mineral oil hydrocarbons (MOHs) in food

Scope

In this document a reply is given to questions and comments from stakeholders on the draft proposals for mineral oil hydrocarbons (MOHs) in food under the legislative framework on contaminants in food.

Questions/ comments on toxicological aspects

Why are all mineral oil aromatic hydrocarbons (MOAH) treated in the same way, while not all MOAH are equally toxic? Can it be considered that 1-2-ring MOAH are safe and do not raise health concerns?

The group of MOAH concerns various types of substances with varying degrees of toxicity, the most toxic ones being genotoxic carcinogens. At the moment it is not possible to distinguish the different MOAH on the basis of their individual toxicological properties. Genotoxicity and carcinogenicity are associated with MOAH with three or more aromatic rings. For 1-2 ring MOAH several studies point towards adverse effects such as mutagenicity and carcinogenicity, however the European Food Safety Authority (EFSA) did not have sufficient toxicological data available for a full risk assessment. This does not mean that 1-2 ring MOAH can be considered to be safe. On the basis of the available data and taking into account the data gaps, EFSA concluded that current exposure of EU consumers to total MOAH raises a possible concern for human health. Therefore the regulatory measures and enforcement will be focussed on total MOAH.

In case of MOAH containing foods, is it possible, to carry out a refined risk assessment and to declare them safe for human health, when they only contain 1-2 ring MOAH?

No this approach is not appropriate. EFSA considered the exposure to total MOAH to be of health concern, so the fact that only 1-2 ring MOAH is present, is not a valid reason to declare certain products to be safe and to apply a different risk management approach. Products containing only 1-2 ring MOAH in concentrations above the ML cannot be placed on the market.

Polyaromatic hydrocarbons (PAHs) fall under the MOAH hump and cannot be excluded from the analytical result for total MOAH. How to deal with this?

PAHs are also MOAH, so they were taken into account for the EFSA risk assessment and they should be quantified together with the other MOAH substances. The regulatory measures will also apply to the PAHs, which fall under the MOAH hump.

Can mineral oils that pass the IP346 test be considered safe?

This test is not appropriate to ensure the absence of MOAH. EFSA concluded that the DMSO affinity decreases with an increasing degree of alkylation, which means that highly alkylated MOAH with more than three aromatic rings may not be extracted into DMSO. Therefore there is no guarantee on the safety of mineral oils that pass the IP346 test as regards the absence of MOAH.

The proposed maximum levels (MLs) for MOAH in food will lead to shortages for certain products, because a big part of the supply chain is contaminated.

The products get contaminated at different steps of the supply chain and this contamination is avoidable. The occurrence data are taken into account for the establishment of MLs. Where the largest part of the production contains concentrations of MOAH below the limit of quantification (LOQ), it is clear that this should also be achievable for the rest of the production. For products for which a large part of the production contains MOAH in quantities above the LOQ, it will be discussed whether temporary higher MLs could be considered, in order to give the food business operators (FBOs) some more time to implement the required mitigation measures.

Questions/comments on the draft MLs for MOAH in food.

An impact assessment is needed before establishing MLs for MOAH in food.

For setting MLs for contaminants in food evidence and input from stakeholders are taken into account, in order to understand the specific production conditions of the different sectors. MLs are proposed for which compliance can be ensured for all foods. Because MLs will be set, which can be achieved by applying the appropriate mitigation measures, the expected economic impacts are minimal. According to the Commissions' Better Regulation Guidelines therefore no further impact assessment is needed.

Should MLs be set for raw agricultural commodities or only for products placed on the market for the final consumer?

In many cases the MOHs that are quantified in products placed on the market for the final consumer originate from a contamination of the raw agricultural commodities. As in most cases the MOHs cannot be removed or can only be partially removed during the production process, the only way of avoiding the contamination of the final product is to avoid the contamination of the raw agricultural commodity. Only by establishing MLs for the raw agricultural commodities can one push the producers of those products to apply the necessary mitigation measures. Therefore, the MLs should apply to raw agricultural commodities, products placed on the market for the final consumer and all intermediate products.

Transitional measures are needed before applying the MLs for MOAH in food.

