

Plans for the Exposure Breakout Session

- Product #1 (~1 hr)
- Product #2 (~1 hr)
- Product #3 (~1 hr)
- Wrap-Up and Prep for Group Report-Out (~30 min)

Exposure Assessment Workgroup (EAWG) Planned Products

- Product 1: Collaborative International Journal Article:
“Assessing Human Exposures for Risk Assessment and Risk Management: An International Perspective”
- Product 2: Collaborative Guidance Document: Incorporating Biomonitoring in Exposure Assessment, Risk assessment and Risk management
- Product 3: Future Collaborative Case Studies for Harmonization of Assessing of Exposures in the Context of Risk Assessment and Risk Management

Breakout Discussion for Product #1 (Exposure Paper)

- Provide overview of draft paper

- Group discussion of 4 case studies
 - Discuss what models, methods, data, approaches (e.g., screening level, probabilistic, tiered) were used/selected for each case study and why
 - Compare and contrast exposure assessment approaches, models, data, results

- Discuss key questions for Results and Discussion

- Review status and completion plans

Content of the Exposure Paper

➤ Abstract

- Overall goal is to move towards a common international understanding and use of reliable and appropriate exposure approaches in support of risk assessment and risk management evaluations.
- Paper also provides an overview of existing approaches in exposure assessment across the three jurisdictions, facilitating dissemination and sharing of exposure data and assessment methodologies, and laying the groundwork for collaborative high priority exposure and risk case studies in the future.

Content of the Exposure Paper

➤ Introduction

- Human exposure assessment can be defined as the process of estimating or measuring the magnitude, frequency and duration of exposure to an agent, along with the number and characteristics of the population exposed, such as: sources, routes, pathways and assessment uncertainties

- Exposure in the context of intended uses, combined with an assessment of the intrinsic hazard of the substance or product, allows regulators to determine the potential risks posed by the introduction of these substances or products

- 3 objectives of paper:
 - summarize existing approaches used in exposure assessment across the 3 TRAD jurisdictions in view of sharing and disseminating exposure models, data and methodologies
 - compare the different approaches in exposure assessment, and identify gaps and challenges for future collaboration on addressing through high priority exposure and risk case studies
 - foster harmonization within governmental organizations across E.U., U.S., and Canada

Content of the Exposure Paper (Cont.)

➤ Methods

- Commonly used methods for exposure assessment include direct and indirect measurements as well as models.
- Screening level and higher tiered (e.g., probabilistic) models and tiered approaches for exposure assessment are used in most jurisdictions
- Screening health assessments limited principally to info considered most critical in assessment of human exposure to a substance and its health-related effects.
- If needed, some substances will undergo a more in-depth assessment of the risks to human health, but only after a screening assessment has been conducted
- An exposure assessment could also be used to identify key factors for risk management actions

Discussion of Case Studies

Case Study	Model(s)	Data	Approach	Sens./Uncert	How Results Used
Benzene					
As in d.w.					
CCA wood					
MeHg fish					

Content of the Exposure Paper (Cont.)

➤ Case Study examples

- Benzene Inhalation Exposure
- Arsenic from CCA-treated Playsets (dermal and non-dietary ingestion)
- Arsenic via drinking water ingestion
- Methyl Mercury Exposure from Fish Consumption

➤ Results

- Compare and contrast exposure assessment approaches, models, data (were there differences in the outcome of a risk assessment in cases where approaches/methods differed?)
- Discuss what models, methods, data, approaches (e.g., screening level, probabilistic, tiered) were used/selected for each case study and why

➤ Discussion

- Commonalities, differences among approaches and tools used by the 3 jurisdictions, limitations, and lessons learned
- Issues and challenges internationally moving forward towards improving current science and use of exposure assessments to inform risk assessments and regulatory decision-making
- Representativeness of the exposure measurement or modeling estimates
- Effectively communicating results and limitations to risk assessors and managers
- Recommended next steps to address the challenges identified

Exposure Assessment Workgroup (EAWG)

Planned Products

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Planned EAWG Product # 2 (Biomonitoring Guidelines Document)

- Product
 - international biomonitoring guidance document

- Goal
 - to improve the way biomonitoring studies are used in exposure assessment and incorporated into the risk assessment process internationally

- Proposed outline (refer to Prof. Greim's presentation for more details)
 - summarize existing and novel approaches in exposure assessment using the results of biomonitoring/biomarker studies
 - identify specific previous case studies in which the results of biomonitoring studies have been incorporated into exposure and risk assessments with a view to provide appropriate guidance for the future
 - identify the key data/knowledge requirements to design, conduct and evaluate biomonitoring studies and incorporate the results in the exposure assessment and risk assessment process

- **Next Steps**

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Planned EAWG Product # 3 (Future Collaborative Case Studies)

➤ Planned Product

- New and additional international collaborative case studies using available exposure assessment tools (e.g., models and available data) and approaches (based on information derived from Products #1 and #2 and at this meeting)

➤ Goals

- provide better shared understanding of available exposure tools and approaches internationally
- apply exposure models, data sets, tools, and approaches to high priority and challenging case studies
- move toward applying, testing and evaluating international harmonization approaches

Next Steps for Product # 3: Proposal for Future Collaborative Case Studies

- Charge: collectively identify high priority chemicals for potential future inhalation, residential, dietary, and multimedia case studies

- Discuss feasibility of proposals and identify a few new case studies based on criteria, such as:
 - complexity
 - issues of common interest (e.g., scientifically and/or regulatory relevant or significant, emerging issues)
 - availability of data (including potential for model evaluation)
 - availability of expertise
 - timelines

- Specify plan for conducting collaborative case studies for global exposure/risk assessments, using methods, models, information identified in Products # 1 and # 2

Future Case Study Suggestions to Date

- lead in air
- lead in toys/jewelry
- BPA
- PFOS/PFOA
- aggregate arsenic (food, drinking water, playsets, air)
- cumulative pyrethroid pesticides
- cumulative metals in fish consumption
- consumer products
- voluntary as well as regulatory efforts
- cumulative risk assessments (chemical and non-chemical stressors; relates to workshop 5)
- screening and prioritization tools for exposure assessment
- exposure models and predictive tools for data poor substances

➤ **other ideas?**

This paper was produced for a meeting organized by Health & Consumers DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumers DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.