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Mineral oil hydrocarbons in food

Scientific Opinion of the Scientific Panel on Contaminants in the Food Chain (CONTAM)

MOCRINIS Workshop
Bologna, 10-11 September 2013

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Introduction

General context

- ✓ In 2008 several batches of sunflower oil contaminated with high levels of mineral oil hydrocarbons (MOH) were imported into EU.
- ✓ Following an urgent request from the European Commission, and based on the ADIs established by JECFA on food grade MOH, EFSA published a statement indicating a low concern for consumers exposed to MOH via the contaminated oils[1].
- ✓ Biedermann and Grob (2009) identified the presence of 17-34 % aromatic hydrocarbons in the MOH contamination of sunflower oils[2].
- ✓ In similar cases, the presence of MOH contamination in several food commodities has been occasionally reported in the RASFF system.
- ✓ In March 2010, EC issued a mandate to EFSA for a scientific opinion covering a comprehensive risk assessment on MOH in food.

[1]EFSA Journal, 2008; 1049 http://www.efsa.europa.eu/it/efsajournal/doc/1049.pdf
[2]Eur. J. Lipid Sci. Technol. 2009, 111, 313-319.

Terms of reference received from EC

Scientific opinion on the risks to human health related to the presence of mineral hydrocarbons in food. In particular:

- Evaluate if there are **new toxicity data available** and if the **current ADIs are still applicable.**
- Explore whether **certain classes** (or subclasses) are **more relevant due to their toxicity** or to differences in the way they are metabolised by the human body.
- **Identify the different sources of the background presence of mineral oil** in food other than adulteration or misuse.
- Contain a **dietary exposure assessment for the general population and specific groups of the population** by taking into account the background presence of mineral oil in food.
- Advise on **classes to be included if monitoring would be set up**.

Scope of the CONTAM opinion

- Food grade MOH have been evaluated by EFSA for several applications. The two most recent opinions were adopted by the ANS Panel for food additive applications:
  - ✓ High viscosity mineral oils (EFSA , 2009)[3]
  - ✓ Medium viscosity (class I) mineral oils (EFSA, 2013)[4]
- These evaluations are relative to specific products and applications, without considering the cumulative exposures from different sources.

The scope of the CONTAM Opinion, as indicated by the Terms of Reference, was to evaluate the range of MOH that have been detected in food.

[3] EFSA Journal 2009; 7(11):1387. http://www.efsa.europa.eu/it/efsajournal/doc/1387.pdf
[4] EFSA Journal 2013; 11(1):3073. http://www.efsa.europa.eu/it/efsajournal/doc/3073.pdf

Approach followed for the risk assessment

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- Sources for the presence of MOH in food: Identified by reviewing existing literature and by expert judgment. Both intended uses of MOH and food contamination were considered.
- Occurrence : Data on MOH occurrence in food were collected via a call launched in August 2010, addressing National Authorities, Universities, food business operators and other stakeholders.
- Hazard assessment:
  - ✓ Toxicological data for individual compounds and mixtures of the main classes present in MOH were reviewed:
    - Mineral oil saturated hydrocarbons (MOSH) were divided into linear, branched and cyclic alkanes.
    - Mineral oil aromatic hydrocarbons (MOAH) were divided into (poly)aromatic, alkylated and partially hydrogenated hydrocarbons. Sulphur-containing MOAH were also included.
  - ✓ For all classes, MOH with carbon numbers between C_{10} and C_{50} were considered in the opinion.

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Sources, occurrence and exposure