Already in 2017 the Commission issued a Recommendation on the monitoring of Mineral Oil Hydrocarbons (MOH) in Food (Recommendation (EU) 2017/84[1]) in which Member States and FBOs were asked to carry out controls on MOH in food and, where MOHs were quantified, to carry out investigations towards the sources of contamination and to apply mitigation measures. The food sector is already for many years aware of the issue of the occurrence of MOHs in food and had therefore sufficient time to start mitigating the sources of contamination. The comments from the different stakeholders as regards the need for deferred application dates and transitional measures for products placed on the market before the application date have been received in good order and they will be taken into account for the discussions with the Member States on the draft proposal. In any case possible transitional measures will not impact on the validity of the Joint statement of 21 April 2022 of the Member States regarding the presence of MOAH in food, including food for infants and young children (including the further clarifications of 19 October 2022)[2]. This means that regardless of possible transitional measures, Member States will still be able to enforce large quantities of MOAH in food on the basis of Article 14 of Regulation (EC) No 178/2002[3].

MLs should be set on the basis of the 'As Low As Reasonably Achievable (ALARA)' principle and not on the basis of the limit of quantification (LOQ).

In accordance with Article 2 of Regulation (EEC) No 315/93[4] , MLs for contaminants in food are set on the basis of the ALARA principle when following good practices at all stages of the production. From the occurrence data it is clear that, when following good practices, in most foods the concentrations of MOAH can be kept below the LOQ. Therefore in many cases 'ALARA' means below the LOQ. This is the reason why MLs are proposed at the level of the achievable LOQ.

On the basis of the occurrence data for specific products, MLs above the LOQ should be established.

As indicated in the point above, the MLs for MOAH in food will be established in accordance with the ALARA principle, when following good practices at all stages of the production. For this the occurrence data will be taken into account, as well as the achievable LOQs. Where needed, in order not to hamper the food supply, it will be discussed whether for certain commodities it would be

[1] Commission recommendation (EU) 2017/84 of 16 January 2017 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food (OJ L 312, 17.1.2017, p. 95, ELI: http://data.europa.eu/eli/reco/2017/84/oj).

[2] https://food.ec.europa.eu/safety/chemical-safety/contaminants/catalogue_en#MOH

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1–24, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

[4] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1, ELI: http://data.europa.eu/eli/reg/1993/315/oj).

appropriate to discuss a progressive time plan to achieve concentrations of MOAH in a certain period of time below the LOQ.

In option 2 of the ML proposal does 'all food' cover both ingredients and final products?

Indeed the different options for the current MLs proposals would cover all foods as defined in Article 2 of Regulation (EC) No 178/2002, so this means raw agricultural commodities, ingredients, products for the final consumer and all intermediate products.

> *'Food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.*

Furthermore Article 2(1) of Regulation (EU) 2023/915 states "*the food listed in Annex I shall not be placed on the market and shall not be used as a raw material in food or as an ingredient in food where it contains a contaminant at a level which exceeds the maximum level set out in Annex I*".

In case higher MLs would be set for certain commodities, also higher MLs should apply to products in which these commodities are used as an ingredient.

Article 3 of Regulation (EU) 2023/915[5] will be applied for the MOAH MLs:

> *Where no specific Union maximum levels are set out in Annex I for food which is dried, diluted, processed or compound food (i.e. composed of more than one ingredient), the following aspects shall be taken into account when applying the maximum levels set out in Annex I to such food:*
>
> *(a) changes of the concentration of the contaminant caused by drying or dilution processes;*
>
> *(b) changes of the concentration of the contaminant caused by processing;*
>
> *(c) the relative proportions of the ingredients in the product;*
>
> *(d) the analytical limit of quantification (LOQ).*

Will it be complex to calculate the applicable ML for processed and compound foods and how to deal with foods for which the exact ingredient composition is not known?

The approach of article 3 of Regulation (EU) 2023/915 (former article 2 of Regulation (EC) 1881/2006) for calculating the applicable MLs in compound and processed foods is in use since many years for all contaminants for which MLs are established under Regulation (EU) 2023/915 and works well. When carrying out controls for MOAH in processed and compound foods, in only a limited number of cases the applicable ML will need to be calculated, when following the below stepwise approach:

[5] Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: http://data.europa.eu/eli/reg/2023/915/oj).

