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# *Latest Developments in Control and Enforcement of Mineral Oil Aromatic Hydrocarbon Levels in Food in the European Union*

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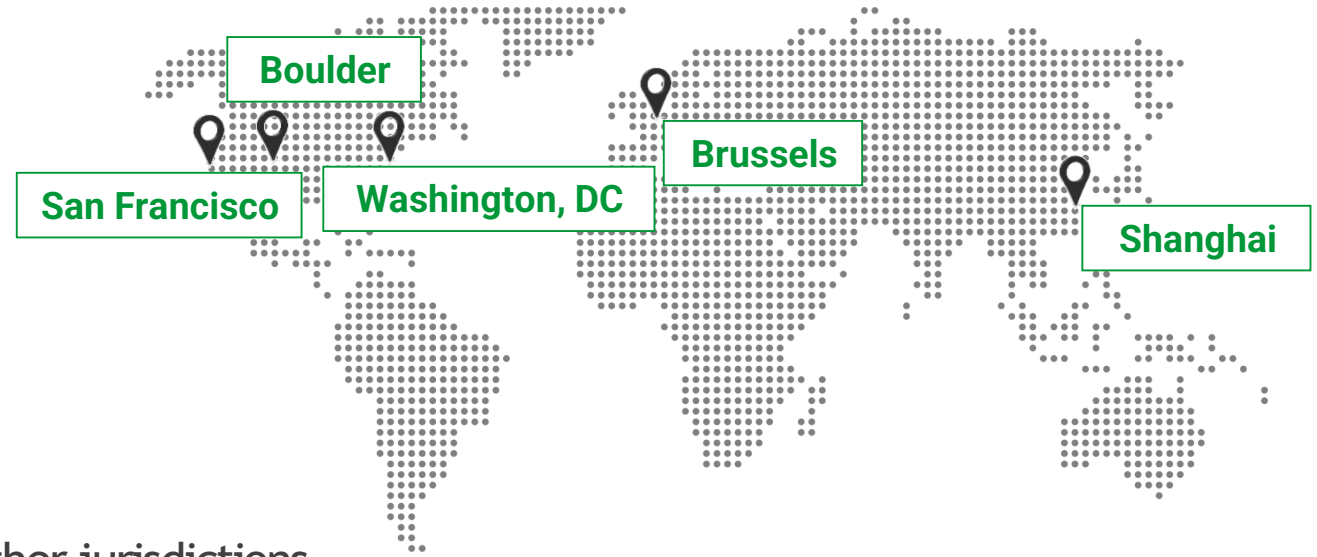


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# *Overview*

- Defining MOH with focus on MOAH – what are we talking about?
- Regulatory and factual background to establishing MOAH maximum levels
- Joint statement of EU Member States on MOAH in food and enforcement of LOQs
- Critical legal analysis of withdrawal or recall requirement relating to presence of MOAH in food
- Anticipated EU legislation re maximum MOAH levels in food
- Practical implementation issues
- Implications for different types of FBOs (producers of final foods, ingredients, food contact materials)
- Conclusions/Take Home Messages

# *DEFINING MOH WITH FOCUS ON MOAH - WHAT ARE WE TALKING ABOUT?*

# *Mineral Oil Hydrocarbons (MOH) (1)*

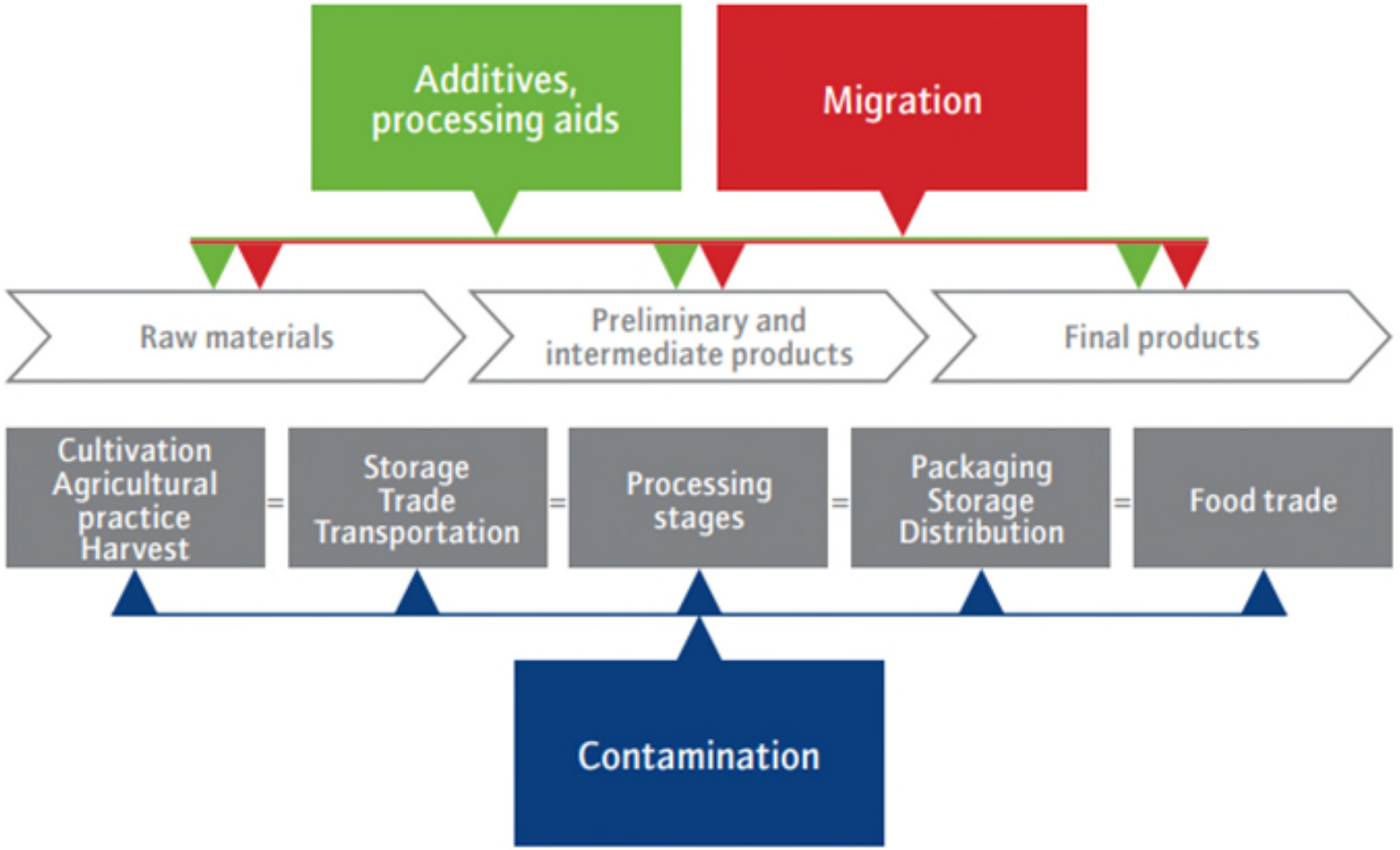
- Hydrocarbons containing 10 to about 50 carbon atoms derived mainly from crude oil, but also from coal, natural gas, and/or biomass

