How human bio monitoring data benefits the risk assessment at EFSA?

Launch event HBM4EU
Stakeholder consultation
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EFSA'S MISSION

- Contribute to the safety of the EU food chain
- by providing scientific advice
- communicating on risks
- cooperating with Member States and other parties
- to deliver a coherent, trusted food safety system in the EU

SCIENTIFIC FIELDS

Plant Health

Plant Protection

Genetically modified organisms

Animal feed

Animal health and welfare

Biological hazards

Chemical contaminants

Food additives

Food packaging

Nutrition

SCIENTIFIC COMMITTEE AND PANELS

Scientific Panels

- 10 Scientific Panels (thematic remit)
- 21 scientists selected on the basis of proven excellence
- Open meetings, transparent work
- Mandatory commitment to independence

Scientific Committee

- 10 Chairs of Scientific Panels plus 6 top level independent scientists
- Horizontal scientific issues, consistency of scientific opinions, harmonised methodologies

WHO TASKS EFSA

EU Commission

EU Parliament

Member States

EFSA self mandate

EFSA
receives question

EFSA's scientists evaluate, assess, advise

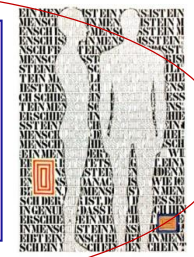
Adoption and
communication

POSSIBLE APPLICATION OF HBM IN FOOD SAFETY RISK ASSESSMENT

Hazard Identification
(Toxicity: Genotox, CMR, ED)

Hazard Characterization
(Dose-effect curves, MoA, Kinetics, etc.)

Exposure Assessment



Risk Characterization

Adapted from Gisela H. Degen; Leibniz Research Centre for Working Environment and Human Factors at the TU Dortmund (IfADo)

EXAMPLE 1: CADMIUM

- Opinion on cadmium in food (Jan 2009)
  - Studies on biomarkers of exposure and effects extensively described
  - Biomonitoring data from the literature and trends of exposure (blood and urin)
  - Cd in urine to measure body burden
  - Meta analysis for dose-response relationship between urinary Cd and biomarker for tubular effects (beta-2-microglobulin) >> $BMDL_{05}$
  - Studies (occupational and others) described and used in comparison
  - Kinetic modelling from Swedish women in reproductive age groups
  - >>> TWI established

EXAMPLE 2: LEAD

- **Opinion on lead in food (April 2010)**
  - Studies on biomarkers of exposure extensively described
  - Biomonitoring data from the literature and trends of exposure
    - ✓ Blood, plasma/serum, urine, bone, hair
  - Pb in blood information could be linked to neurodevelopmental effects in children >> $BMDL_{01}$
  - BMDLs also for: Pb in blood >< renal effects and systolic blood pressure, Pb in bone mineral >< systolic blood pressure
    - ✓ Adults: nephrotox and cardiovascular effects
  - Kinetic modelling for the relationship of Pb in blood and dietary exposure
  - >>> MOE calculated

EXAMPLE 3: DEOXYNIVALENOL (DON)

- Deoxynivalenol (…… Jan 2017)
  - Opinion on deoxynivalenol, and its acetylated and modified forms in food and feed
  - Studies described (very little biomarkers of effect)
  - Experimental study on DON biomarkers in urine (2013-May 2015) >>> difficulties due to lack of expertise/knowledge in house
  - Very first in CONTAM (and at EFSA) to collect biomarker data and apply them in the opinion

EXAMPLE 4: BISPHENOL A (BPA)

- **Exposure calculated from the diet and back-calculated from the biomarker of exposure**
  - **Conclusion: same order of magnitude**

Table 33: Average internal exposure to total BPA, as estimated by forward and backward exposure modelling. For some age classes, such as infants and children, several values are given which refer to subgroups among the age classes

Age class	Age(years)	Average internal exposure (ng/kg bw per day)	
		Forward modelling [(a)]	Backward modelling [(b)]
Infants	0–1	42/157/177/226/387	< 10
Toddlers	1–3	384	Not available
Children	3–10	301	49/107
Adolescents	10–18	172	48
Adults	18–65	134/134/140	39
Women of cba	18– 2	140	36
Elderly/very elderly	≥65	124	56

cba, childbearing age.
(a) Internal exposure assessed by combining exposure over all routes. For some age classes several values are given that refer to subgroups among the age class (see Table 31 for details).
(b) When biomonitoring data were available for more than one age class, several values are given.

CONCLUSIONS 1

- Depending on biomarkers used, HBM data were used in EFSA to "validate " dietary exposure estimates but also to detect health effects;

- HBM data are particularly important in exposure assessment and could play an important role in post market monitoring;

- Further development of BM of exposure to monitor substances of interest for EFSA is needed;

CONCLUSIONS 2

- HBM data need to be combined with other data and tools for interpretation in risk assessment:
  - ✓ Information on dietary intake (FFQ , 24h recalls)

- Access to individual HBM data is needed:
  - ✓ Data format compatible with EFSA's format for chemical concentration and intake data

STANDARDISATION & HARMONIZATION

Coordinated approaches
Standard protocols
Compatible systems

APPROPRIATE DATA MODEL

- A data model comprises 3 components:
  - the **structure** in which the data can be reported
  - the **catalogues** to describe the terms in a standardized way
  - and the **business rules** to check the validity of the reported data

SSD IS IMPLEMENTED FOR…

Currently implemented for:


Chemical contaminants


Pesticide residues


Additives


Food contact materials

Implementation in progress (from 2018)


Veterinary drug residues

Thank you very much!