Sources of exposure

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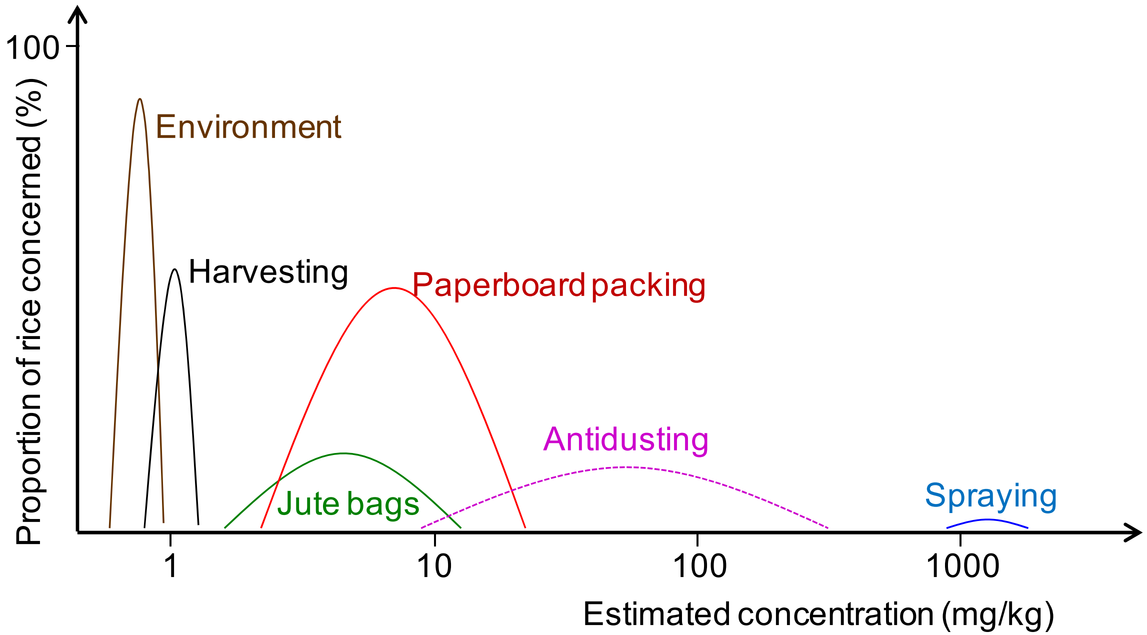
- MOH enter food from many sources, following intended use of food grade MOH or contamination via various routes.
- Depending on the source, the composition of MOH mixtures varies, from e.g. food grade MOH (white oils, virtually MOAH free) to lubricants or other contaminants containing 10 – 35 % MOAH.
- Main sources identified by the CONTAM Panel:
  - ✓ **Contamination via the environment**
    - e.g. exhaust gasses from vehicles, oils from diesel engines, road tar and tyres debris
  - ✓ **Food processing**
    - e.g. release agents in bakery products, transfer from machine lubricants
  - ✓ **Migration from food contact materials**
    - e.g. batching oils from sisal and jute bags, transfer from recycled paper and board packaging
  - ✓ **Food additives**
  - ✓ **Pesticides**

Main limitations to characterise occurrence in food

- For many foods, multiple sources can contribute to the presence of MOH.
- Due to the wide use of MOH, additional unidentified sources may exist.
- MOH composition may be source-specific, but compositions from different sources overlap in the analysis of MOH concentration.
- Analytical limitations preclude the possibility to identify different sources.

The rice example



Occurrence dataset

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- 1455 results were provided from 4 European countries, but mostly from 1 laboratory in Switzerland.
- Most of the data were from 1997-2000 and from 2008-2010.
- Vegetable oils, followed by animal fat, eggs, bread and rice were the most represented food groups.
- 30 % of the results were below the limits of detection/quantification.
- Sufficient data were available only for MOSH. MOAH fraction was determined only in few samples, and it was estimated to be indicatively in the range 15-35% of total MOH in different food groups.
- Highest average background concentrations were reported in confectionery (46 mg/kg), vegetable oils (41-45 mg/kg) and canned fish (40 mg/kg).