- The definition is somewhat arbitrary:
  - For EFSA, MOH encompass oil and waxes even when they are strongly modified, and the resulting products are similar to the ones obtained from petroleum
  - However, hydrocarbons naturally present as food components (example: surface wax on plants) or oligomeric hydrocarbons from polyolefins (POSH) are excluded

- MOH can be divided into two categories: Mineral Oil Saturated Hydrocarbons (MOSH) and Mineral Oil Aromatic Hydrocarbons (MOAH)

# *Mineral Oil Hydrocarbons (MOH) (2)*

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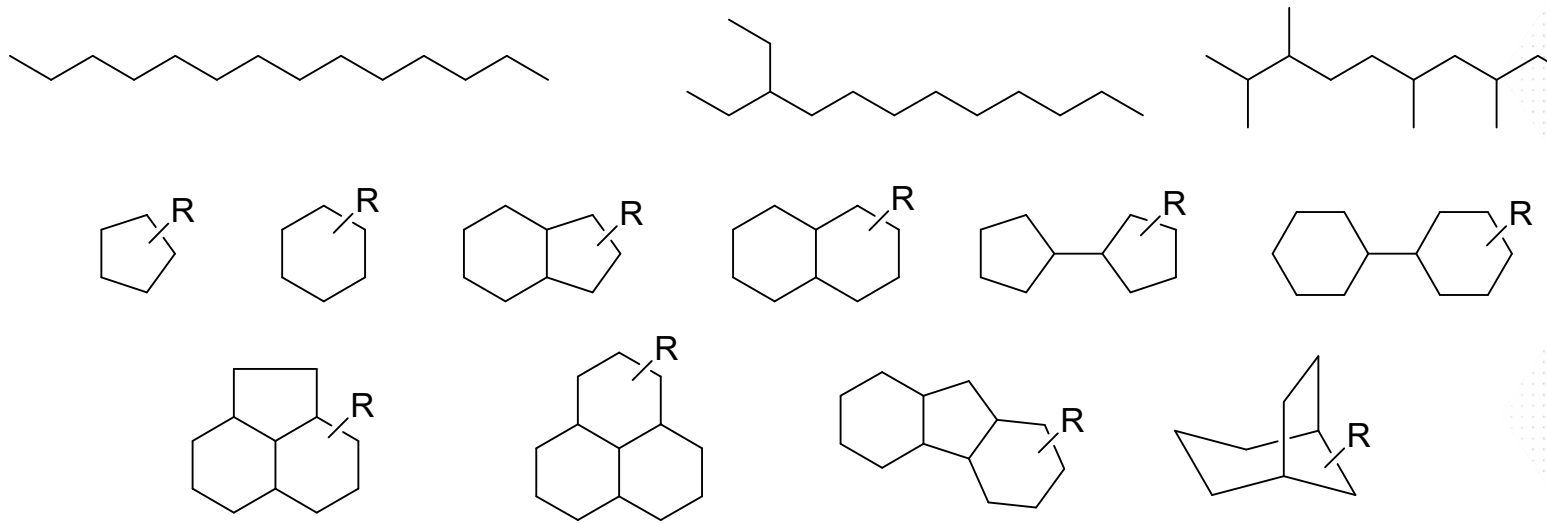
# *Mineral Oil Saturated Hydrocarbons (MOSH)*

- Comprises linear, branched, and (poly)cyclic alkanes. The key characteristic is that all are saturated: no double bonds are present. No aromatic rings.



