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Von: [redacted]
Gesendet: Mittwoch, 18. September 2024 14:15
An: [redacted]
Cc: [redacted]
Betreff: EU-Maßnahmen zu MOAH in Lebensmitteln „3. Option" / Hier: Anhörungsbesprechung am 16.9.2024 und Stellungnahme FoodDrinkEurope
Anlagen: Annex 3 - Final FoodDrinkEurope comments.pdf

Priorität: Hoch

Sehr [redacted]

wir hatten uns in Gesprächen bereits mit dem geänderten Verordnungsentwurf zur Regelung von MOAH als Kontaminante in Lebensmitteln, der sogenannten „3. Option", befasst und Sie auch über die erarbeiteten Positionierungen der Wirtschaft informiert.

Vor dem Hintergrund der anstehenden Beratungen zwischen der Kommission und den Mitgliedsstaaten hatte das zuständige Referat des Bundesministeriums für Ernährung und Landwirtschaft (BMEL) einige Fachverbände zur Anhörungsbesprechung am 16.9.2024 eingeladen; zugegen waren auch Vertreter der Bundesländer, von Landeslaboratorien, das BfR sowie durch Sie war das BMWK beteiligt.

Die Verbände konnten die bereits schriftlich vorgetragenen Einschätzungen des gesamten Regelungspaketes, einschließlich der Vorschläge zum Monitorring und zur Analytik erläutern. Nach meiner persönlichen Wahrnehmung wurden die Anliegen und Argumente der Verbände zur Weiterentwicklung des Konzepts der „3. Option" offen diskutiert. Für die Wirtschaftsbeteiligten gilt diese Option einvernehmlich als der Schritt in die richtige Richtung, die zur spezifischen, problemorientierten Regelung führen kann, sofern Klarstellungen und rechtssichere Formulierungen erfolgen.

Das BMEL teilt grundsätzlich die Kritik an der nicht eindeutigen Formulierung zur Ergänzung des Artikels 3 (Verarbeitungsfaktoren und Berechnung von Werten für zusammengesetzte Produkte) sowie den Wunsch nach erforderlicher Ergänzung von Messunsicherheiten. Es kam m. E. aber auch zum Ausdruck, dass das BMEL für einen breiteren Anwendungsbereich plädiert durch die Berücksichtigung von prozessbedingten Einträgen. Auch teilt das BMEL nicht die Anliegen nach Verlängerung von spezifischen übergangsfristen, sondern unterstützt ein schnellstmögliches Wirksamwerden. Der weitere Zeitplan und Diskussionsbedarf auf EU-Ebene ist vom BMEL jedoch schwer einzuschätzen.

Insofern sehen wir uns als Verbände nicht in allen Anliegen unterstützt und sind in Sorge, dass es möglicherweise zu „Rückschritten" kommt. Wir haben uns, wie Sie wissen, parallel auch an die Kommission gewandt; wir hoffen auf diesem Weg auf die Unterstützung durch das BMWK. U. E. sollte eine ausgereifte, rechtssichere und risikoorientierte Regelung Vorrang vor „zeitnahen Erfolgen" haben, zumal wir den gesundheitlichen Verbraucherschutz durch Wirkung des SCoPAFF-Statements bezüglich MOAH-Befunden als sichergestellt erachten.

An dieser Stelle die Information für Sie, dass die Projektgruppe MOH-Orientierungswerte dabei ist, mit der ALB gemeinsame Hinweise abzustimmen zur Anwendung des SCoPAFF-Statements; wir hoffen auf baldige Veröffentlichung.

Ergänzend senden wir Ihnen als Anlage ferner die finale Stellungnahme von FoodDrinkEurope zu den Regelungsvorschlägen für Mineralölkohlenwasserstoffe vom 12.9.2024. FoodDrinkEurope hat die Positionierung erweitert und plädiert wie der Lebensmittelverband für eine praktikable, verhältnismäßige Regelung, die nicht über das Erfordernis des wissenschaftlich begründeten gesundheitlichen Verbraucherschutzes hinausgeht und auch die Aspekte des Schutzes der Märkte, der Vermeidung von Lebensmittelverschwendung und die Nachhaltigkeit berücksichtigt.