MOSH Concentrations in bread and rice

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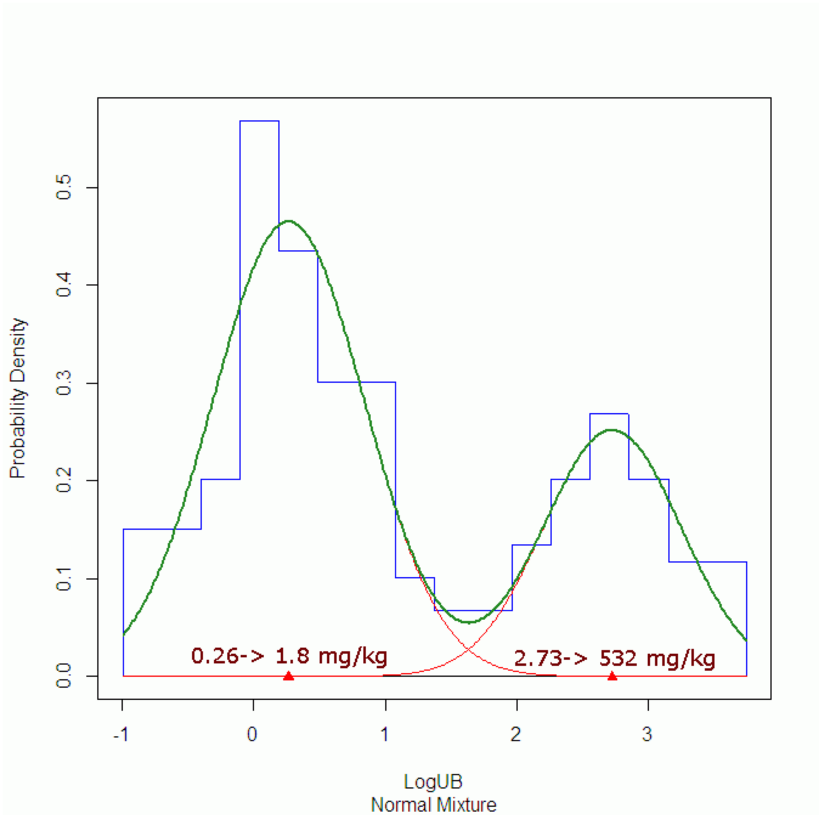
- High average concentrations were observed in bread and rice (261 mg/kg for bread and 131 mg/kg for rice).
- Influence of high values, likely related to use of release agents in bread and spraying agents in rice.
- 2 distributions were identified by a mathematical model.
- Means of the low distributions were included in the background occurrence data.
- Means of the high distributions (532 and 977 mg/kg for bread and rice) were taken as worst cases.



Contribution from recycled paperboard

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- Data from 2 surveys on dry food packaged in recycled paperboard without barrier were considered and compared with background concentrations.
- In general, higher concentrations were observed in recycled paperboard. E.g., breakfast cereals: 9.8 mg MOSH/kg in recycled paperboard vs 6.0 mg MOSH/kg overall mean.
- Highest average concentrations observed in creme pudding mix (32.4 mg MOSH/kg) and semolina (23.9 mg MOSH/kg).
- MOAH about 10-20% of MOSH concentrations.

In dry food, packaging in recycled paper can provide a relevant contribution to overall presence of MOSH and MOAH.

Food consumption data

- Consumption data were taken from **the EFSA Comprehensive European Food Consumption Database:**
  - ✓ Data available from 32 different dietary surveys carried out in 22 European countries.
  - ✓ Average and high (95th percentile) consumptions estimated.

Classification of the subjects in the dietary surveys according to age groups

Subject	Age
Infants	< 12 months old
Toddlers	≥ 12 months to < 36 months old
Other children	≥ 36 months to < 10 years old
Adolescents	≥ 10 years to < 18 years old
Adults	≥ 18 years to < 65 years old
Elderly	≥ 65 years to < 75 years old
Very elderly	≥ 75 years old

Exposure estimates: 3 scenarios considered

- Chronic exposure to background MOSH concentrations:
  - 0.03 to 0.07 mg/kg b.w. per day in adults and elderly (up to 0.1 mg/kg b.w. per day for high consumers).
  - **Highest exposure for 3-10 year old children** (up to **0.17 and 0.32 mg/kg b.w. per da**y for average and high consumers, respectively).
- Specific scenarios for consumption of bread and rice with high MOSH levels (use as release or spraying agents):
  - Chronic exposure up to **6.4 mg/kg b.w. per day for bread** and **1.3 mg/kg b.w. per day for rice**.
- Contribution of exposure to dry food packed in recycled paperboard (without barrier):
  - **Relevant contribution to total dietary exposure**.
  - E.g. up to 0.11 mg MOSH/kg b.w. per day from high consumption of breakfast cereals in children (compared to a total background exposure of 0.32 mg/kg b.w. per day). @

Hazard identification and characterisation

Toxicokinetics of MOSH and MOAH

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MOSH

- **Oral absorption decreases with increasing carbon number. Virtually no absorption at > C_{50}.** Branched-alkanes are slightly less absorbed than linear and cyclo-alkanes of comparable molecular weights.
- Alkanes are metabolised to the fatty alcohols and generally to fatty acids. **Linear alkanes more easily metabolised than cyclic- and branched-alkanes**.
- MOSH with carbon number between **C_{16} and C_{35} can accumulate in the organism**. High accumulation potential observed in Fischer 344 rats. **Accumulation in different tissues, such as adipose tissue, lymph nodes, liver and spleen, is observed in humans**.