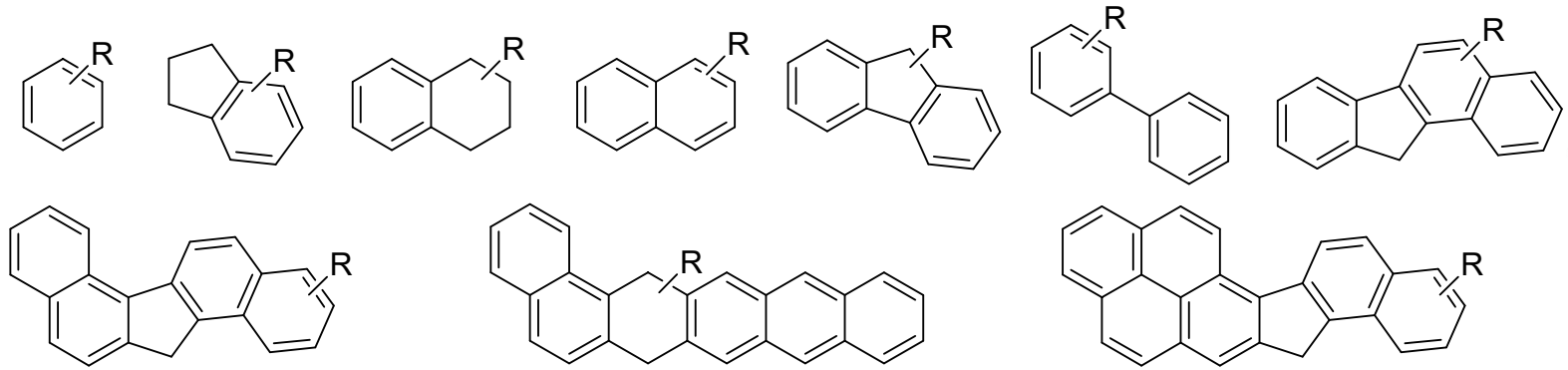

R: saturated alkyl chain (linear, branched or cyclic)

- Overall, the updated 2023 EFSA risk assessment of MOH in food concluded that the current dietary exposure to MOSH for all age classes raises no concern for human health.

# *Mineral Oil Aromatic Hydrocarbons (MOAH) (1)*

- Comprises hydrocarbons with at least one aromatic (benzene) ring




R: saturated alkyl chain (linear, branched or cyclic)

- The updated 2023 EFSA risk assessment of MOH in food found that no new studies since 2012 on acute toxicity, repeated-dose toxicity, or carcinogenicity were available for MOAH – neither in animals nor in humans. However, new studies confirm the conclusions of the EFSA 2012 opinion that the genotoxicity of MOH is associated with the presence of some three or more ring MOAH.

 | 

# *Mineral Oil Aromatic Hydrocarbons (MOAH) (2)*

- Little is known regarding the toxicity of 1-2 ring MOAH. Due to the lack of adequate oral toxicity studies, it was not possible to identify a reference point for this fraction. Therefore, a risk characterization of this MOAH fraction could not be performed, and thus, might raise a concern.

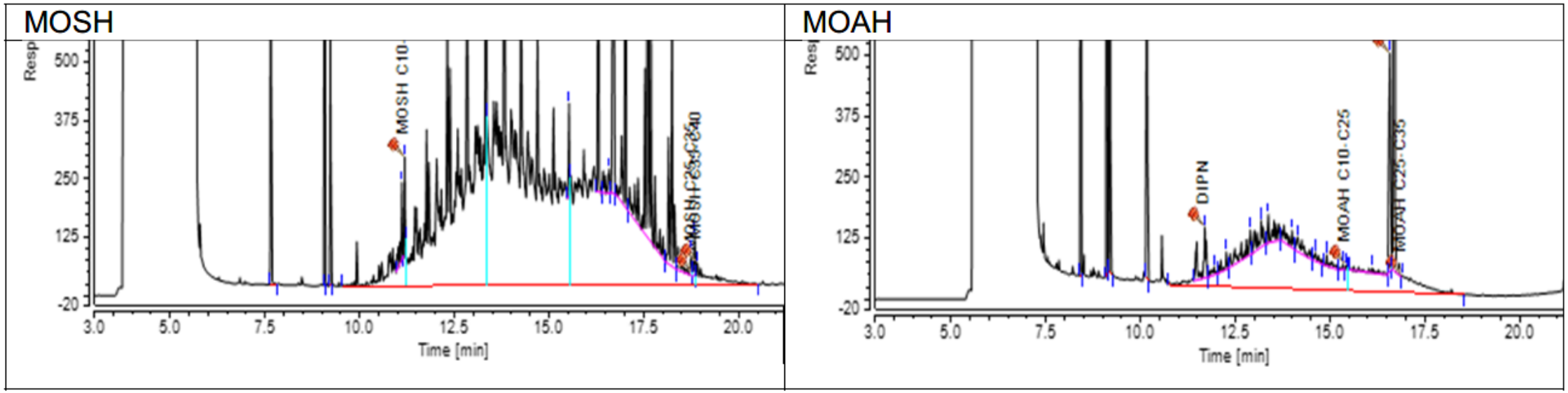
- EFSA used a surrogate RP approach derived from the increased incidence of total tumor-bearing animals observed in a carcinogenicity study of non-alkylated polycyclic aromatic hydrocarbons (PAH), using the sum of eight PAH.

- Based on the use of margin of exposure of ≥ 10,000 being considered of low concern for human health, MOAH dietary exposure raises a possible concern for human health.

