Outcomes of the FoodDrinkEurope Workshop on Exposure Assessment

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Content

- Modelling in science
- FDE and Additive Data Collection
- Variability of the data
- FoodDrinkEurope Workshop
- Conclusions

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Modelling in Science

Modelling approaches are scientifically recognised methods for e.g. assessing exposure to food contact material migrants:

•Report of ILSI Europe Expert Group "ILSI Guidance for Exposure Assessment of Substances Migrating from Food Packaging Materials" http://europe.ilsi.org/events/past/PackagingWorkshop2007.htm

•Castle L (2003) Approaches to assess risk and assign priorities to chemicals used to make food contact materials. Final report for Food Standards Agency project A03023. FSA, London

•Castle L, Hart A, Holmes MJ, and Oldring PKT (2006) Approach to stochastic modelling of consumer exposure for any substance from canned foods using simulant migration data. Food Additives and Contaminants 23:528–38

•Duffy E, Hearty AP, Gilsenan MB and Gibney MJ (2006a) Estimation of exposure to food packaging materials. 1: Development of a food packaging database. Food Additives and Contaminants 23(6):623–633

•….

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Modelling in EU legislation

Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

Recital 32

As migration testing is complex, costly and time consuming ***it should be admissible that compliance can be demonstrated also by calculations, including modelling,*** *other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing.*

Article 16 Supporting documents

That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance

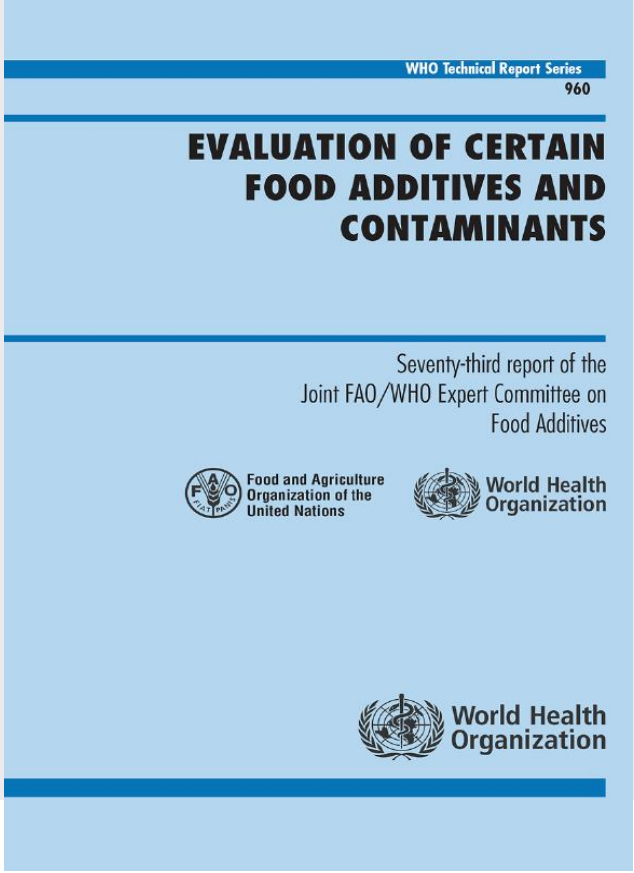
Annex V – Compliance testing – Chapter 2 testing for specific migration

2.2.3. *Migration modelling*

To screen for specific migration the ***migration potential can be calculated based on the residual content of the substance*** *in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed such as to overestimate real migration*

Modelling in International Standards

73rd report of the Joint FAO/WHO Expert Committee on Food Additives – Evaluation of certain food additives and contaminants



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Modelling in R&D - FACET

- FoodDrinkEurope is a partner in the EU funded FP7 project FACET (**F**lavourings, **A**dditives, food **C**ontact materials **E**xposure **T**ask)
- FACET is composed of 21 partners from Academia (e.g. University College Dublin, etc) Industry (e.g. FoodDrinkEurope and the packaging supply chain) food safety agencies (e.g. AFSSA) and the Commission's Joint Research Center (JRC)
- EFSA, DG Sanco and DG RTD are involved in FACET's executive board and are closely following the project developments
- FACET started in 2008 and will finish in summer 2012

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The Modelling Approach in general

- Exposure assessment using probabilistic methods take into account the variability and uncertainty of the values.
    - In reality, consumption, concentration and exposure are not fixed values but are variable and uncertain
- Probabilistic modelling requires the use of complex mathematical models.
- Each uncertain variable can be represented by a distribution function instead of a single value.
- Distributions are used to represent inputs for exposure assessments that are variable and/or uncertain

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Additives – FoodDrinkEurope Data Collection

- In the framework of the so-called “Food Improvements Agents Package” an EFSA re-evaluation programme on food additives was laid down in Regulation EU No 257/2010.
- The additives were grouped and prioritised for their re-evaluation.
- FoodDrinkEurope is carrying out different data collection exercises in order to collect and compile information on the concentration of the different additives in the different foodstuffs in which they are permitted.