- **Step 1**: as a **first screening** the MOAH concentration can be checked against a screening threshold of 0.5, 1.0 or 2.0 mg/kg[6], depending on the declared fat content of the analysed food.
    - In case the product **complies in the first screening**, the product can be **declared compliant without the need for a further calculation of the ML**. This will be the case for the vast majority of the samples.
- **Step 2**: in case the product contains MOAH > the LOQ of 0.5, 1.0 or 2.0 mg/kg depending on the fat content, a **second screening** can be done against the **highest ML** of the ingredients.
    - In case the product does not comply with the highest ML of the ingredients, the products can be **declared non-compliant, without further calculations**.
- **Steps 3.1 and 3.2**: only in the limited number of cases, when no decision on compliance or non-compliance can be taken on the basis of screening 1 or screening 2, the exact ML needs to be calculated.
    - In case the ingredient composition is known, this can be done as prescribed in article 3(1) of Regulation (EU) 2023/915, taking into account:
        - the appropriate concentration and dilution factors;
        - the relative proportions of the ingredients in the product;
    - Because ingredients that make out less than 5% of the ingredient composition, will have a very limited impact on the MOAH concentration of compound foods, as a pragmatic approach and '**third screening**' the **ML can be calculated on the basis of the MLs of ingredients that are present in a more than 5% quantity** in the product, their percentage in the final product and possible concentration or dilution factors. For the ingredients that are present in a less than 5% concentration a default screening concentration can be calculated.
        - Step 3.1: default screening concentration of 0.50 mg/kg for the ingredients present in < 5% quantity: if the product complies with the calculated ML under **screening 3.1**, the product is compliant.
        - Step 3.2: default screening concentration of 10 mg/kg for the ingredients present in < 5% quantity: if the product does not comply with the calculated ML under **screening 3.2**, the product is non-compliant.
        - In the other cases a calculation of the exact ML, taking into account the ingredients that are present in a less than 5% concentration is needed: **step 4**.
    - In case the **ingredient composition or processing factors are not known, see step 5**

[6] Screening value:

- 0,50 mg/kg for ingredients with a < 4% declared fat/oil content
- 1,0 mg/kg for ingredients with ≥ 4% and ≤ 50% declared fat/oil content
- 2,0 mg/kg for ingredients with > 50% declared fat/oil content

- **Step 4**: for the cases not covered by steps 3.1 and 3.2, **the ML needs to be calculated in accordance with article 3(1) of Regulation (EU) 2023/915, taking into account the contributions of all ingredients**, including those present in less than 5%. After calculation of the exact ML, a decision on compliance/ non-compliance can be taken. In case certain information on the ingredient composition, concentration or dilution factors are missing, see step 5.
- **Step 5**: in case the **exact ingredient composition or relevant dilution or concentration factors are not (fully) known**:
    - The **competent authority requests from the FBO the information, which is needed for calculating the exact ML. In case the FBO does not provide the required information, the competent authority can define itself** in accordance with article 3(2) of Regulation (EU) 2023/915 **a processing factor**, based on the available information and with the objective of a maximum protection of human health.
        - *Art. 3(2): Where the food business operator does not provide the necessary concentration, dilution or processing factor or where the competent authority deems that factor inappropriate in view of the justification given, the competent authority shall itself define that factor, based on the available information and with the objective of maximum protection of human health. Where the food business operator does not provide the necessary concentration, dilution or processing factor or where the competent authority deems that factor inappropriate in view of the justification given, the competent authority shall itself define that factor, based on the available information and with the objective of maximum protection of human health.*
    - FBOs should, in case the supplier doesn't want to share the ingredient compositions, request a sufficiently low MOAH concentration in the ingredients that they purchase, in order to have a safety margin to ensure the compliance of the final products.

In examples 1 and 2 in the Annex to this document this approach is illustrated.

How to calculate the applicable ML for processed and compound foods, which contain ingredients for which MLs are lowered in the course of time?

As a default approach it should be assumed that the ingredients comply with the ML that is applicable at the time of sampling. In case the product does not comply, the competent authority should contact the FBO and it is up to the FBO to justify that the ingredient was placed on the market in a period in which a higher ML applied and that the ingredient complies with that ML. In case the FBO does not respond to the competent authority or in case the FBO is not able to provide proof (within a reasonable deadline set by the competent authority), that the product is compliant, the product shall be declared non-compliant.

For calculating the indicative level for compound and processed foods, should both indicative levels and maximum levels be taken into account?

For the answer to this question cfr. the chapter on questions and comments on the monitoring Recommendation.

For certain commodities with large amounts of endogenous interfering substances, the achievable LOQs are higher than the proposed MLs.

The European Reference Laboratory will be consulted on the achievable LOQs for commodities with high amounts of endogenous interfering substances and this information will be taken into account for the discussions on the MLs.

For coffee, tea and herbal infusions transfer studies show that the transfer to the brew is very limited. Are MLs for these commodities necessary?

The results of the transfer studies will be discussed with the Member States in order to evaluate the need for MLs for MOAH in coffee, tea and herbal infusions.