# *Quantifying MOSH and MOAH (1)*

- MOSH and MOAH are very complex mixtures and, therefore, extremely difficult to analyze
- The Joint Research Centre (JRC) from the European Commission has published a *Guidance on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials*, that was updated in 2023 to provide minimum performance requirements for the analysis of MOSH and MOAH

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# *Quantifying MOSH and MOAH (2)*

| Parameter | Criterion |
|---|---|
| Applicability | Foods specified in Regulation (EC) No 915/2023 |
| Specificity | Free from matrix or spectral interferences |
| Recovery | 80-110 % (The recovery can be lower than 80%, when applying a sample preparation with aluminium oxyde for the determination of mineral oil saturated hydrocarbons or when permorming a sample preparation with epoxidation for the analysis of mineral oil aromatic hydrocarbons. |
| Within-laboratory reproducibility (intermediate precision) (RSDR)<br>Food with a fat content < 4 % | ≤ 15 % |
| Within-laboratory reproducibility (intermediate precision) ($RSD_R$)<br>Food with a fat content >= 4 % | ≤ 20 % |
| LOQ<br>Food with a fat content of < 4 % | ≤ 0.50 mg/kg |
| LOQ<br>Food with a fat content of 4 - 50% | ≤ 1.0 mg/kg |
| LOQ<br>Food with a fat content of > 50 % | ≤ 2.0 mg/kg |

- These performance criteria apply to both analysis of MOSH and MOAH.
- Due to the widespread use of MOH, additional notes are added to ensure that laboratories do not contaminate samples with mineral oil and that the reagents and equipment used for sampling and analysis is also clean from oil.
- Matrixes can lead to difficulties in analysis, so a very complex decision tree and auxiliary methods shall be used when necessary.

 

# *REGULATORY AND FACTUAL BACKGROUND TO ESTABLISHING MOAH MAXIMUM LEVELS*

# *Current Regulatory Framework Applicable to MOH (1)*

- **Food contaminants:**
  - **Regulation (EEC) No. 315/93** (framework Food Contaminants Regulation):
    - ***"contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all stages [of the food supply chain]"*** (Article 2(2))
  - **Regulation (EU) 2023/915** on maximum levels (ML) for certain contaminants in foods:
    - *"Maximum levels should be set at a strict level, which is reasonably achievable by following good (…) manufacturing practices and taking into account the risk related to the consumption of the food. In the case of a possible health risk,* ***maximum levels for contaminants should be set at a level, which is as low as reasonably achievable (ALARA).***" (Recital (2))
    - Establishes maximum levels in specific food for the MOAH benzo(a)pyrene and the sum of polycyclic aromatic hydrocarbons: benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene (Article 2(1) and Part 5.1 of Annex I)

 

# *Current Regulatory Framework Applicable to MOH (2)*

- **Food additives:**

  **Regulation (EU) No. 231/2012** laying down purity specifications for food additives

  - Establishes purity criteria for benzo(a) pyrene in food additives E 153 (vegetable carbon) and E905 (microcrystalline wax) of less than, or not more than, 50 µg/kg respectively
  - Microcrystalline wax (E 905): Petroleum wax; Hydrocarbon wax; Fischer-Tropsch wax; Synthetic wax; Synthetic paraffin

- **Food processing aids:**

  **France: Arrêté of 19 October 2006**:

  - Mineral oils meeting detailed specifications set are permitted under certain conditions for use for certain applications

 

# *Current Regulatory Framework Applicable to MOH (3)*

- Food contact materials (FCMs)

- Currently, material-specific requirements, e.g.,
  - Plastics
  - Paper
  - Inks
  - ….

 

# *Regulation of MOH in FCMs (1)*

| Plastics Regulation | FCM | Specifications | SML |
|---|---|---|---|
| Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity | 93 | Not to be used for articles in contact with fatty foods for which simulant D1 and/or D2 is laid down. **Average molecular weight not less than 350 Da**. Viscosity at 100 °C: not less than 2,5 cSt (2,5 × 10-6 m2 /s). **Content of hydrocarbons with Carbon number less than 25: not more than 40 % (w/w).*** **See EFSA opinion published in Feb. 2023 (additional requirement: mandatory hydrogenation step in manufacturing step)** * EFSA Journal - 2023 - - Safety assessment of waxes paraffinic refined derived from petroleum-based or synthetic.pdf | **0.05 mg/kg*** **(Up to 5 mg/kg)** |
| Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity | 94 | **Average molecular weight not less than 500 Da**. Viscosity at 100 °C: not less than 11 cSt (11 × 10-6 m2 /s). **Content of mineral hydrocarbons with Carbon number less than 25: not more than 5 % (w/w).** | - |
| White mineral oils, paraffinic, derived from petroleum-based hydrocarbon feedstocks | 95 | **Average molecular weight not less than 480 Da**. Viscosity at 100 °C: not less than 8,5 cSt (8,5 × 10-6 m2 /s). **Content of mineral hydrocarbons with Carbon number less than 25: not more than 5 % (w/w).** | - |

# *Regulation of MOH in FCMs (2)*

| Plastics Regulation | FCM | Specifications | SML |
|---|---|---|---|
| Petroleum hydrocarbon resins (hydrogenated) | 97 | Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermalpolymerisation of dienes and olefins of the aliphatic, alicyclic, and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation, and additional processing.<br>Properties:<br>• Viscosity at 120 °C: > 3 Pa.s,<br>• Softening point: > 95 °C as determined by ASTM Method E 28-67<br>• Bromine number: < 40 (ASTM D1159)<br>• The colour of a 50 % solution in toluene < 11 on the Gardner scale<br>• **Residual aromatic monomer ≤ 50 ppm (This is a limit on MOAH)** | |

 