Für Ihre Fragen stehe ich gerne zur Verfügung und verbleibe mit freundlichen Grüßen

[redacted]
Wissenschaftliche Leitung

Brussels, 12 September 2024

FoodDrinkEurope comments on latest draft legislative proposals for the risk management of mineral oil hydrocarbons (MOH)

We thank the Commission for the organization of the Stakeholder Forum on 18 January on the draft legislative proposals for the risk management of mineral oil hydrocarbons (MOH) and for taking in account concerns shared by FoodDrinkEurope and its members, together with other specific remarks raised by several of our sector associations.

The newly presented "3rd option" heads in a good direction compared to the previous options. It takes a differentiated and time-stretched regulatory path that is proportionate to the complexity of these contaminants that need to be mitigated at source, be it on the environment or through ingredients, lubricants or food contact materials among others. MOH can enter the food chain in many ways and can stretch to processes occurring in different supply chains in Third Countries.

The new "3rd option" is definitely an improvement compared to the previous options, however it is by no means a fully developed proposal. We think it still raises numerous questions related to the categories, the nature of the ingredients which can also be compound foods, the indicative values and the monitoring.

In our view, the scope of the current proposals for MLs for MOAH for complex ingredients, e.g. within B2B supply chains, and compound foods and the expected calculations will create constant scenarios of unclarity and misinterpretations by stakeholders and regulators alike. This not only within the European Union, but also with our commercial partners all over the world.

The food industry has put a great deal of effort into identifying and implementing effective minimization measures in all process chains within the EU and beyond , and will continue these efforts with increasing knowledge. Industry experience has shown that recommendations and guidance based on the ALARA ('As Low As Reasonably Achievable) principle and monitoring data, provide good support to mitigation measures.

We remain fully committed to investigate the sources of MOH in food and mitigating their presence down to ALARA as described in Regulation (EU) 2023/915 (provision 2), to guarantee the highest level of protection to consumers. We acknowledge that the reference to the ALARA principle is incorporated into this new revised proposal.

Still in this revised proposal, and to be able to cover thoroughly the huge scope implied in the proposal to mitigate the occurrence of MOH in food, we strongly encourage the Commission to proactively seek broader engagement from stakeholders, particularly those outside of the EU, to identify early on the impacts of the proposed maximum levels on their farmers and producing industries.

We view positively the inclusion of Confirmation and Characterization and of the Measurement Uncertainty. The sources and mitigation of MOH is a broader food safety issue across regions of the world. Moreover, many analytical challenges still prevail and we are highly concerned about the lack of harmonized, robust analytical methods for all food matrices. Including laboratory representatives from all Member States and even from Third Countries in this discussion is crucial to improve methodologies and increase capacities and efficiency. This will contribute to a successful enforcing of the regulation and the monitoring of mineral oils in foods across supply chains around the world.

Any EU measures on contaminants need to protect consumers but simultaneously be proportionate and clearly understood by stakeholders to improve the safety and quality of raw materials and ingredients sourced from Third Countries. The latter also with food security, avoidance of food waste, and sustainability in mind.

In this context and in addition to our presentation in the forum of January 2024 and follow-up letter, we would like to provide further feedback.

1. Analytical Methodology and Commercial Labs

FoodDrinkEurope, like other agri-food chain stakeholders, continues to highlight that the level of development of available analytical methods and laboratory capacities throughout Europe is far from sufficient, or equally distributed throughout the European Union, to implement this regulation appropriately, both in the context of official controls and the required self-monitoring by FBOs ('autocontrols'). We kindly ask the Commission not to disregard this situation.

The lack of fully developed validated methods for all matrices and specific quantification of measurement uncertainties will consequently lead to legal disputes. Meanwhile small and medium sized FBOs will be in a disadvantageous monitoring situation in Europe and in particular in third countries. Moreover:

- Due to the continued complexities in the analytical methods, we request the EU Commission to ask the JRC to speed up the method development for all relevant

food matrices defined before proceeding with MLs requirements while lacking robust analytical methods.