Will the MLs for processed products only apply to contaminations that were already present in the raw agricultural commodities or also to contaminations that occurred during the production process, transport and packaging?

The MLs will apply regardless of the source of the contamination. The MLs will apply to contaminations that were present in raw materials, ingredients or that occurred during the production process, transport and packaging. This includes also contaminations of foods due to the use of authorised but contaminated food additives and food contact materials. Because the MLs will apply regardless of the source of the contamination, for enforcement purposes there will no need for the competent authorities to know the source of the contamination. However it goes without saying that, following an ML exceedance, the FBO will need to investigate and identify the source of the contamination, in order to avoid further contaminations in the future. Examples 3 and 4 in the Annex to this document illustrate this principle.

Questions/comments on the draft monitoring Recommendation on the monitoring of MOHs in food and on indicative levels (ILs) for mineral oil saturated hydrocarbons (MOSH) in food.

EFSA concluded that the current consumer exposure to MOSH does not raise health concerns, so why are regulatory measures proposed for MOSH in food?

MOSH causes various adverse effects in humans, such as the accumulation in various organs. Indeed EFSA concluded that the current consumer exposure to MOSH does not raise health concerns, however the margin for a safe exposure is limited. This means that, in case all current mitigation measures would be dropped and the exposure to MOSH would further increase, the conclusions of the EFSA opinion might change. Therefore, the continued monitoring of MOSH in food and the application of mitigation measures against MOSH in food remain necessary. Therefore, the establishment of indicative levels for MOSH in food is appropriate.

While indicative levels (ILs) should not be used as thresholds for removing products from the market, some Member States might use them for this purpose.

Indicative levels should not be used as a threshold to remove products from the market, this is clearly indicated in the draft Recommendation. 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 or Art. 14 of the Regulation (EC) No 178/2002 following a case-by case risk assessment.

The Recommendation should include requirements for the confirmation and characterisation of total MOSH in suspect results, as indicated in the JRC Guidance.

The draft Recommendation refers to Regulation (EC) No 333/2007[7]. In the draft amendment to Regulation (EC) No 333/2007 a reference is made to the JRC Guidance. This means that for the scope of the Recommendation, the requirements of the JRC Guidance will apply for MOSH and MOAH.

For calculating the indicative level for compound and processed foods, should both indicative levels and maximum levels be taken into account?

It is not the intention that MLs and ILs would be combined.

For calculating the MLs for MOAH of compound foods, only the MLs should be taken into account and the LOQ for foods for which no ML for MOAH is set. ILs are not enforcement limits, so they should not be used in the calculation of MLs.

The calculation of indicative levels is only relevant for foods for which no ML applies:

- ILs can be calculated for MOSH in food
- ILs can be calculated for MOAH in foods in which no ingredients are used for which an ML is set.

For example

- For **MOAH** in processed vegetables, processed fruits, processed meat and offal, processed fish and other seafood, processed eggs no MLs apply. The **ILs** for these apply to the processed product, so no further calculation is needed.
- For **MOAH** in compound foods, which contain processed vegetables, processed fruits, processed meat and offal, processed fish and other seafood, processed eggs an ML can be calculated, because in most cases in these foods ingredients will be used for which an ML applies. therefore for MOAH in those compound foods an **ML** should be calculated and not an IL.

[7] Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down methods of sampling and analysis for the control of levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29, ELI: http://data.europa.eu/eli/reg/2007/333/oj).

- For **MOSH** in processed vegetables, processed fruits, processed meat and offal, processed fish and other seafood, processed eggs no MLs apply. The **ILs** for these foods apply to the processed product, so no further calculation is needed.
- For **MOSH** in compound foods, which contain processed vegetables, processed fruits, processed meat and offal, processed fish and other seafood, processed eggs, the IL should be calculated on the basis of the **ILs** for the ingredients, the ingredient composition and the appropriate dilution and concentration factors.

This approach is illustrated in example 5 in the annex to this document.

Questions/comments on analytical aspects

Are the MLs and ILs analytically achievable? Are validated/ standardised methods available?

The Joint Research Centre of the European Commission has published a Guidance on the sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials, [8] so a validated method is available. The proposed MLs and ILs take into account the JRC Guidance. The LOQs are achievable for most commodities. However it is acknowledged that not all laboratories can achieve these LOQs, so, where needed, FBOs should subcontract analyses to the state-of-the-art labs, which can achieve them. The other laboratories should optimise their methods as soon as possible. For certain commodities with a large quantity of endogenous interfering substances, the LOQs might be higher than those of the JRC Guidance. The European Reference Laboratory on Processing Contaminants will be consulted on these cases and, where needed, it will be discussed whether higher MLs might be appropriate, taking into account the achievable LOQs.