# *Regulation of MOH in FCMs (3)*

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| Member State - Paper | FCM | Specifications | SMLs |
|---|---|---|---|
| **The Netherlands** – Chapter II (Paper) of Dutch Regulation on Packaging and Consumer Articles | - | Paraffin, liquid (refined mineral oil) meeting the following specifications: ◦ colour weaker than Standard Saybolt 30; ◦ odour nearly absent; ◦ and whose absorption of UV light meets the requirements defined in Annex B (Assessment Methods) (listed in several sub-sections of Chapter II)<br>NB: Listing with same specifications in other chapters of Dutch Reg. (Rubber, metal, wood & cork, coatings, epoxy polymers)<br><br>Also listings for "paraffin, microcrystalline," "paraffin, solid, including synthetic," and "petrolatum (vaseline)" | - |
| **Germany** – Draft MOH Ordinance (not adopted) | | Covered: **alkylated aromatic hydrocarbons of carbon numbers C15 to C35** containing **one or more rings** (other than diisopropylnaphthalenes)<br>FCMs made of paper/paperboard with recycled paper content may be used provided behind a functional barrier<br>Functional barrier requirement not applicable if manufacturer ensures migration to food prevented or applicable requirements limit the content of MOAH in final articles<br>*calculated from area-related result of the test using food simulant | 0.5 mg/kg or 0.15 mg of sum of MOAH per kg food* |

# *Regulation of MOH in FCMs (4)*

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| Member State - Inks | Substance | Substance No. / SML | Specifications |
|---|---|---|---|
| **Germany** - Printing Inks Ordinance amending Consumer Goods Ordinance 2/12/2021 | Refined waxes obtained from petroleum or from synthetic hydrocarbons, high viscosity<br>= FCM 94 in Plastics Reg. | 326<br><br>0.05 mg/kg | Average molecular weight: at least 500 Da<br>Viscosity at 100 °C: at least 11cSt (11x10-6 10-6 m2 /s)<br>Content of mineral hydrocarbons with a carbon number less than 25: not more than 5 % by weight |
| | Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity<br>= FCM 93 in Plastics Reg. | 377<br><br>No SML | Not to be used for articles in contact with fatty foods for which simulant D1 and/or D2 is laid down.<br>**Average molecular weight not less than 350 Da.**<br>Viscosity at 100 °C: not less than 2,5 cSt (2,5 × 10-6 m2 /s). **Content of hydrocarbons with Carbon number less than 25: not more than 40 % (w/w).** |
| | White mineral oils, paraffinic, obtained from petroleum-based hydrocarbons<br>= FCM 95 in Plastics Reg. | 380<br><br>No SML | **Average molecular weight not less than 480 Da.**<br>Viscosity at 100 °C: not less than 8,5 cSt (8,5 × 10-6 m2 /s). **Content of mineral hydrocarbons with Carbon number less than 25: not more than 5 % (w/w).** |

# *Regulation of MOH in FCMs (5)*

| Member State - Inks | Substance | Specifications |
|---|---|---|
| France – Order of 13 April 2022 | MOAH with 1-7 aromatic rings | **Until 31 Dec 2024**: prohibition on the use applies for **MOAH** where the mass concentration in ink of those substances is greater than **1%** and<br>**as from 1 January 2025**: when it is greater **0.1%,** or where the mass concentration in ink for compounds of **3 to 7 aromatic rings is greater than 1 ppm**; |
| | MOSH with 16-35 carbon atoms | **As from 1 Jan 2025**: prohibition of use of MOSH, where the mass concentration in ink of those substances is greater than **0.1%.** |

 

# *Chronology of Significant Developments in Addressing Potential MOAH Risks (1)*

- **June 2012:** EFSA issues its Scientific Opinion on MOAH in Food:
  - **MOAH with three or more aromatic rings** may be mutagenic and carcinogenic and, therefore, of potential concern
- **2017**: Recommendation (EU) 2017/84 on the monitoring of mineral oil hydrocarbons in food and food contact materials
  - EU Member States requested to monitor mineral oil hydrocarbons (MOH) in food and to determine whether presence due to migration from food contact materials
- **2019:** EFSA rapid risk assessment on possible risks from MOAH contamination of infant and follow-on formula
  - *"in the absence of information on the presence or absence of 3-7 ring polycyclic aromatic compounds (3-7 PAC), the detection of mineral oil aromatic hydrocarbons (MOAH) in food should be considered of potential concern for human health."*
- **June 2020:** ScoPAFF statement that infant and follow-on formula containing 1mg/kg of MOAH (LOQ at time) should be withdrawn from market

 

# *Chronology of Significant Developments in Addressing Potential MOAH Risks (2)*

- **December 2021:** Foodwatch report on studies of MOAH/MOSH contamination of food products:
  - MOAH found in 12% of samples in range between 0.63 mg/kg and 82 mg/kg

- Joint statement of the Member States regarding presence of MOAH in food, adopted in **21 April 2022** ScoPAFF meeting and **clarified in 19 October 2022** ScoPAFF meeting

- Updated **2023** JRC Guidance on sampling, analysis, and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials

- **July 2023** EFSA update of risk assessment of MOAHs in food

- Draft Commission Regulation to amend Contaminants Regulation (EU) 2023/915 regarding maximum levels of MOAH in food (SANTE on PLAN **2023**/2345)

 

