fcra food chemical risk analysis

Interpretation of Exposure Data and Path Forward

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Interpretation of Dietary Exposure Data for Mineral Oil Hydrocarbons

- What are exposure data and how are they generated?
- Terms and principles

  "Occurrence" vs. "Usage"
- Potential sources of exposure to MOH
- Uncertainties in exposure data –

  Occurrence/usage;

  Food consumption

  Exposure scenarios
- Major sources of exposure – real or hypothetical?
- Proposals for further investigations

EFSA Opinion* raises many questions concerning exposure – Some could be answered today, others need further research

What are exposure data and how are they generated?

Simple situation – a single eating occasion:

"Intake" or "exposure" = Concentration of chemical in item * Amount consumed

Need to consider bodyweight:

"Intake" or "exposure" = $\dfrac{\text{Concentration of chemical in item} * \text{Amount consumed}}{\text{Bodyweight}}$

Multiple food sources:

Intake = $\dfrac{\Sigma(\text{Concentration of chemical in item a…. x} * \text{Amount consumed a…. x})}{\text{Bodyweight}}$

Over time …

Dietary Exposure Analysis – terms and principles

- Dietary Exposure Analysis relatively new discipline

- Approaches vary between sectors*

- <u>Contaminants</u> experts use 'occurrence' to mean distribution of possible concentrations (including zero / ND) – all foods potentially contaminated

- <u>Additives</u> experts use 'occurrence' to mean the proportion of the supply that contains the additive – only a small proportion contains the additive

$$\text{Intake} = \frac{\underline{\text{Concentration} * \text{Occurrence} * \text{Amount consumed}}}{\text{Bodyweight}}$$

- 'Occurrence' of food additive often assumed to be **100%**

- <u>Food contact materials</u> exposure based on migration coefficients

- <u>Processing aids & contaminants</u> no established approach

- Differences due to differences in sources of exposure (inherent / adventitious / deliberately added)

- Makes combining data from different sources difficult

* Good source of information: GUIDEA (www.ilsi-guidea.org)   4

Potential sources of exposure to MOH

Food contact materials:
- Food packaging materials made from recycled paper and board
- Off-set printing inks applied to paper and board for food packaging
- Mineral oils used as additives in the manufacture of plastics
- Wax paper and board
- Jute or sisal bags with mineral batching oil
- Lubricants for can manufacture
- Wax coating directly applied to food
- Adhesives

Contaminants:
- Environmental contaminants
- Harvesting machinery: diesel oil, lubricating oil
- Lubricating oils in machinery used in food processing
- Cleaning agents, solvents

Food additives, processing aids and other uses:
- Release agents for bakery ware and sugar products.
- Oils for surface treatment of foods, such as rice, confectionery.
- Mineral oils in feeds, e.g. binders for minor additives added as powder.
- Defoamers.
- Authorised paraffinic waxes (e.g. for chewing gum or coating of certain fruits)
- Pesticide formulations.
- Anti-dusting agents for cereals.

Plus breast milk, natural occurrence in plants and animals, hydrocarbons formed from food components, MOH entering food chain through feed

etc.

Complex mapping of exposure routes –
- Errors ?
- Omissions ?

Uncertainties in exposure data - Occurrence

Over 25 potential routes of exposure.

For many foods MOH can be present from several sources with different overlapping distributions.

Uncertainties associated with occurrence / concentration data:

- Occurrence data incomplete

- Often based on older data

- Subject to targeted sampling

- EFSA data call identified limited resources – two main data providers

- The entire dataset consists of 1,455 data points

- Of which 338 from Germany, France and Italy (all regarding vegetable oils)

- Preponderance of results in foods from Switzerland may not be representative for EU

- Over 50% of values related to vegetable oil, animal fat and eggs

- 30 % of values not detected (< LOD) or not quantified (< LOQ)

- Migration data based on food packaged in direct contact with board without an inner bag or migration modelling from amount present in packaging.

Uncertainties in exposure data - Occurrence

Highest MOSH levels reported in occurrence data

	MOSH mg/kg	N
Bread & rolls (high)	532	?
Grains (high)	977	?
Non-chocolate confectionery	46	26
Vegetable oil	41-45	515
Fish products (canned)	40	45
Oilseeds	38	54
Animal fat	22-24	174
Fish meat	21	40
Tree nuts	20-21	19
Ices & Desserts	14	7
Bread & rolls (background)	1.8	(101)
Grains (background)	4.1	(72)

Numbers of samples very limited

In the context of chronic exposure, widespread contamination at low levels can be of greater significance than sporadic occurrence at much higher concentrations.

? Are data obtained up to 20 years ago relevant to current food industry practice?

? Can targeted samples taken for compliance testing be relied upon?

? Are data representative of practice across EU?

? Are there sufficient data points for some food categories?

