Collaborative Project on Exposure Assessment

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With
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Recommended Next Steps from the Nov 2008 Exposure Breakout Group (1st International Risk Dialogue in Brussels)

- ad hoc international exposure working group to review existing approaches in exposure assessment worldwide (models and measurements)
- facilitate dissemination and sharing of exposure data and assessment methodologies
- work on collaborative high priority exposure and risk case studies
- facilitate information on biomonitoring study designs
- *organize hands-on international exposure training*

Exposure Assessment Workgroup (EAWG) Planned Products

- Product 1: Collaborative International Journal Manuscript: "Assessing Human Exposures for Risk Assessment and Risk Management: An International Perspective"

- Product 2: Collaborative International Guidance Document: "Incorporating Biomonitoring in Exposure Assessment, Risk Assessment and Risk Management"

- Product 3: Proposals for Future Collaborative Case Studies for Harmonization of Assessing of Exposures in the Context of Risk Assessment and Risk Management

Expected Benefits of EAWG Planned Products

- Provides venue for better integrated and internationally collaborative data sharing, model comparisons, model evaluation, and exposure/risk assessments

- Fosters harmonization within Agencies and across EU, US, and Canadian Agencies in conducting pertinent and reliable exposure assessments in support of various risk assessment and risk management activities

Steps Involved in Developing Product #1 (Exposure Paper)

- Develop goals and draft outline of the paper after the 1st Brussels Meeting
- Identify candidate exposure case studies for the collaborative paper
- Discuss and finalize paper outline and example case studies during the June 4, 2010 TRAD Ottawa Conference
- Develop timeline and identify leads and coauthors for the various sections
- Conduct teleconferences to update and share progress
- US, EU, CAN draft respective sections of paper (on-going)
- Produce a preliminary draft of the manuscript prior to this meeting
- Review status and completion plans of the draft paper during the Exposure Breakout session of this Conference

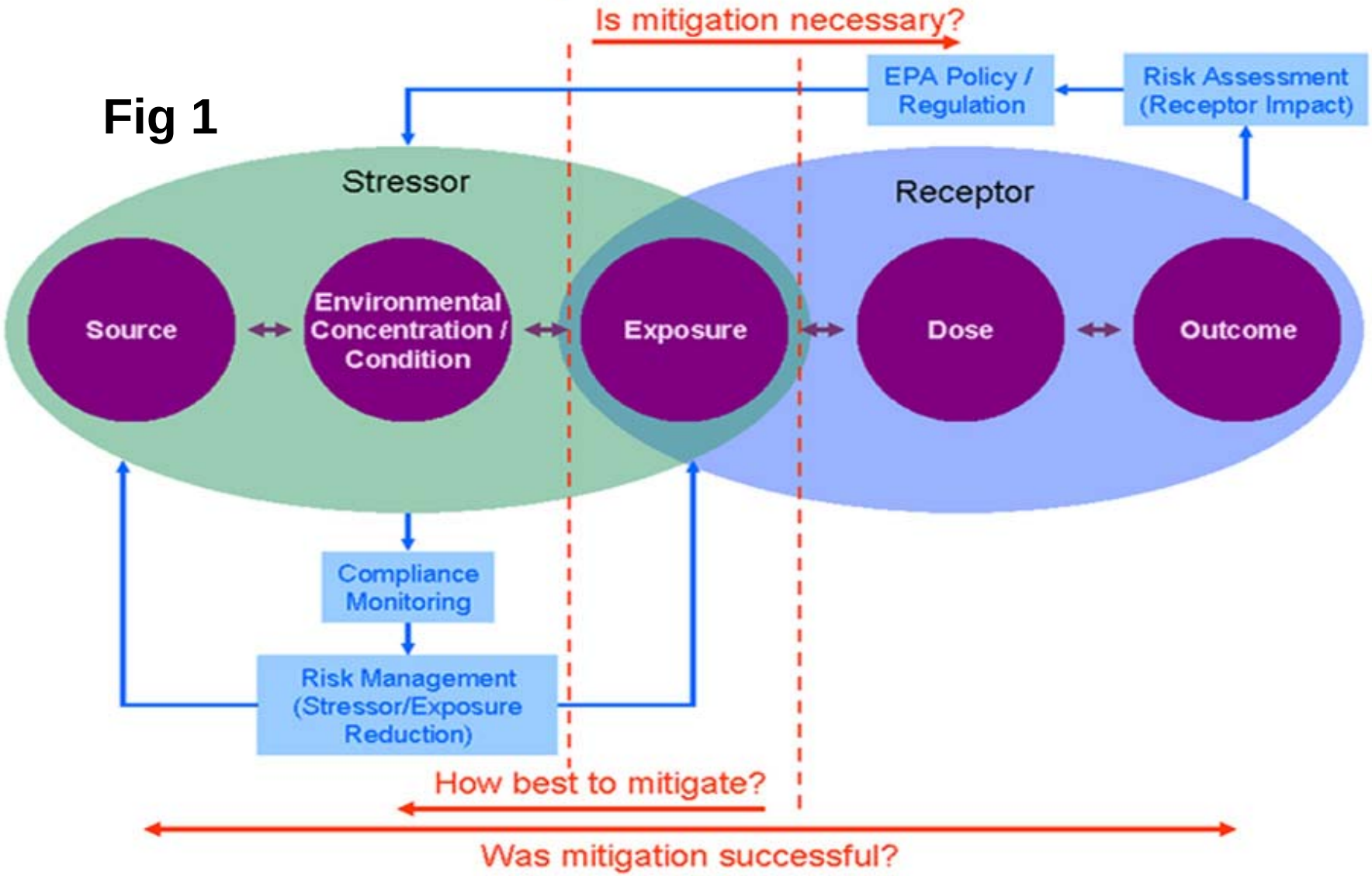
Content of the Exposure Paper

- Abstract
  - Main goal it to move towards a common international understanding and use of reliable and appropriate exposure approaches in support of risk assessment and risk management evaluations