# *JOINT STATEMENT OF EU MEMBER STATES ON MOAH IN FOOD AND ENFORCEMENT OF LOQS*

# *What did Joint Statement of the EU Member States Say? (1)*

- EU Member State agreement to withdraw or recall any food in which **sum of MOAH (C10-C50) concentrations** meets or exceeds the following relevant maximum limit of quantification (LOQ):
  - 0.5 mg/kg for dry foods with a low fat/oil content (≤ 4% fat/oil)
  - 1 mg/kg for foods with a higher fat/oil content (> 4% fat/oil, ≤50% fat/oil)
  - 2 mg/kg for fats/ oils or foods with >50% fat/oil
- Implicit application of withdrawal or recall requirement to final foods only?
- Replaces SCoPAFF statement of 23 June 2020 on MOAH in infant and follow-on formula
- Legal basis for withdrawal or recall cited as Article 14 of the General Food Law (Regulation (EC) No 178/2002)
- "*Responsibilities of food business operators in accordance with Article 19 of the General Food Law*" also emphasized

 

# *What did Joint Statement of the EU Member States Say? (2)*

- EU Member States to:
  - Perform controls on presence of MOAH in microcrystalline wax used in food contact materials to confirm whether a source of food contamination and take preventive measures, if necessary
  - Check whether food grade microcrystalline wax used in food contact materials complies with specifications for food additive E905, in particular re: presence of benzo[a]pyrene
  - Evaluate whether changes needed to specifications of certain additives or FCMs

- **Analysis and sampling methods** according to Regulation (EC) No 333/2007 on sampling and analysis for the official control of contaminants
  - Reference to (previous) JRC Guidance on sampling and analysis

 

# *Overview of MOAH LOQ Enforcement in the EU (1)*

- Joint Statement "*applicable as from the moment the minutes of the SC PAFF meeting of 21 April 2022 are published*" (ScoPAFF Meeting 21 April 2022)
- In practice, EU Member State deviation in scope of implementation of LOQs and timing
- **Spain:**
  - Spanish Food and Nutrition Safety Agency (AESAN):
    - "*once…the final [2023 EFSA] opinion is published, the Commission and Member States will take appropriate risk management measures ...*"
- Some EU Member States have simply incorporated LOQs in enforcement control manuals (with immediate effect?)
- **Netherlands:**
  - NVWA announced temporary enforcement policy of MOAH in food Tijdelijk handhavingsbeleid NVWA MOAH in levensmiddelen per 1 januari 2024 (nedverbak.nl) from 1 January 2024 but…
    - **No requirement to withdraw** if meet or exceed 2 mg/kg action limit for foods with a fat content > 50%, save in exceptional circumstances

 

# *Overview of MOAH LOQ Enforcement in the EU (2)*

- **EU Rapid Alert System for Food and Feed (RASFF)**
  - Since 4 February 2020, the RASFF network records **31 notifications** relating to presence of MOAH in food, of which:
    - *15 notifications for fats and oils; 8 for cereals and bakery products; 2 for nuts, nut products and seeds; 2 for soups, broths, sauces and condiments; 1 for cocoa and cocoa preparations, coffee and tea; 1 for herbs and spices; 1 for prepared dishes and snacks and 1 for other food products (coconut milk powder)*
    - *20 notifications from Germany; 4 from Switzerland; 3 from Belgium; 1 from France; 1 from Italy; 1 from Luxembourg; and 1 from the Netherlands*

 

# *CRITICAL LEGAL ANALYSIS OF WITHDRAWAL OR RECALL REQUIREMENT RELATING TO PRESENCE OF MOAH IN FOOD*

# *Legal Status of Joint Statement*

- Not legally binding (yet) - simply an agreement between EU Member States
- Withdrawal/recall requirement applicable immediately from date of adoption – no warning!
- Raises obvious questions concerning legitimate expectation and legal certainty

 

# *Are the Requirements for Relying on the Precautionary Principle Met? (1)*

- **Joint Statement clearly based on precautionary approach:**

  - Withdrawal or recall required where *"… quantified presence of MOAH, which are possible genotoxic carcinogens, in food"*

- *"Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority…and the precautionary principle where the conditions laid down in Article 7(1) are relevant..."* (Article 6(3) of Regulation (EC) No 178/2002)

- *Article 7 of Regulation (EC) No 178/2002 (Precautionary principle)*

  *1. …where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures…may be adopted, pending further scientific information for a more comprehensive risk assessment.*

  *2. Measures adopted…shall be proportionate and no more restrictive of trade than is required…The measures shall be reviewed within a reasonable period of time…"*

 

# *Are the Requirements for Relying on the Precautionary Principle Met? (2)*

- Has "*the possibility of harmful effects on health [been] identified*" by a risk assessment?
  - Only for 3 to 7 aromatic ring MOAH (incomplete risk assessment), not for 1 to 2 aromatic rings (no risk characterisation)
  - LOQs not reflecting latest 2023 EFSA updated risk assessment
    - *Confirm that genotoxicity associated with presence of MOAH with three or more aromatic rings*
    - *"Due to the lack of adequate oral toxicity studies, it was not possible to identify a reference point for the 1-2 ring MOAH. Therefore, a risk characterisation of this MOAH fraction could not be performed. The CONTAM Panel concluded that, in the absence of reliable toxicity data, the dietary exposure to 1-2 ring MOAH might raise a concern."* (Summary, EFSA Update of the risk assessment of mineral oil hydrocarbons in food, 12 July 2023)
  - *"The Commission informed the Member States on stakeholder comments in favour of waiting for the updated EFSA risk assessment before taking further risk management measures."* (Summary Report of 21 April 2022 ScoPAFF meeting)
- Supporting case law of European Court of Justice:
  - *"…a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken..."* (Case T-429/13, paragraph 120)
  - *"[precautionary measures] cannot validly be based on a purely hypothetical approach to the risk, founded on mere assumptions which have not yet been scientifically verified."* (paragraph 77, Joined Cases C-58/10 to 68/10)

