EUROPEAN MARGARINE ASSOCIATION

IMACE Standpoint on Setting maximum levels for Mineral Oil Aromatic Hydrocarbons (MOAH) in foods

Mrs Siska Pottie

IMACE Managing Director

Thursday, 18 January 2024

European Comission Online Forum on MOH

Who are we ?

- ✓ The voice of the margarine producers
- ✓ Established in 1958
- ✓ Representing > 70% of the European Margarine Sector
- ✓ Representing both B2B and B2C companies
- ✓ Committed to the advancement of sustainable and healthy food systems

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Our Members

CORPORATE MEMBERS

ASSOCIATION MEMBERS

Die Lebensmittelindustrie

SWISS OLIO

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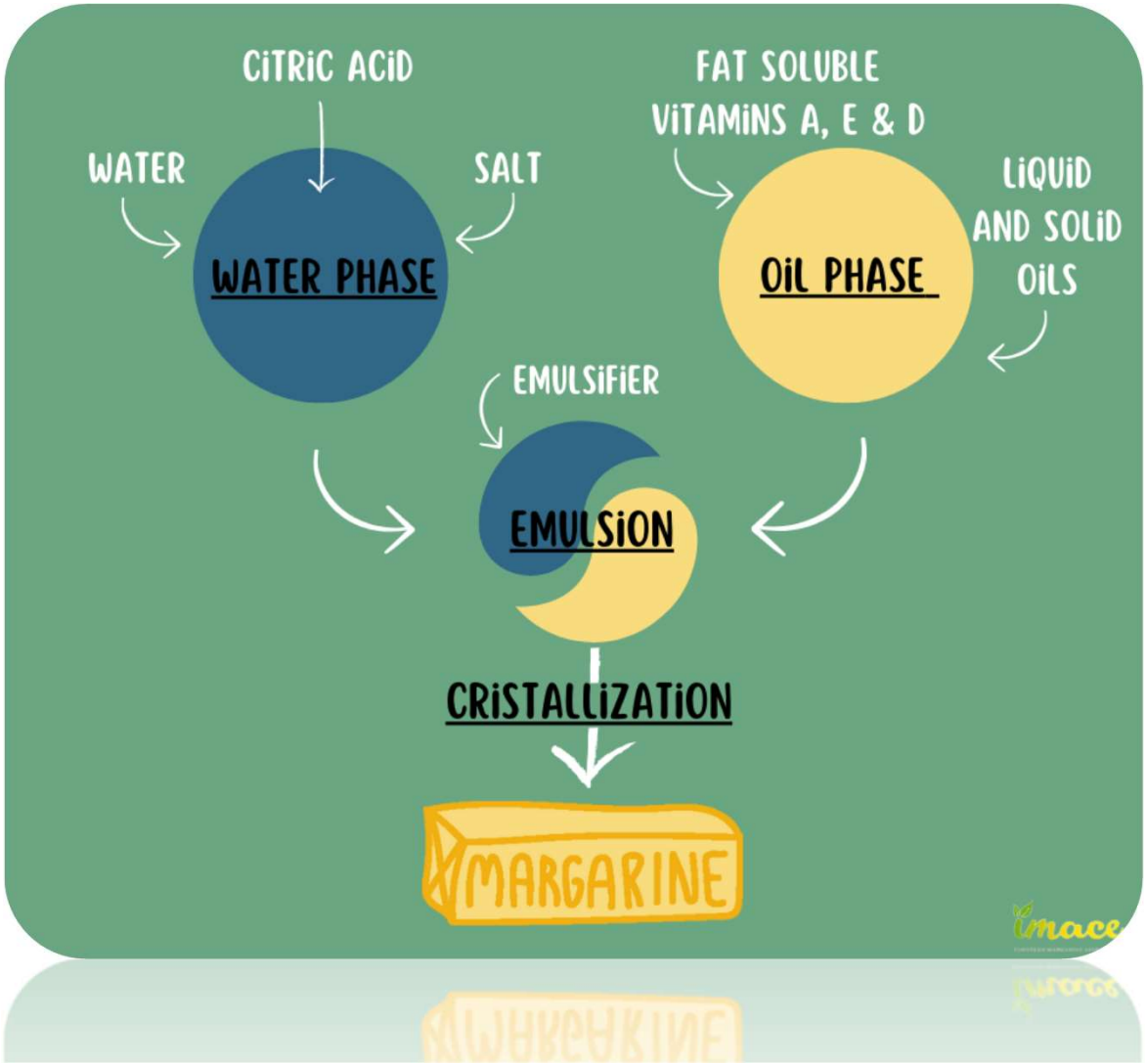
The Recipe….