The MLs/ ILs cannot be achieved due to interferences with naturally occurring substances.

The Joint Research Centre provides specific guidance on sample preparations, to ensure that naturally present substances (for example olefins) do not interfere with the analysis. In case of doubt on the presence of endogenous interferences, a confirmatory analysis with two-dimensional gas chromatography (GC x GC) should be performed.

How to deal with diverging results by different laboratories of the same sample.

In several cases, where MOAH were quantified in food, the analysis results were confirmed by an independent laboratory. This shows that it is possible to carry out reproducible analyses. For products that contain endogenous substances that might interfere with the analysis, in case of doubt, a confirmatory analysis via GCxGC should be carried out by an accredited laboratory.

Are guidelines available on how the sum of MOAH should be determined?

The updated JRC Guidance explains how to integrate the MOAH fraction.

[8] https://op.europa.eu/en/publication-detail/-/publication/97cb92c2-d29e-11ed-a05c-01aa75ed71a1

The draft Regulation on methods of analysis for MOH in food should also mention the need for a confirmatory analysis with GCxGC in some cases.

Those provisions will be added to the draft Regulation and the EURL Processing Contaminants is working on a guidance on GC x GC.

Questions/comments on sampling

Differences in sampling approaches can cause a divergence in the analytical results for the same lot. How can this be avoided?

The draft Regulation amending Regulation (EC) No 333/2007 as regards the methods of sampling and analysis for the control of levels of mineral oil hydrocarbons in foodstuffs will ensure that uniform sampling methods will be used, which ensure the reliability and consistency of official controls on MOHs in food. The general sampling requirements of Regulation (EC) No 333/2007 will apply to controls of MOHs in food. In addition, some specific additional requirements will be added to Regulation (EC) No 333/2007, in order to avoid the contamination of the samples with MOHs during the sampling procedure.

Is it really necessary to test each batch of sample containers on the presence of MOAH. It is much more cost-efficient to anneal all sample containers at high temperature, without carrying out tests on the presence of MOAH.

The updated JRC Guidance foresees the following:

> *Unpackaged food should be sampled in containers, which are inert for mineral oil. Only containers that do not release interfering substances and do not adsorb MOH should be used. Glass or polyethylene terephthalate (PET) containers have the identified properties and are most preferred. Each new batch of sample containers should be checked for mineral oil contamination. If a mineral*
> *oil contamination is detected, the containers should be washed before use with purified n-hexane and dried at the highest temperature possible. Glass sample containers could also be annealed, preferably at 400 °C. Mineral oil contamination of sample containers needs to be checked for each new batch after such treatment.*

This text is not part of the draft Regulation on analytical methods for MOHs in food but, in the Regulation, reference is made to the JRC Guidance. The JRC guidance serves as a help for lowering the risk of contamination of the sample before analysis, in order to give reliable analytical results. However, it is up to the individual operator to decide how secure they want to be. If they do not properly check the sampling containers for MOH contamination, then there is a risk of non-compliance because of that.

It should be explained how it should be ensured that no contamination occurs during the sampling due to the use of personal care products.

The draft Regulation on the methods for the sampling and analysis of MOHs in food foresees that the detailed precautions for the sampling and analysis of MOHs in food from the JRC Guidance should be followed. The JRC Guidance foresees that the person that carries out the sampling, should take all necessary precautions, to avoid contamination of the sample. For example, the use of cosmetics (e.g. hand creams) should be avoided. The easiest way of doing so, is not to use personal care products, when sampling food for the analysis of MOHs in food.

Questions/comments on enforcement

Part of the measured MOAH might originate from authorised lubricants, food additives or food contact materials. Is MOAH contamination from such sources allowed?

EFSA recommended that the technical specifications of white mineral oils and waxes used as food additives and food packaging materials should be updated, with detailed information about the MOAH content and composition. The DG SANTE teams dealing with food additives and food contact materials are current discussing the appropriate regulatory measures for MOAH in food additives and food contact materials. In any case the regulatory measures for MOHs under the contaminants legislation will apply regardless of the source of the MOHs, even if the source is an authorised food additive or food contact material.

For certain methods the measurement uncertainty (MU) is quite high, which makes it difficult to draw conclusions on the compliance of a lot. How to deal with this?