 

# *Are the Requirements for Relying on the Precautionary Principle Met? (3)*

- Is the withdrawal or recall requirement based on the LOQs proportionate and non-discriminatory?
- Communication (COM(2000) 1 final) on the precautionary principle
  - *"…reliance on the precautionary principle is no excuse for derogating from the general principles of risk management. These general principles include: • proportionality, • non-discrimination…The principle of non-discrimination means that…different situations should not be treated in the same way, unless there are objective grounds for doing so…Measures should not be discriminatory in their application"* (Section 6.3)
- Same LOQ applied for all MOAHs and foods (subject to fat content) without distinction, irrespective of the fact that:
  - MOAHs "*a diverse group of chemical compounds*" (European Commission Catalogue - European Commission (europa.eu)) not specifically defined
    - Contrast maximum levels for Polycyclic Aromatic Hydrocarbons (PAHs) in Contaminants Regulation (EU) 2023/915 which names specific substances used as markers of the contamination
  - Safety concerns identified by EFSA for 3 to 7 aromatic ring MOAH only
  - ALARA (which may be higher than LOQ) may depend on technical limitations for different foods and not simply dependent on fat content
  - Dietary exposure varies depending on specific foods
    - *"Maximum levels should be set …taking into account the risk related to the consumption of **the food**."* (Recital (2) of Regulation (EU) 2023/915 on maximum levels for contaminants in food)
  - Even some "*serious*" contaminants (aflatoxins) not regulated at LOQ levels under Contaminants Regulation (EU) 2023/915

 

# *Are the Requirements for Relying on the Precautionary Principle Met? (4)*

- Supporting case law of the European Court of Justice:
  - *"the scheme laid down…covers, indiscriminately,…all amino acids and their derivatives, without distinguishing possible categories or types of substances…the risk analysis …must still clearly identify the common elements or characteristics of the substances concerned, whose real risk for human health cannot be excluded.*

    …

    *the risk analysis and the resulting application of the precautionary principle appear to concern only certain amino acids,…insufficient to justify a [restriction]…which applies without distinction to all amino acids." (Case C-282/15, paragraphs 64 and 65)*

 

# *Are the Requirements for Relying on the Precautionary Principle Met? (5)*

- Concerns raised re September 2023 Commission Guidelines for harmonised risk management approach for food products containing genotoxic carcinogens:
  - *"[The German] competent authorities continue to have concerns about the implementability of the proposed approach...In particular,* ***the lack of legal certainty in the implementation in enforcement due to the absence of the required risk assessment and proportionality check in individual cases****…"* (Summary report of meeting of SCoPAFF meeting 22 September 2023 (sante.g.3(2023)11118040))
- Are the limits "*provisional (…) pending more scientific information for a more comprehensive risk assessment*" (Article 7 of Regulation (EC) No 178/2002)?
  - Consistent with anticipated codification in Contaminants Regulation (EU) 2023/915 (without review clause)?

 

# *ANTICIPATED EU LEGISLATION RE MAXIMUM MOAH LEVELS IN FOOD*

# *Anticipated EU Legislation Concerning Maximum MOAH Levels (1)*

- **Draft Commission Regulation to amend Contaminants Regulation (EU) 2023/915 regarding maximum levels of MOAH in food (SANTE PLAN 2023/2345)**
  - Codifies discriminatory application of the SCoPAFF statement limits (set at LOQ)
    - *"…concerns for human health [of 1 and 2 ring MOAH] cannot be excluded. Maximum levels for MOAH should therefore be set…"* (Recitals 6 and 7)
  - "*in most foods occurrence of quantifiable concentrations of MOAH can be prevented*"
    - Except for foods where concentration below LOQ cannot be achieved, subject to higher maximum level to be lowered in future in accordance with contamination mitigation measures identified by FBO
    - Annex considers ***either*** applying LOQs to a wide range of foods ***or*** to all foods other than fresh or frozen primary products
  - *"taking into account the '[ALARA]' principle maximum levels for MOAH in food should be set at the [LOQ]"* (Recital 8)
    - Application of LOQs to broad food categories ignores that ALARA dependent on what is achievable by GMP which is food specific

- **Express absence of transitional period** because "*Member States have been enforcing controls of MOAH on the basis of Article 14 of Regulation (EC) No 178/2002 in infant and follow on formulae since June 2020 and in all foods since February 2022, and taking into account the fact certain MOAH are genotoxic carcinogens…"* (Recital (9))
  - Ignores perspective of **third country (non-EU) suppliers** who may be unaware of Joint Statement in absence of notification of any draft legislation to WTO
  - Enforcement only recent in practice
  - Need for **progress on analytical methods and laboratory capability** and **insufficient risk characterisation of MOAH require a transition period**

 

# *Anticipated EU Legislation Concerning Maximum MOAH Levels (2)*

- **Commission Discussion paper as regards maximum levels for MOAH in food**
  - Commodity groups which are main source of exposure, except for "*unprocessed products, in which hardly any MOAH is found*"
  - Onus on FBOs to justify higher levels for specific foods and propose contamination mitigation measures with timelines (*today's Stakeholder forum*)
  - Anticipates exemption for food additives - dealt with under amendment to Food Additive Specification Regulation (EU) No. 231/2012 (April 21 2022 ScoPAFF summary report and 2023 EFSA Opinion)
- **Draft Implementing Regulation amending Regulation (EC) No 333/2007 as regards methods of sampling and analysis for control of levels of MOAH in food (SANTE PLAN 2023 2726)**
  - Annex lays down measures to avoid cross-contamination of MOAH from other sources