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What are the types of margarine and vegetable fat spreads?

- Types:
  - **Soft** and spreadable margarines (in tub)
  - **Liquid** cooking blends (in bottle)
  - **Hard blocks** for baking (in wrapper)
  - **B2B** Specific margarine Products for use in other food sectors such as bakery
- **Fat levels** of vegetable fat spreads vary **from 10 % to less than 90 %**
- Definitions*:
  - ***Margarine*** = fat percentage: > 80 % & < 90 %
  - ***Vegetable spread*** = fat percentage: < 80 % & > 10 %

*CMO regulation 1308/2013

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REGULATION

REGULATION (EU) No 1308/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 December 2013

establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007

Appendix II

Spreadable fats

Fat group	Sales description	Product categories
Definitions		Additional description of the category with an indication of the % fat content by weight
A. Milk fats Products in the form of a solid, malleable emulsion, principally of the water-in-oil type, derived exclusively from milk and/or certain milk products, for which the fat is the essential constituent of value. However, other substances necessary for their manufacture may be added, provided those substances are not used for the purpose of replacing, either in whole or in part, any milk constituents.	1. Butter	The product with a milk-fat content of not less than 80 % but less than 90 %, a maximum water content of 16 % and a maximum dry non-fat milk-material content of 2 %.
	2. Three-quarter fat butter (*)	The product with a milk-fat content of not less than 60 % but not more than 62 %.
	3. Half fat butter (**)	The product with a milk-fat content of not less than 39 % but not more than 41 %.
	4. Dairy spread X %	The product with the following milk-fat contents: — less than 39 %, — more than 41 % but less than 60 %, — more than 62 % but less than 80 %.
B. Fats Products in the form of a solid, malleable emulsion, principally of the water-in-oil type, derived from solid and/or liquid vegetable and/or animal fats suitable for human consumption, with a milk-fat content of not more than 3 % or the fat content.	1. Margarine	The product obtained from vegetable and/or animal fats with a fat content of not less than 80 % but less than 90 %.
	2. Three-quarter-fat margarine (***)	The product obtained from vegetable and/or animal fats with a fat content of not less than 60 % but nor more than 62 %.
	3. Half-fat margarine (****)	The product obtained from vegetable and/or animal fats with a fat content of not less than 39 % but not more than 41 %.