  - 2008/2009 Data collection on the so-called TIER3 Additives
  - 2009 Data collection on 35 colours
  - 2011 Data collection on preservatives, antioxidants & waxes
  - …more will follow

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Data Collection - FoodDrinkEurope's Membership

- Information on additive concentration is provided by FoodDrinkEurope's membership*

  - **26 National Federations (incl 3 observers)**
  - **25 European Sector Associations**
  - **18 Major Companies**

- National Federations and European Sector Associations have additional members, who are also requested to provide information

* FoodDrinkEurope's membership does not cover all manufacturing industries in a particular sector or country

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Variability of the data

- Fragmented nature of the European food and drink industry +
- Many different food and drink products sold across the EU 27 Member States =
- Varied feedback received from members representing many different climates, farming practices, national/ regional traditions
  - Food categories, subcategories, national specialties
  - Additive usage concentrations and presence probability
- Variability and uncertainty have an impact on the exposure estimations

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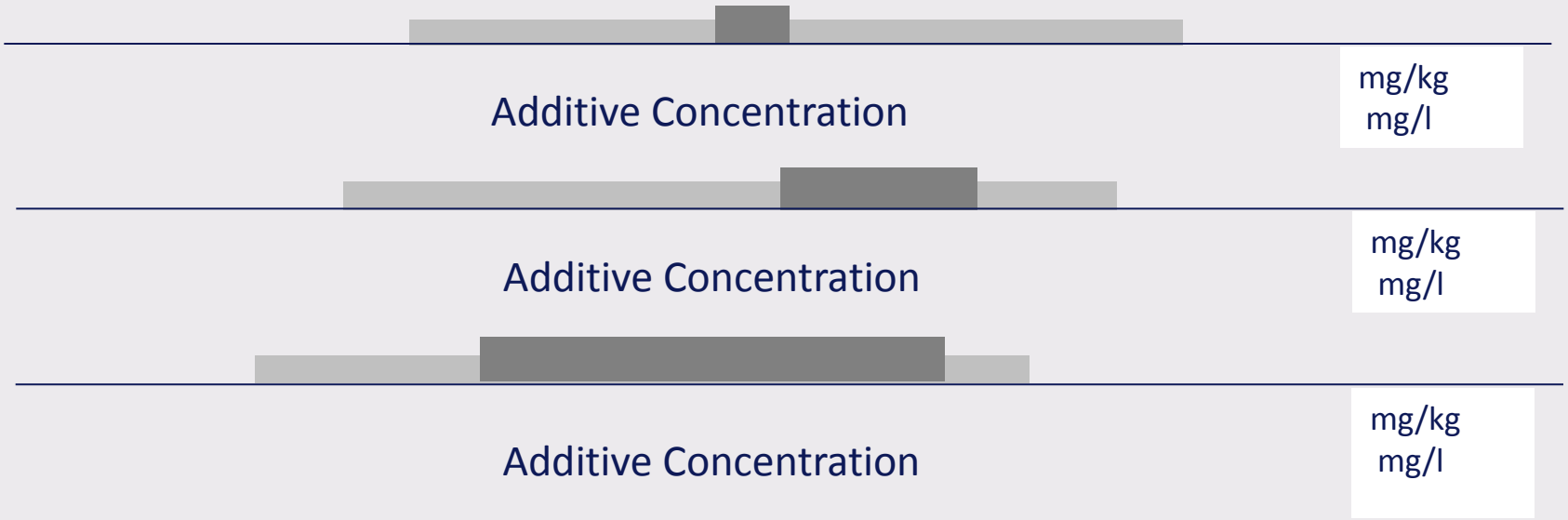
Data Compilation

- The values provided by CIAA's membership were presented using a so-called « double range approach »



- The double range approach provides an indication of the distribution of the different concentrations reported for both each food category and additive.