In accordance with points D.1.3. and D.2. of the Annex to Regulation (EC) No 333/2007, decisions on the compliance of a lot need to be taken, taking into account the measurement uncertainty. This means that the measurement uncertainty of the method (as indicated on the analysis certificate) needs to be deducted from the analytical result. If the result of that subtraction is lower than or equal to the ML, the lot is compliant. This way it is ensured that an identified non-compliance is really an exceedance of the ML and that it is not due to the high measurement uncertainty.

Will the measurement uncertainty (MU) also be applied on results of auto-controls.

The provisions of Regulation (EC) No 333/2007 also apply to auto controls, so indeed the MU also needs to be applied to those results.

How can enforcement be done, when the LOQ of the method is higher than the ML?

For results from methods with an LOQ that is higher than the ML, when the result is below the LOQ, there are no guarantees on the compliance of the product. However, when with such a method a result above the LOQ and by consequence above the ML is obtained (corrected for the measurement uncertainty), the lot can be declared non-compliant.

Now that for certain foods temporary MLs above the LOQ are under discussion, can MS still enforce concentrations of MOAH above the LOQ in those foods in accordance with the 2022 Member States statement of the SC PAFF?

As there is no safe threshold for exposure to genotoxic carcinogens, the temporary MLs above the LOQ are no safe levels. Therefore, pending the establishment of these MLs, Member States can still enforce quantities of MOAH above the LOQ in those foods on the basis of Article 14 of Regulation (EC) No 178/2002.

Clear thresholds are needed above which market withdrawals and recalls should be done. The enforcement approaches of the Member States should be harmonised.

Under the current statement of the SC PAFF of 21 April 2022 the Member States enforce MOAH in food on the basis of a case-by-case risk assessment in accordance with article 14 of Regulation (EC) No 178/2002. Once maximum levels for MOAH in food will be established, there will be a clear threshold for enforcement.

Questions/ comments on awareness raising in third countries

It is difficult to reach FBOs in third countries and to convince them on the need to apply mitigation measures against MOHs in food. Can DG SANTE help in this regard?

DG SANTE prepared an information note on MOHs in food for third countries, which can be circulated by EU FBOs to their suppliers in third countries: https://food.ec.europa.eu/document/download/073ffc30-a422-47e8-abdb-81028ce18295_en.

The note has also been circulated to the EU delegations in third countries for circulation among third country competent authorities.

At the Codex Committee on Contaminants in Food 17 under agenda item 21 on emerging issues the Codex members were informed on the issue of MOHs in food and on the need to apply mitigation practices in their production.

-Report CCCF17: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-17%252FReport%252FFINAL%2BREPORT%252FREP24_CF17e.pdf

-EU comments in CX/CF 24/17/19: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-17%252FWorking%2Bdocuments%252Fcf17_19.pdf

Annex

Example 1: pragmatic approach for deciding on the compliance of compound and processed foods.