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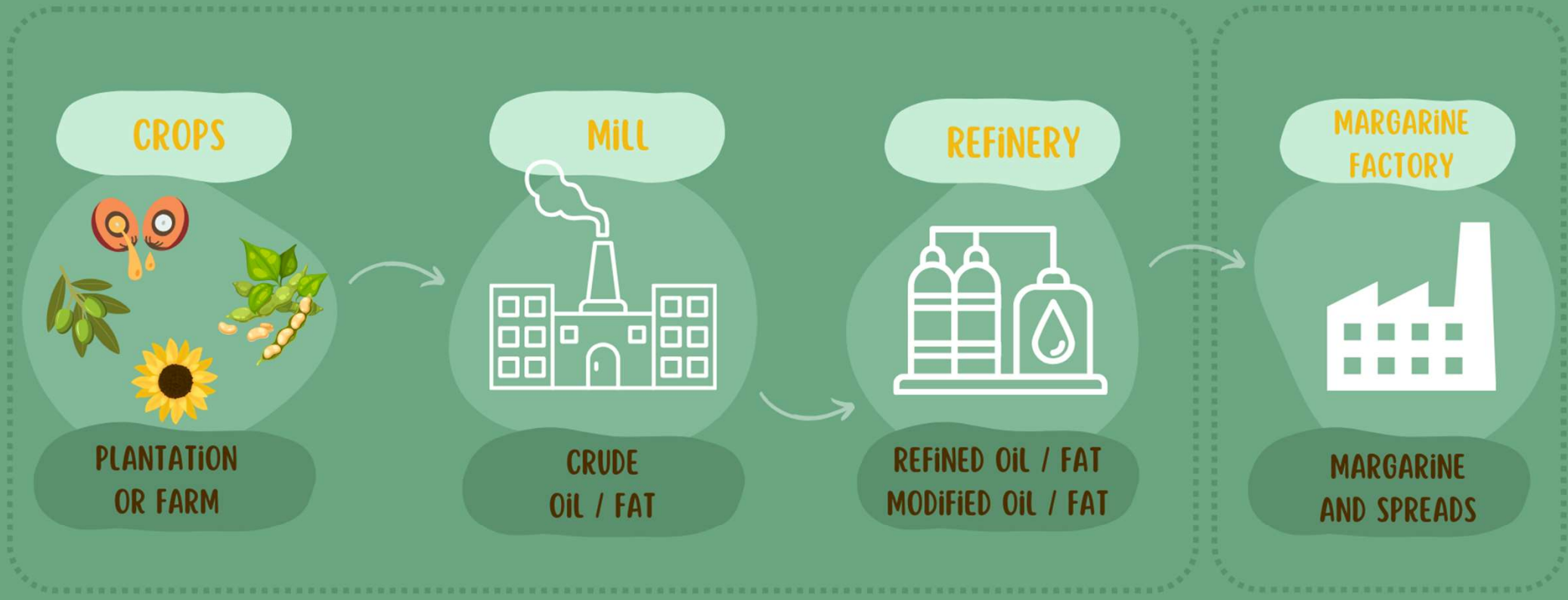
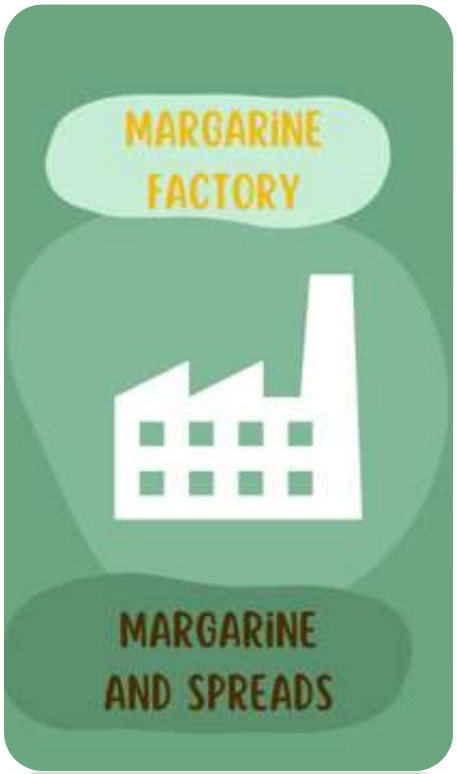
MITIGATION OF MOH CONTAMINATION THROUGH THE SUPPLY CHAIN



MAIN SOURCES.
WE HAVE NO CONTROL FOR MITIGATION

LIMITED SOURCES WITH LIMITED CONTROL TO MITIGATE

Examples of mitigation measures in place at factory level



- ✓ Using compliant agricultural raw materials
- ✓ Using food grade lubricants
- ✓ Using appropriate packaging materials
- ✓ Analysis as per Good Manufacturing Practices (GMP) and HACCP Standards
- ✓ Control of air quality at factory level
- ✓ Appropriate and continuous staff training
- ✓ Other measures as appropriate