Extreme Range

Typical Range

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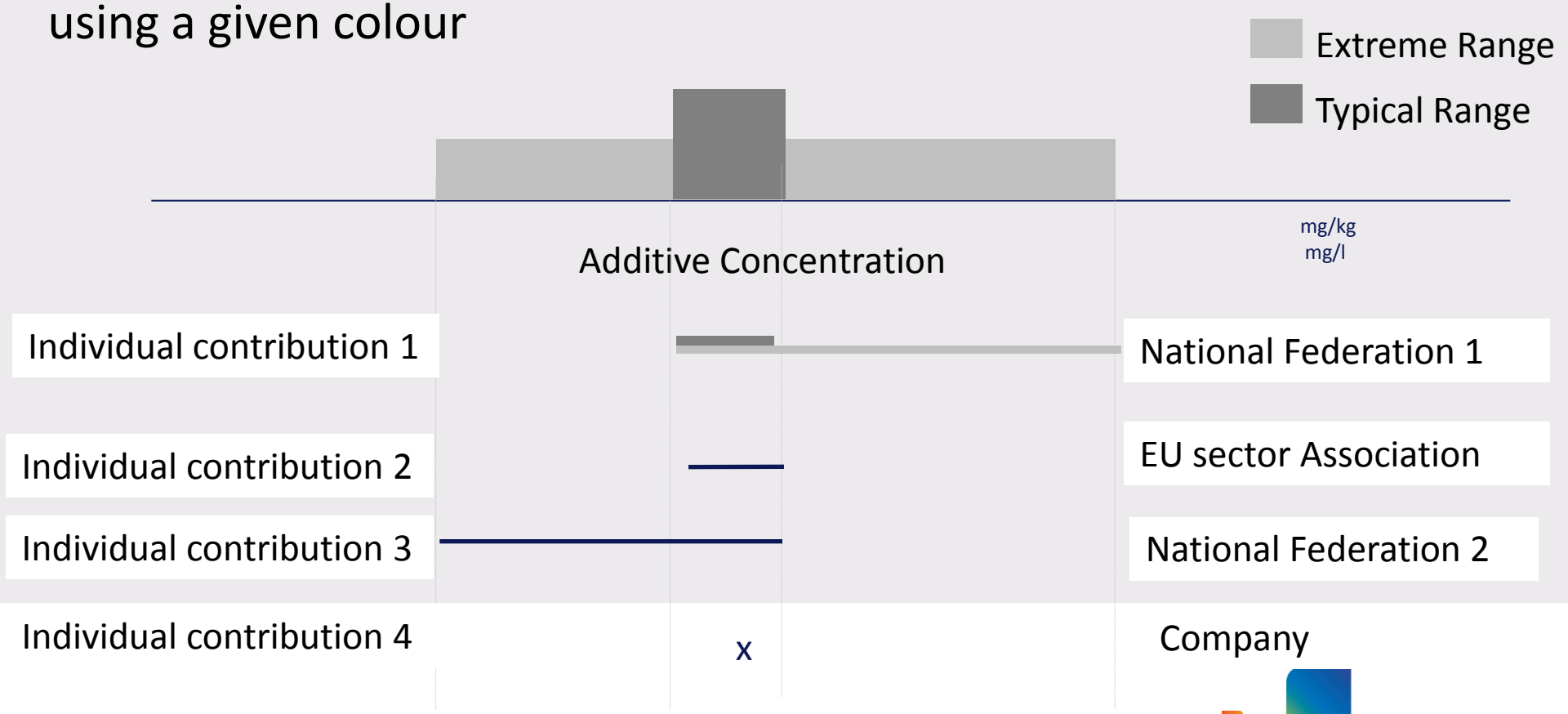
Composition of the double range

Example for a given category (encompassing different applications) using a given colour



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Overestimated exposure estimations (1)

- Values reported by FoodDrinkEurope used in a specific product application (e.g. flavoured fermented milk) are extrapolated to an overall category (e.g. dairy and dairy products) as defined in EFSA concise consumption database
- For obvious reasons only e.g. coloured products contain any colour. Not even all coloured products contain neither the same additive nor a colour at all.
- The highest reported level represents the highest concentration of the additive provided by FoodDrinkEurope's membership. Its use disregards the representative values provided by the majority of the members.

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Overestimation exposure assessment TIER 3 additives

It assumes that **ALL** products encompassed by a given food category would **ALWAYS** contain a given additive at its **HIGHEST** reported level

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Workshop Managing Variability and Uncertainty in Risk Assessment and Risk Management workshop

Aim of the workshop:

- To raise awareness of the use and power of probabilistic and other methods, when combined with reliable food consumption data, to estimate likely intakes of intentionally added compounds or other compounds, such as contaminants or residues.
- Highlight the importance of these methods for new additives, novel foods or pesticide residues, etc., with no history of exposure, and for contaminants showing variability of occurrence in the food chain.
- Highlight factors influencing risk assessment and how these can influence the conservativeness of risk assessment.

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Audience

- EFSA
- Project partners (FACET, EXPOCHI)
- Academia,
- Specialists in the areas of:
  - pesticides
  - contaminants,
  - the addition of nutrients,
  - flavourings
  - food contact material
  - other
- ILSI
- National risk assessors,
- Risk managers (European Commission and national authorities)
- Industry,
- Representatives of the Scientific Committee of the European Parliament
- BEUC

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Individual contributions

The importance of harmonised data bases
What is required to achieve realistic exposure assessment?
Facet example intake study – case study
Additives/Flavourings
Food contact material/Residues/Contaminants
Residues
Contaminants – case study cadmium
Nutritional Modelling

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Conclusions

- Exposure assessment approaches go from conservative screenings to progressively more realistic estimates
- More realistic exposure estimations would improve the current risk assessment and risk management processes
- More realistic estimates require sufficient detailed data and evaluation of uncertainties

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Conclusions

- Uncertainties are unavoidable, but have to be identified and assessed to estimate the impact on the final exposure assessments.
- Reliable, detailed databases on concentration/ usage and on food consumption are key to determine realistic scenarios

A joint challenge for all stakeholders: industry, academia, risk managers and assessors

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