- In view of differences of laboratory capacities, using commercial laboratories leads to delays in testing, resulting in prolonged turnaround times. FBOs have limitations in managing product storage before release, causing disruptions in the supply chain.
- Suppliers based outside the EU may require extra time to align their processes with regulations. The information notice sent out by the EU COM, while helpful, is not sufficient for supply chains in Third Countries to be changed in the expected (short) time-frame.
- While the JRC Guidance prescribes the types of containers (non-MOH adsorbing PET and glass) and how to clean (with purified n-hexane) and seal (glass annealed at 400° C)[1], not all production sites or sites of sampling during export/import process are equipped to fulfil those requirements. We therefore wonder about the commercial availability of MOH-free and non-MOH adsorbing PET and glass and whether a commercial source will be provided.
- The proposed two-dimensional gas chromatography as an analytical method would be an improvement. This still does not resolve the issue of no standardised methods for matrices besides, e.g., for oils.
- We reiterate that for some commodities, the limits of quantification (LOQs) s for MOH cannot always be met, even by reputable laboratories with extensive experience in measuring MOH.
- The Commission's proposal lays out a very wide scope that may require in-depth investigations and testing upstream of supply chains. We stress that this is not feasible for SMEs; and even for larger enterprises this is a huge challenge. The limited availability of capable laboratories, particularly in Third Countries, will be a bottleneck to ensure supply.

2. Clarification on Recital 9/Article 3 point 4: Dried, diluted, processed and compound foods

It is our understanding that the revised Option 3 means that there will be no separate MLs for processed/composite foods and Art. 3 must be applied in such cases. To calculate the theoretical MOAH level of a compound food, Recital 9/Article 3 point 4 implies that FBOs:

[1] Page 7, FAQ document on the draft regulatory measures on mineral oil hydrocarbons (MOHs) in food

- know the full composition (%) of their ingredients; recipes are (mostly) not available from suppliers as there are legal Intellectual Property (IP) protections in place.
- Know the initial contamination level for each ingredient/material for which a MLs is to be established.
- where necessary, FBOs need to consider the dilution or concentration factor as per article 3;
- apply the theoretical (fat based) levels for all other ingredients for which no ML is set; and
- take into account the use levels of the ingredients to properly calculate the MLs and/or theoretical levels to ensure the compound food does not exceed the theoretical level when all of the above is taken into account.

All these considerations, illustrate the complexity of the proposed calculation in complex recipes and the difficulties to put in practice along supply chains. Ingredients often are sourced from several countries, tested in different labs, etc. It leaves room for a lot of misinterpretation by both stakeholders and authorities.

We also foresee a lot of confusion by the application of the calculation parameters for ingredients not listed in *section 5.5.* and consequently the impact of this regulation among operators of different food sectors and categories.

It is not clear from the text that the limits of determination mentioned as "*zero contribution*" should only apply to ingredients that are not specified in the regulation itself. There is the risk that these will be understood as *target values* for all processed and compound foods that are composed of both the listed ingredients and non-specified ingredients. The latter would effectively amount to a maximum quantity regulation for all composite products. This could equal the very restrictive approach and principle of zero tolerance we had in the previous options. This should not be the case.

We see a contradiction in the additionally proposed MOAH indicative values, which specify MOAH values above the determination limits for raw materials and processed products which are **not listed in Annex I Section 5.5**.

Clarification in the wording of **Article 3(4)** is therefore urgently required in order to enable a uniform understanding throughout Europe by all users, including authorities. A simplification is needed for the proposal to be operational.

Furthermore, the provision stating that *inputs during the production process can or should be disregarded* is difficult to apply in practice. There is not one definition of a "process". It is clear for dilution and drying processes, but for "processed or compound food", the series of processing steps involved in the manufacture of packaged

composite products can be not only numerous but very complex. In principle, many entry points are possible from a wide variety of process and packaging materials at different stages during manufacturing. These may not be easily distinguishable from one another. Thus, may make the determination of entry point and source of contamination very difficult.

In the case of findings in end products, the actual source of the contamination usually cannot be assigned with legal certainty. Which is why this exemption clause is probably intended to facilitate the calculation of maximum quantities in principle, but will not realistically be feasible in practice in the manufacturing and supply chains without further specification. From a monitoring perspective, it is completely left open how the processes and entry points are to be determined to offer legal certainty during enforcement.