Uncertainties in exposure data – Food consumption

- EFSA 'Comprehensive' data obtained from 28 surveys in 17 EU countries

- Not all datasets include all age groups

- Different purposes – different methods – different classification systems combined into one - FoodEx

- Surveys less than one day excluded (mostly)

- Four surveys of 7 consecutive days; others 2-3 days, few consecutive

- Short survey duration leads to over-estimates of chronic consumption

    Data reviewed at: http://fcra.co.uk/research-development/:

- There appears to be an overall over-estimation of food consumption that particularly affects younger children leading to energy intakes up to twice requirements

- Certain foods appear to be contributing very high energy intakes: fats and oils, flavoured fermented dairy products, snack foods, processed fruit and vegetables, desserts and fine bakery wares.

? Does the use of short duration food consumption survey data provide a sound basis for chronic exposure assessments?

? Are FoodEx categories relevant to occurrence data?

Uncertainties in exposure scenarios – methods of modelling

- "All mineral oil products except microcrystalline waxes accumulated in tissues in a dose- and time-dependent manner".

- "Under the assumption that 10 g MOSH can be accumulated it could take approximately 10 years to reach the estimated body burden".

- "If it is assumed that 85-90 % of the MOSH absorbed by humans are eliminated within a year, this suggests that part of the MOSH ingested might be accumulated virtually over a lifetime".

- "This possibility of strong accumulation must be taken into consideration when extrapolating data from relatively short term animal experiments (mostly 90 days) to humans of maybe 90 year in age".

? Are exposure scenarios based on 2-7 day periods relevant?

? Are data on different ages from infants to elderly relevant?

? Would an index of cumulative exposure by age provide a better metric?

? Is individual bodyweight correction appropriate?   60kg?

Major sources of exposure

Bread and rolls - release agents

"Before the introduction of modern 'non-stick' materials, mechanised bread manufacture required the use of lubricants to prevent bread from adhering to the baking pans and thus allow a smooth, continuous operation. "

"Extensive enquiries within the European baking industry have revealed that former practices have now changed and that the use of mineral hydrocarbons as bakery release agents is essentially obsolete. Use of white mineral oils as dough divider oils is small and is only used in those industrial bakeries where older designed equipment is still used. " Tennant, 2001.

?   Are data obtained in 1991/94 relevant to current food industry practice?

Grains for human consumption - spraying agents

"The proportion of the gross domestic supply (i.e. production plus imports, less exports) that is imported to the EU is 20% for wheat, 50% for rice, 10% for barley, 23% for maize and 6% for rye. " Tennant, 2001.

?   Why assumed that regular consumers of such products may be always exposed to occasional high levels of MOSH?

?   Is it realistic to separate high and background occurrence data?

Major sources of exposure

Breast milk

? Important, but significant for long-term cumulative exposure?

Vegetable fat/oil and Animal fat

Difficult to obtain reliable consumption data because 'hidden' in other foods.

? How reliable are animal and vegetable fat consumption estimates?

Ices and desserts

Source of MOSH not identified.

? Does occurrence data relate to 'Pudding powder' packaging migrant?

? Is 'occurrence' significant?

Bread and rolls

? Are high consumption data realistic (>12 g/kg bw/day)?

Confectionery (Non-Chocolate)

"The use of white mineral oils as release agents for confectionery is now obsolete." Tennant, 2001.

? Are data obtained in 1991/94 relevant to current food industry practice?

Uncertainty Analysis

Table 27: Summary of qualitative evaluation of the impact of uncertainties (relating to exposure) on the risk assessment of the human dietary exposure of MOH.

Sources of	Direction
Occurrence data not representative of all food commodities in which MOH could be present	-
Occurrence data not equally distributed across Europe	+/-
Use of a mathematical model to calculate the average occurrence values in bread and grains	+/-
Occurrence data in foods packaged in recycled paper limited in number	+/-
Occurrence data mainly related to targeted investigations	+

(a): + = uncertainty with potential to cause over-estimation of exposure/risk; - = uncertainty with potential to cause under-estimation of exposure/risk.

Other possible factors not described in Opinion:

Sources of uncertainty	Direction
Limited values for many food categories	+/-
Data from targeted compliance surveys	++
Use of short-term food consumption survey data for chronic exposure	++
Assumption of 100% occurrence in many food categories	+++
Certain food industry practices may be obsolete	+++
FoodEx categories not matched to occurrence data	++
Exposure model based on total MOH – no classification by molecular mass, carbon number, etc.	+
Lifetime exposure not assessed	++

Proposals for further investigations and path forward

- Consult with food industry experts to identify current practices in relation to:

  Bakery release agents

  Bakery dough dividers

  Grain de-dusting

  Confectionery release agents

  etc.

- Base monitoring plans on current practices

- Identify MOH class (molecular mass, carbon number, etc.) in surveys

- Identify source of packaging migrant exposure data covering all applications and taking usage patterns into account – FACET*

- Investigate models for estimating total vegetable and animal fat consumption

- Consider options for generating appropriate models of long-term chronic / cumulative exposure

*http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food/FACET