MOAH

- Limited information is available indicating high absorption, rapid distribution , extensive metabolism and no bioaccumulation.

Toxicity of MOSH and MOAH

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MOSH

- Only moderate liver cell hypertrophy and no adverse effects relevant to humans are observed for MOSH mixtures with C_{10}-C_{13}.
- MOSH mixtures with **>C_{16} can bioaccumulate and form microgranulomas in liver and mesenteric lymph nodes (MLN)**. **Histiocytosis (microgranulomas) in MLN considered of low toxicological relevance** by the CONTAM Panel.
- MOSH related **lipogranulomas are observed also in human liver, spleen and lymph nodes**, with no clear associations with adverse effect. No information is available on exposure levels at which lipogranuloma formation occurs in humans.

MOAH

- **Polycyclic aromatic hydrocarbons (PAHs) with more than 3 rings with little or no alkylation are genotoxic carcinogens**. Some highly alkylated PAHs can act as tumour promoters. Simple MOAH with few rings are carcinogens but most likely non genotoxic.

Hazard characterisation

MOAH

- No dose-response data on carcinogenicity for MOAH, thus **no hazard characterisation was possible** for this fraction.

MOSH

- **Key effect** for MOSH: **microgranuloma formation in liver** in the most sensitive species (Fischer 344 rat).
  - ✓ **The lowest NOAEL available** from MOH-mixtures covering the range of exposure (19 mg/kg b.w. per day) **was selected as Reference Point (RP) for the background exposure**, from a study in low melting point waxes[5].
  - ✓ **A higher RP** (45 mg/kg b.w. per day)[6] **was selected to assess high exposure levels of MOSH** due to release agents in bread and spraying practice in rice, since no waxes are used in these practices.

[5]Toxicol.Pathol. 1996, 24, 214-230.
[6]Toxicol.Pathol. 1992, 20, 426-435.

Main limitations for the hazard characterisation of MOSH

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- Little is known on the **mode of action of the microgranuloma formation in liver of Fischer 344 rats**.
  - ✓ The effect could be not relevant for humans.
  - ✓ Humans could have different sensitivity than Fischer 344 rats.

- **MOSH mixtures** tested in toxicological studies (white MOH products intended for food use) are **characterised by physico-chemical properties** with little relationship to their chemical composition.

- Humans are exposed to a composition of different MOH mixtures in food. None of the tested MOSH mixtures is representative of this composition of mixtures:
  - ✓ Existing ADIs for food grade MOH could not be used for risk characterisation.
  - ✓ **Inappropriate to establish a health based guidance value** (e.g. TDI).

  Due to these deficiencies, a Margin of Exposure (MOE) approach was selected for the risk characterisation of MOSH.

Risk characterisation

Risk Characterisation

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MOAH

- No quantitative risk characterisation possible.
- MOAH content of MOH present in food may be up to 30-35%. This fraction may be potentially genotoxic and carcinogenic.

CONTAM Panel considers the exposure to MOAH of potential concern.

MOSH, background exposure

MOE approach, using 19 mg/kg b.w. per day as RP.

- MOEs for average consumers ranged from 100 to 680 in various age classes.
- Lowest MOEs (59-110) for high consumers in toddlers and other children.

MOSH, exposure to high MOSH levels in bread and rice

MOE approach, using 45 mg/kg b.w. per day as RP.

- Bread: MOEs in the range 16-65 and 7-32 for average and high consumption.
- Rice: MOEs in the range 35-1900 and 12-200 for average and high consumption.

CONTAM Panel considered the exposure to MOSH of potential concern.

Main conclusions and recommendations

Main conclusions of the CONTAM Panel

- ✓ Based on their potential mutagenicity and carcinogenicity, exposure to MOAH through food is of potential concern.
- ✓ Considering the formation of liver microgranulomas in the Fischer 344 rats as the critical endpoint, there is potential concern associated to the current background exposure to MOSH and with use of white oils as release agents in bread and for spraying of grains.
- ✓ Migration of MOSH and MOAH into dry food packed in recycled paperboard without barrier can contribute significantly to the total dietary exposure.