3. List of raw materials and ingredients with maximum MOAH values in the section 5.5 in Annex I

This list of raw materials and ingredients characterizes MOAH as "process contaminants". This is intended to enable the assessment of raw materials and ingredients upstream in the process chains before further processing. However, the list contains various ambiguities that need to be clarified. For example:

- References to existing definitions may be necessary, i.e., in the area of animal-based foods (such as animal fats).
- It is questionable why sugar is listed as an ingredient category. We are not aware of any corresponding data to derive 0.5 ppm as the maximum MOAH level.
- Marine oils and essential oils differ greatly in composition and manufacturing processes. Therefore, grouping them in one category is not appropriate. The table lists both raw materials, such as spices or oil seeds, and further processing products made from these raw materials, such as essential oils or vegetable oils. This makes the classification incoherent.

4. Monitoring recommendation

While monitoring remains a core activity for the improving the control of contaminants in food, the monitoring of MOSH in this case is questionable as it contradicts EFSA's panel conclusion[2].

[2] In its update of the risk assessment of mineral oil hydrocarbons in food, EFSA concluded: "It is likely to very likely that the present dietary exposure to MOSH does not raise concerns for human health".

It is recommended to *"validate analysis methods for MOSH and MOAH in food on the basis of two-dimensional gas chromatography, in order to distinguish the presence of MOSH and MOAH from biogenic substances, which might interfere with the analysis in certain types of food"*. For more clarity on the scope, we propose adding *"biogenic substances and other endogenous hydrocarbons, e.g. POSH"*.

The theoretical calculation for MOAH in dried, diluted, compound and processed foods in the proposed regulation for MLs is the same as the calculation set out in the monitoring recommendation for these foods. To avoid legal complexity, a clearer distinction between the monitoring recommendation and the proposed regulation is needed.

We propose to only have commodities for which no MLs are established to be part of the monitoring recommendation, as this will help food industry to focus on the one hand on mitigation measures for the susceptible raw materials as by the main regulation, and start monitoring and collecting data as per the proposed monitoring recommendation. We suggest a simplification of the proposed legal complexity and avoid overlap between measures.

Recital 11 of the monitoring recommendation states: *Those levels should not affect the possibility to place on the market any food, but investigations should be carried out, when the concentration of MOSH and MOAH in a foodstuff exceeds those levels.* The recommendation should state clearly that indicative levels (ILs) are not food safety levels and thus should not be used as a threshold to remove products from the market.

5. Proposed regulation in combination with legal use of food additives and food contact materials

In the FAQ the EU Commission mentions that: "*regulatory measures for MOHs under the contaminants legislation will apply regardless of the source of MOHs, even if the source is an authorized food additive or food contact material*". There is then a discrepancy with point 9 of the Draft Monitoring Recommendation, which states: "*Where following the investigations MOSH and MOAH are detected in or originate from food contact materials, Member States should collect data on the food contact material (e.g. type and composition of the packaging material, presence of functional barrier, shelf life of the packaged food) and carry out further investigations in the establishments of the manufacturers, processors and distributors of food contact materials, to establish the systems operated by the businesses concerned (e.g. production and processing methods of food contact material, and documentation required under Commission Regulation (EC) No 2023/20068 on good manufacturing practices) as indicated in the guidance*". This should be corrected accordingly.

Moreover, MLs are not (yet) established for food additives and food contact materials. The above statement in the "FAQ" does not seem to take that into consideration. If a current, authorized food additive or food contact material is used it should not be cause for action.

While there are ongoing discussions about setting MLs in food additives, we would like to re-emphasise that the two Regulations (i.e. on foods and food additives) should be aligned both at timelines and ML values.

Conclusion

While asking for a more proportionate approach, we urge the Commission to aim for a regulation that is clear and comprehensible. A regulation that provides operators and enforcing authorities with sufficient certainty and clarity in its application.

We look forward to appropriate revisions of the drafts based on this feedback that fully take in account the identified unclarities of **Recital 9/Article 3 point 4**, the ongoing challenges across supply chains, and the analytical gaps **to make the proposals for MOH workable in practice**.

With more clarity on the scope and continuing with achievable levels based on ALARA, businesses will be able to target the precise points along their supply chains and invest in concrete actions for further mitigation of mineral oils where needed and when feasible.