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Example data* on contribution of vegetable oil ingredients to MOAH contamination in margarine

Can NOT be controlled

Can be controlled by Margarine sector

Raw material(s), agricultural practice, transport & storage

- Tropical oils:
  - Average value: 2.43 ppm
  - Highest: 14 ppm
  - Lowest: <1 ppm
  - % above 2 ppm: 37.8%
- Non-tropical oils:
  - Average value: 1.07 ppm
  - Highest: 2.1 ppm
  - Lowest: <1 ppm
  - % above 2 ppm: 3.6%

Manufacturing

- Food grade lubricants

Packaging

- Migration: < 0.1 ppm

Vegetable fat spread

- >50% fat products
  - Average value: 1.15 ppm
  - Highest: 5.5 ppm
  - Lowest: <1 ppm
  - % above 2 PPM: 2.9 %
- <50% fat products
  - Average value: 0.57 ppm
  - Highest: 1.3 ppm
  - Lowest: <0.15 ppm
  - % above 2 PPM: 0 %
  - % above 1 PPM: 16.7%

Levels found in final product match the levels found in oil and fat ingredients. The main risk are the tropical oils

***Source of data:** Historical data & EFSA report

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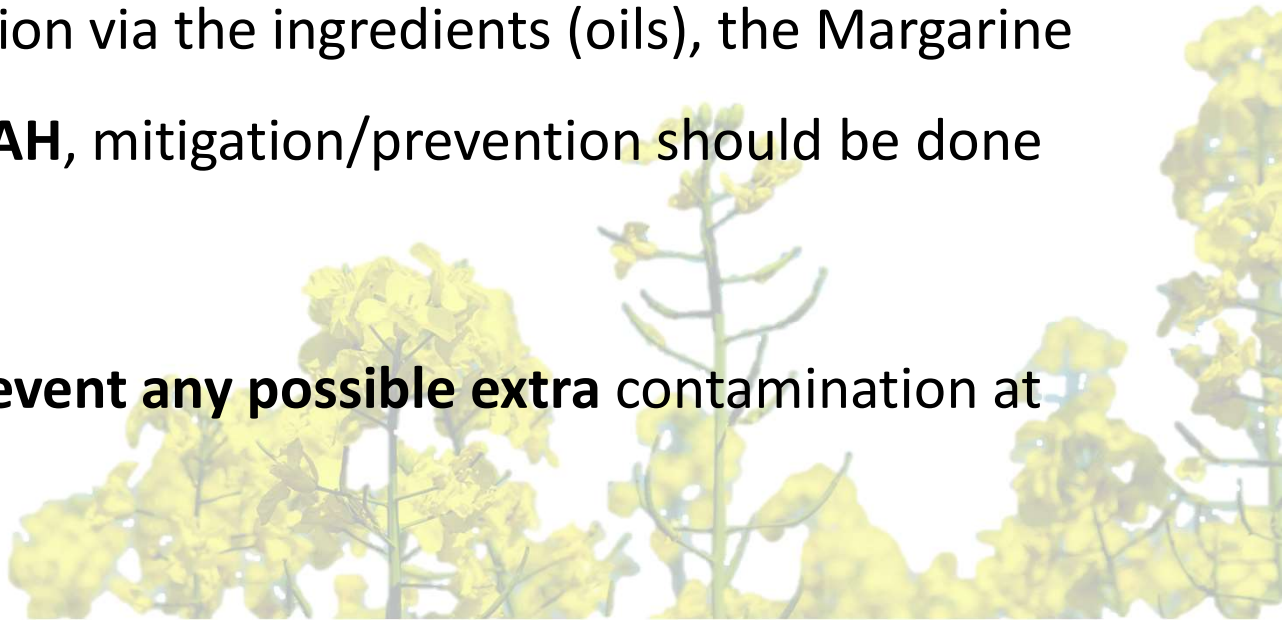
Situation of Margarine producers