Main Recommendations of the CONTAM Panel

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- ✓ Future monitoring should distinguish between MOSH and MOAH, and between subclasses of MOSH based on carbon numbers and chemical structures.
- ✓ Migration from recycled paperboard used for food packaging can be effectively prevented by the inclusion of functional barriers into the packaging assembly, segregation of the recycled fibre sources and by increasing the recyclability of food packages.
- ✓ Relevance of liver microgranulomas observed in rat for humans should be further investigated.
- ✓ The toxicological evaluation of MOH should focus on the molecular mass range and structural sub-classes, rather than chemico-physical properties such as viscosity.

Acknowledgments (1)

CONTAM Panel (2009-2012) :

Jan Alexander, Diane Benford, Alan Boobis, Jean-Pierre Cravedi, Alessandro Di Domenico, Daniel Doerge, Eugenia Dogliotti, Lutz Edler, Peter Farmer, Metka Filipič, Johanna Fink-Gremmels, Peter Fürst, Thierry Guérin, Helle Katrine Knutsen, Miroslav Machala, Antonio Mutti, Martin Rose, Josef Schlatter and Rolaf van Leeuwen.

CONTAM *ad hoc* working group on mineral oil hydrocarbons:

Jan Alexander (chair), Jan Beens, Alan Boobis, Jean-Pierre Cravedi, Thierry Guerin, Konrad Grob, Unni Cecilie Nygaard, Karla Pfaff, Shirley Price and Paul Tobback.

Acknowledgments (2)

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) and the **CEF working group on food contact materials** for the support provided on the sections of the opinion dealing with the presence of MOH in food contact materials and exposure from foods packed in recycled paper.

EFSA Staff:

Davide Arcella , Gina Cioacata, Jean Lou Dorne, Dimitrios Spyropoulos, Natalie Thatcher, and Francesco Vernazza.

Thank you for your attention

Questions?

EFSA: http://www.efsa.europa.eu/
CONTAM Panel: http://www.efsa.europa.eu/en/panels/contam.htm

Hazard characterisation

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"Are current ADIs still applicable?"

- Current ADIs are established for MOH intended for food use by SCF (1995), JECFA (2002) and EFSA are relative to products characterised mainly by physico-chemical properties**.**
  - ✓ The CONTAM Panel concluded that **MOSH mixtures should be assessed based on molecular mass range and subclass composition** rather than on physico-chemical properties.
- Due to new interpretation of hystiocytosis in MLN and on newly available studies:
  - ✓ The CONTAM Panel concluded that **revision of the temporary group ADI for low- and medium- viscosity oils class II and III is warranted**.
  - ✓ **The other existing ADIs are of low priority for revision**.

Overview of the established ADIs

	SCF (1995)				FAO/WHO (2002)				EFSA (2009)			
	ADI (mg/kg b.w. per day)	NOAEL (mg/kg b.w. per day)	Uncertainty factor	Comments	ADI (mg/kg b.w. per day)	NOAEL (mg/kg b.w. per day)	Uncertainty factor	Comments	ADI (mg/kg b.w. per day)	NOAEL (mg/kg b.w. per day)	Uncertainty factor	Comments
High viscosity P100(H)	0-4[a]	1 951	500	90-day NOAEL	0-20	1 951	100	90-day NOAEL	12	1 200	100	2-year NOAEL
Medium and low viscosity, class I P70(H)	0-4[a]	1 951	500	90-day NOAEL	0-10	1 200	100	2-year NOAEL	(12)[b]	(1 200)	(100)	2-year NOAEL
Medium and low viscosity, class II N70(H)	No ADIs established				0-0.01[a]	2	200	90-day NOAEL	–	–	–	
Medium and low viscosity, class III P15(H), N15(H)	No ADIs established				0-0.01[a]	2	200	90-day NOAEL	–	–	–	
Microcrystalline wax high melting point wax	0-20	1 951	100	90-day NOAEL	0-20	1 951	100	90-day NOAEL	–	–	–	
Low melting point wax	No ADI established				Withdrawn				–	–	–	

a: Temporary group ADI. In 2012 JECFA withdrawn the temporary group ADIs.

b: EFSA concluded that the ADI established for high viscosity mineral oil could have been potentially applicable also to medium- and low-viscosity mineral oil class I. In 2013 the EFSA ANS Panel established an ADI of 12 mg/kg b.w. per day for this grade.