 

# *Anticipated EU Legislation Concerning Maximum MOAH Levels (3)*

- **Latest intelligence on timing**
  - Stakeholders to comment and provide data by **27 February 2024**
  - Expected Standing Committee vote on draft Regulation by Q3-Q4 (?)
  - Possible adoption by early 2025 (?)
  - In meantime: **Joint EU Member States Statement remains valid, and thus request for recall/withdrawal**

 

# *PRACTICAL IMPLEMENTATION ISSUES*

# *Practical Implementation – Issues with Available Analytical Methods*

- **April 2022 ScoPAFF meeting summary report:**
  - *"A Member State informed that food business operators expressed concerns on how the statement will be implemented by Member States in advance of…the reliability of the analytical methods."*
- **Updated 2023 JRC Guidance on sampling, analysis, and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials**
  - *"The analysis of MOH in food and FCM, especially in food with high fat content, is very demanding in terms of methodology and interpretation."*
- **Shortcomings acknowledged by EU Member States**
  - Dutch Food Authority already stated in October 2023 the following to their national industry
    "*(…) according to the JRC Guidance, the "**LC-GC-FID method** is referred to as the method of choice for the quantification of mineral oils in routine analysis" (…) it is notably recognized by experts that **it does not perform well enough to distinguish the MOAHs of most concern, which should definitely not be present in food [i.e., 3-7 PAC]**, from the others (which could then be considered as "**false positives**"). Food business operators and the EU Member States may discuss analytical problems **leading to potential false positives and disproportionate and, therefore, unjustified recalls and withdrawals**."*
- **Commission Discussion paper as regards a monitoring Recommendation on mineral oil hydrocarbons in food**
  - *"EFSA identified various challenges as regards the sensitivity and the specificity of the analytical methods…it is recommended to validate more sensitive analytical methods, in order to achieve the target LOQs for MOAH"*

 

# *Practical Implementation – Commercially Workable?*

- Current risk management focus on final foods does not address sources
  - Will it achieve its aim?
  - Contractual/commercial implications? Indemnities?
- Laboratory capacity:
  - Accreditation and certification?
  - Workload?
- ALARA implemented?
- Global supply chain disruption?
- Products already in supply chain (no transition period)?

 

# *IMPLICATIONS FOR FBOs*

# *Implications for FBOs (1)*

- **Producers of final food products** where quantified presence of MOAH detected:
  - Comply with competent authority mandatory recall or withdrawal following official controls
  - Voluntary recall or withdrawal following FBO own controls (Article 19 of Regulation (EC) No 178/2002)

- **Food ingredient suppliers** (including food additives):
  - Downstream customers will likely request assurances concerning MOAH levels from upstream suppliers

- **Producers of final food products & food ingredient suppliers** (including food additives):
  - MOAH control to be included in HACCP (Hazard Analysis and Critical Control Points) plans
    - Dutch Food Safety Authority temporary MOAH enforcement policy: *"the NVWA [may] conduct an inspection to verify whether a company is fulfilling its responsibilities regarding raw material control and hazard analysis related to MOAH. If this is not the case, and the NVWA identifies a violation in the area of HACCP, the NVWA will enforce…"*

 

# *Implications for FBOs (2)*

- **Food contact materials:**
  - Specific actions to control MOAH to be set under FCM legislation
  - 21 April and 19 October ScoPAFF summary reports and latest 2023 EFSA Opinion suggest future update of technical specifications in dedicated EU food contact material and/or additives legislation

- **Options for challenging control finding of MOAH quantifiable limit:**
  - Question sampling plan, analytical method used
  - Request second expert opinion (documentary review of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert) or counter sample (Article 35 of Regulation (EU) 2017/625)
  - Use of more advanced analytical methods to further characterise MOAH

 

# *TAKE HOME MESSAGES*

# *Take Home Messages (1)*

- European Commission "*trying to run before it can walk*" in addressing potential MOAH risk:
  - Inadequate analytical methods – require improvement
  - Restrictions imposed before risk identified for certain (1 and 2 aromatic ring) MOAH
  - For the Commission, ALARA = LOQ applying irrespective of specific food - is this assumption correct?
  - One size fits all MOAH approach, notwithstanding a family of different substances
  - Rushed legislative adoption inconsistent with Commission proposal to permit higher maximum MOAH limits for certain foods
- Raises questions re: legal basis of withdrawal and recall obligation – legal challenge?
  - Non-binding agreement adopted without transition period – legitimate expectation? Legal certainty?
  - Conditions for reliance on precautionary principle not met (no risk assessment (cannot be ruled out ≠ identified health risk), discriminatory and disproportionate, not provisional measures)
  - Issues reflected by EU Member State deviations in scope of enforcement and misgivings
  - When the analytical methods are improved, will the Commission amend the maximum limits to align with the new (lower) LOQs?
    - Concern of legal uncertainty

 

# *Take Home Messages (2)*

- Implications for various food supply chain actors
  - Final food producers caught directly by Joint Statement and draft Regulation
  - Amendment of technical specifications in dedicated food additive and food contact material anticipated
  - Pressure on other ingredient suppliers to provide assurances re MOAH levels to downstream users
  - All FBOs required to address MOAH in HACCP plan
  - FBO to consider strategy where quantifiable MOAH detected in product (question sampling, challenge withdrawal and recall obligation?)
  - FBOs to make case that MOAH concentrations below LOQs in their product cannot be achieved

 

# Thank You!

**Any questions?**

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