- Main points of potential contamination with MOAH is at **Ingredient Level** (including agricultural raw materials)
- Main ingredients of concern for the margarine sector are the **tropical oils**
- In case of MOAH contamination via the ingredients (oils), the Margarine industry **cannot mitigate MOAH**, mitigation/prevention should be done earlier in the supply chain
- Any possible measures to **prevent any possible extra** contamination at factory level are **duly in place**



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Swift Regulatory Action

- IMACE has welcomed the recent EFSA Opinion on MOH
- IMACE appreciates the efforts of the European Commission to follow up with appropriate regulatory measures swiftly
- We support setting maximum levels of MOAH at all stages of the supply chain, including agricultural raw materials, ingredients and final foods
- We are of the opinion that the ALARA principle should be used to set those levels

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EC Proposed Regulatory Options

In order to achieve a **high level of consumer protection** Regulatory measures should apply to:

- **All foods** as defined by Art 2 of the General Food Law (GFL) (EC) 178/2002

  " '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". It is our understanding that option 2 regulates the agricultural raw materials, the ingredients and the end-products"

- **Are placed on the market** as defined by Art 3. point 8 of the GFL (EC) 178/2002

  "Placing on the market" means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves"

- and as per Art 14.1 of the GFL (EC) No 178/2002

  "Food shall not be placed on the market if it is unsafe"

- and Art 2.1 of the Contaminants regulation (EU) 2023/915

  "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..."

Hence applying also to B2B products/ingredients

- *As precedented by the measures taken for 3-MCPDE and GE*

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Use of the ALARA Principle

- The current EC proposal refers to:
  - *"maximum levels for MOAH in foods should be set at the Limit of Quantification"* as the reference value for setting the '*As Low As Reasonably Achievable Principle*' (ALARA)
- Whereas the LOQ:
  - Solely refers to the a **technical ability of an analytical method**
- Whereas the ALARA principle:
  - Is based on the **technical feasibility for preventing the occurrence** of MOAH in food

Setting regulatory limits based on the LOQ means in practice that, rather than a scientific, risk based approach as required by the GFL:

- Commercial analytical laboratories determine what is acceptable level based on their competence (and commercial advantage that comes from developing better test methods).
- Lowering LOQs to extremely low levels increasing costs and complexity for manufacturers with no public health benefit.

Therefore to provide legal certainty and in line with Recital 2 of Regulation 2023/915:

- A maximum level for MOAH needs to be set based on the ALARA (as low as reasonably achievable) principle and not on LOQ
- A concrete maximum value is required without reference to the LOQ in the regulation.

IMACE Proposal:

Replace: 'Therefore, taking into account the "As Low As Reasonably Achievable Principle" maximum levels should be set at the limit of quantification.'

with: *'Therefore, the maximum levels should be set according to the "As Low As Reasonably Achievable Principle.'*

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Alignment with maximum levels set at ingredients

- Should different maximum levels be set for specific oils and fats (e.g. tropical oils and fats), those different limits should also be reflected in the values set for products made with those ingredients
- Corresponding transition periods should be envisaged taking into account the feasibility in the upstream supply chain

Transition periods

- Vegetable oils and fats are ingredients with a long self-life
- Products that have been produced with ingredients/raw material that legally entered the European market prior to the implementation of the Regulation should be able to be used until the end of their self-life
- Consider B2B realities when setting transition period (e.g., vegetable oil -> margarine -> cookie)
- Avoid considerable amounts of food waste

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Monitoring Recommendation on MOSH

- We welcome the updated Monitoring Recommendation on MOSH
- We understand that our category falls under “vegetable oils and fats” as per CMO Regulation (EU) No 1308/2013 “spreadable fats” (clarification in the document required)