- Cookies containing 20% palm oil, 20% sugar, 20% wheat flower, 20% of eggs, 10% of cocoa mass, 4% of cocoa powder, 3% of an additives, 3% of a flavouring. Fat percentage 30%.
- Example 1.1 (step 1): measured concentration corrected for the measurement uncertainty: 0.60 mg/kg. Screening 1: 0.60 mg/kg < screening value of 1.0 mg/kg. Conclusion: compliant.
- Example 1.2 (steps 1 and 2): measured concentration corrected for the measurement uncertainty 5.0 mg/kg. Screening 1: 5.0 mg/kg is > screening value of 1.0 mg/kg. Screening 2 against highest ML of the ingredients: 5.0 mg/kg > 4.0 mg/kg for palm oil. Conclusion: non-compliant.
- Example 1.3.1 (steps 1, 2 and 3.1): measured concentration corrected for the measurement uncertainty 1.3 mg/kg. Screening 1: 1.3 mg/kg is > screening value of 1.0 mg/kg. Screening 2 against highest ML of the ingredients: 1.3 mg/kg < 4.0 mg/kg for palm oil. Conclusion: ML needs to be calculated. Screening 3.1:
  - Palm oil: 0.20 * 4.0 mg/kg = 0.8 mg/kg
  - Sugar: 0.20 * 0.50 mg/kg = 0.1 mg/kg
  - Wheat flour: 0.20 * 0.50 mg/kg * 0.1 mg (assumed PF of 1.0 for converting wheat grains into wheat flour) = 0.1 mg/kg
  - Eggs: 0.20 * 0.50 mg/kg = 0.1 mg/kg
  - Cocoa mass: 2.0 mg/kg * 0.10 * 1 (PF cocoa beans to cocoa mass) = 0.2 mg/g
  - Other ingredients, which are present in < 5% make out 10% in total of the ingredient composition: 0.10 * 0.50 mg/kg = 0.05 mg/kg
  - Screening 3.1 calculated ML: 1.35 mg/kg.
  - Measured concentration corrected for the measurement uncertainty of 1.3 mg/kg < ML of 1.35 mg/ kg. Conclusion product compliant.
- Example 1.3.2 (steps 1, 2, 3.1 and 3.2): measured concentration corrected for the measurement uncertainty 2.5 mg/kg. Screening 1: 2.5 mg/kg is > screening value of 1.0 mg/kg. Screening 2 against highest ML of the ingredients: 2.5 mg/kg < 4.0 mg/kg for palm oil. Conclusion: ML needs to be calculated. Screening 3.1: 2.5 mg/kg > estimated ML of 1.35 mg/kg. Conclusion screening 3.2 needs to be performed:
  - Palm oil: 0.20 * 4.0 mg/kg = 0.8 mg/kg
  - Sugar: 0.20 * 0.50 mg/kg = 0.1 mg/kg
  - Wheat flour: 0.20 * 0.50 mg/kg * 0.1 mg (assumed PF of 1.0 for converting wheat grains into wheat flour) = 0.1 mg/kg
  - Eggs: 0.20 * 0.50 mg/kg = 0.1 mg/kg
  - Cocoa mass: 2.0 mg/kg * 0.10 * 1 (PF cocoa beans to cocoa mass) = 0.2 mg/g

- Other ingredients, which are present in < 5% make out 10% in total of the ingredient composition: 0.10 * 10 mg/kg = 1.0 mg/kg
- Screening 3.2 calculated ML: 2.3 mg/kg.
- Measured concentration corrected for the measurement uncertainty of 2.5 mg/kg > estimated ML of 2.3 mg/ kg. Conclusion product non-compliant.

- Example 1.4 (steps 1, 2, 3.1, 3.2 and 4): measured concentration corrected for the measurement uncertainty 1.9 mg/kg. Screening 1: 1.9 mg/kg is > screening value of 1.0 mg/kg. Screening 2 against highest ML of the ingredients: 1.9 mg/kg < 4.0 mg/kg for palm oil, conclusion ML needs to be calculated. Screening 3.1: 1.9 mg/kg > estimated ML: 1.35 mg/kg (see bullet above). Screening 3.2: 1.9 mg/kg < estimated ML of 3.2 mg/kg. Conclusion exact ML needs to be calculated in step 4:
  - Palm oil: 0.20 * 4.0 mg/kg = 0.8 mg/kg
  - Sugar: 0.20 * 0.50 mg/kg = 0.1 mg/kg
  - Wheat flour: 0.20 * 0.50 * 0.80 mg/kg (assumed PF of 1.0 for converting wheat grains into wheat flour) = 0.10 mg/kg
  - Eggs: 0.20 * 0.50 mg/kg = 0.1 mg/kg
  - Cocoa mass: 2.0 mg/kg * 0.10 * 1 (PF cocoa beans to cocoa mass) = 0.2 mg/g
  - Cocoa powder: 2.0 mg/kg * 0.04 * 2 (PF cocoa beans to cocoa powder) = 0.16 mg/kg
  - An additive with an ML of 2.0 mg/kg: 2.0 mg/kg * 0.03 = 0.06 mg/kg
  - A flavouring – essential oil 10.0 mg/kg * 0.03 = 0.3 mg/kg
  - Calculated ML 1.82 mg/kg.
  - The concentration of 1.9 mg/kg corrected for the measurement uncertainty is non-compliant with the legal ML of 1.82 mg/kg.

Example 2: pragmatic approach for deciding on the compliance of compound and processed foods.