Possible indicative levels for MOSH in food

- Vegetable oils and fats: 15 mg/kg
- Coffee, tea, herbal infusions, food supplements, chocolate and confectionary, processed fish, processed seafood, offal, processed meat and processed offal products: 10 mg/kg
- Eggs, grains, grain containing products, tree nuts, pulses, oilseeds, products containing tree nuts, pulses and oilseeds, composite products, dairy, dairy containing products, imitation dairy and imitation meat, seasonings, dry infant and dry follow-on formulae, cereal based foods for infants and young children and babyfood: 5.0 mg/kg
- Liquid infant and follow-on formulae: 1.5 mg/kg.

Sampling & Analytical methods: More research needed

Sampling:

- Different preparation of sampling in different labs impacting largely the results

- No EU uniform & validated sampling method existing yet

Analytical Methods:

- Determination of total MOSH/MOAH (currently most used)
  - JRC guidelines available, however, significant error of measurement

- Method to separate and quantify 3-7 ring MOAH from 1-2 ring MOAH
  - Not validated, lack of established method, only very limited number of labs can measure and quantify

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IMACE's Standpoint on MOAH

- ✓ Setting maximum levels for MOAH at **raw material and ingredient level** (where mitigation can take place)
- ✓ **Alignment** of maximum levels for margarines and spreads with those of their ingredients
- ✓ Use of the **ALARA principle** and not on the LOQ
- ✓ Providing **workable transition periods,** considering also **B2B**
- ✓ **Uniform sampling** and **analysis methodology** to be defined

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Contact us!

Do you want to know more about the commitments of the margarine sector? **Contact us!**

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Backup slides

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EFSA Opinion on Mineral Oils (13 September '23)

MOSH

- Need for further data and investigation on MOSH
- Present dietary exposure to MOSH does not raise concern for human health for all age classes

MOAH

- Not possible to identify a reference point for the 1–2 ring MOAH. In the absence of reliable toxicity data, the dietary exposure to 1–2 ring MOAH might raise a concern
- Additional data on toxicity and exposure to three or more ring MOAH needed

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MOAH max 2 PPM	
Ingredients	content MOAH on spec
oil1	2,00
oil2	2,00
oil3	2,00
final product (fat based)	calculated MOAH content
results	2,00
final product (80% FAT)	calculated MOAH content
results	1,60

YES

NO

MOAH 2 ± x (typical value)	
Ingredients	content MOAH on spec
oil1	2,00
oil2	2,00
oil3	2,00
final product (fat based)	calculated MOAH content
results	2,00
final product (80% FAT)	calculated MOAH content
results	1,60

BtB Formula/Blend used as ref. in the calculation

Ingredients	%
oil1 = liquid oil	20,0
oil2 = palm oil	30,0
oil3 = palm fraction	50,0
Total	100,0

Ingredients	content MOAH on spec
oil1	2,50
oil2	2,50
oil3	2,50
final product (fat based)	calculated MOAH content
results	2,50
final product (80% FAT)	calculated MOAH content
results	2,00

Ingredients	content MOAH on spec
oil1	2,00
oil2	2,00
oil3	3,50
final product (fat based)	calculated MOAH content
results	2,75
final product (80% FAT)	calculated MOAH content
results	2,20

Ingredients	content MOAH on spec
oil1	2,00
oil2	3,00
oil3	3,00
final product (fat based)	calculated MOAH content
results	2,80
final product (80% FAT)	calculated MOAH content
results	2,24

Ingredients	content MOAH on spec
oil1	2,00
oil2	5,00
oil3	2,00
final product (fat based)	calculated MOAH content
results	2,90
final product (80% FAT)	calculated MOAH content
results	2,32

Ingredients	content MOAH on spec
oil1	3,00
oil2	3,00
oil3	3,00
final product (fat based)	calculated MOAH content
results	3,00
final product (80% FAT)	calculated MOAH content
results	2,40

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