- An unknown mixture of vegetable oils.
- Example 2.1 (step 1): measured concentration corrected for the measurement uncertainty is < LOQ of 2.0 mg/kg. Screening 1: the concentration is below the screening value of 2.0 mg/kg. Conclusion: compliant.
- Example 2.2 (steps 1 and 2): measured concentration corrected for the measurement uncertainty 12.0 mg/kg. Screening 1: 12.0 mg/kg is > screening value of 2.0 mg/kg. Screening 2 against highest ML of the possible ingredients: 12.0 mg/kg > 10.0 mg/kg for olive pomace oil. Conclusion: non-compliant.
- Example 2.3 (steps 1, 2 and 5) measured concentration corrected for the measurement uncertainty 4.0 mg/kg. Screening 1: 4.0 mg/kg is > screening value of 2.0 mg/kg. Screening 2 against highest ML of the ingredients: 4.0 mg/kg against highest ML of the possible ingredients: 4.0 mg/kg < 10.0 mg/kg for olive pomace oil (highest ML for an edible oil). Conclusion: the exact ML should be calculated, but this is not possible due to lacking information. In case the required information is not

provided by the FBO, the competent authority can define itself the processing factor/ ingredient composition, with a view of a maximum protection of human health. The competent authority can assume that all ingredient oils are from the ML category of 2.0 mg/kg and by consequence the oil mixture is non-compliant, unless the FBO can prove otherwise.

Example 3: illustration that the ML applies regardless of the source of the contamination.

A mixture of 2 oils: 50% sunflower oil and 50% sesame oil. ML: 0.5 * 2.0 mg/kg + 0.5 * 6.0 mg/kg= 4.0 mg/kg.

The sunflower oil contains 1.6 mg/kg of MOAH. The sesame oil contains 5.0 mg/kg of MOAH. In the final mixed oil 6.5 mg/kg of MOAH is measured with a 30% measurement uncertainty: 3.3 mg/kg MOAH from the ingredients and 3.2 mg/kg of MOAH because during the mixing process machinery oil leaked into the product. After considering also measurement uncertainty (6.5 mg/kg – 0.3 * 6.5 mg/kg = 4.55 mg/kg) it is concluded that the product is non-compliant with the ML of 4.0 mg/kg.

Example 4: illustration that the ML applies regardless of the source of the contamination.

Chocolate composed out of 60% cacao mass and 40% sugar. ML 0.6 * 2.0 mg/kg + 0.4 * 0.5 mg/kg = 1.4 mg/kg.

The cacao mass contains 1.2 mg/kg MOAH. The sugar contains no MOAH. The final chocolate contains 4.0 mg/kg of MOAH is measured with a measurement uncertainty of 30%: 0.72 mg/kg of the contamination comes from the ingredients and 3.28 mg/kg from the transfer of MOAH from the paper wrapper (use of FCM 93 wax authorised for plastic FCM, but not for paper and board FCM). After considering also measurement uncertainty (4.0 mg/kg – 0.3 * 4.0 mg/kg = 2.8 mg/kg) it is concluded that the product is non-compliant is non-compliant with the ML of 1.4 mg/kg.

Example 5: illustration that MLs and ILs should not be combined for calculating ML

Example 5.1: the ML for MOAH for 80% grilled paprikas in 20% sunflower oil should be calculated as follows:

- Sunflower oil ML 2.0 mg/kg x 0.20 = 0.40 mg/kg
- Grilled paprikas
    - Fresh paprikas default concentration: 0.50 mg/kg
    - Grilled paprikas default concentration in case of 50% moisture loss: 1.0 mg/kg
    - Contribution of the grilled paprikas to the ML of paprikas in oil: 1.0x 0.80 = 0.80 mg/kg
- ML grilled paprikas in oil: 0.40 + 0.80 = 1.2 mg/kg
- As an ML for MOAH can be calculated for paprikas in oil, no IL should be calculated for MOAH for paprikas in oil.

Example 5.2: IL for MOSH for 80% grilled paprikas in 20% sunflower oil should be calculated as follows:

- IL sunflower oil 15 mg/kg x 0.20 = 3.0 mg/kg
- IL processed vegetables: 5.0 mg/kg x 0.80 = 4.0 mg/kg
- IL grilled paprikas in oil: 7.0 mg/kg

Example 5.3 ILs MOSH and MOAH in grilled paprikas

- IL MOAH grilled paprikas: 2.0 mg/kg (no ML applies to grilled paprikas)
- IL MOSH grilled paprikas: 5.0 mg/kg (no ML applies to grilled paprikas

Summary

- ML MOAH grilled paprikas in oil: 1.2 mg/kg (example in accordance with ingredient composition in the example above)
- IL MOAH grilled paprikas: 2.0 mg/kg (no ML applies to grilled paprikas)
- IL MOSH grilled paprikas in oil: 7.0 mg/kg (example in accordance with ingredient composition in the example above)
- IL MOSH grilled paprikas: 5.0 mg/kg (no ML applies to grilled paprikas)