- 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 assessment is used in the context of its intended application (See Figure)
  - Specific goals of this paper are, to:
    - summarize existing approaches used in exposure assessment by the different jurisdictions
    - compare the different approaches in exposure assessment, and identify gaps and challenges
    - foster harmonization within governmental organizations across E.U., U.S., and Canada in laying the groundwork for collaborative high priority exposure and risk case studies in the future

Role of Exposure Research in the Risk Assessment/Risk Management Context

Fig 1

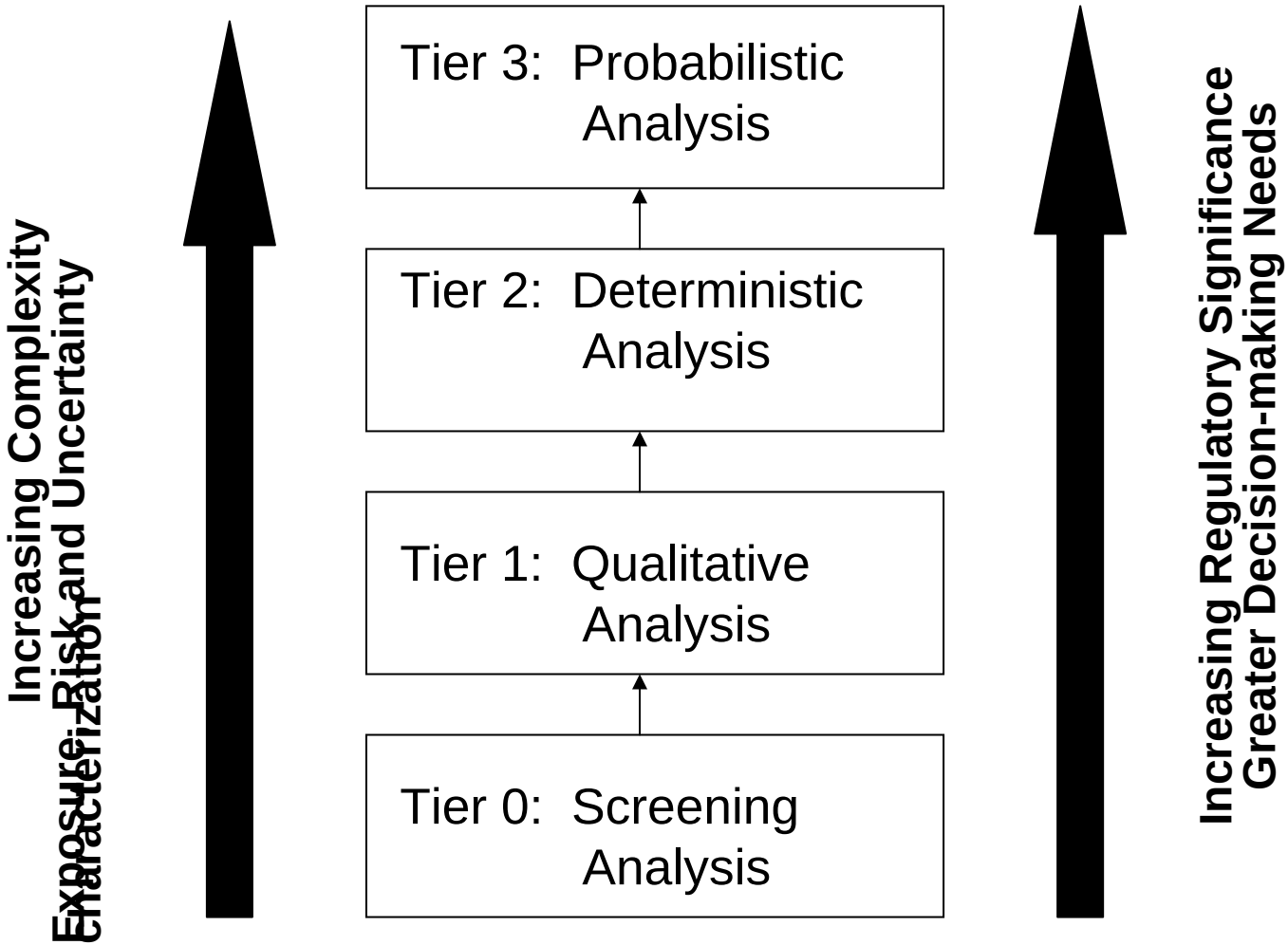


Source: L. Reiter, Exposure Science in the 21st Century, Presented to NAS, October 2008

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 are available in most jurisdictions (the U.S. EPA models are discussed and summarized in Williams et al., 2010)
  - Similar tiered approaches are described in the EU technical guidance documents which support the different regulations dealing with chemicals, including REACH
  - In Canada, screening assessments conducted under the Canadian Environmental Protection Act (1999) assess whether or not a substance is likely to pose a risk to human health with a focus on those compounds that pose the greatest risk (Health Canada 1999).
  - Screening health assessments are limited principally to the information that is 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
  - Exposure assessments may be used to characterize projected reductions in exposures which may occur through alternative risk management actions

Approach for Tiered Analysis

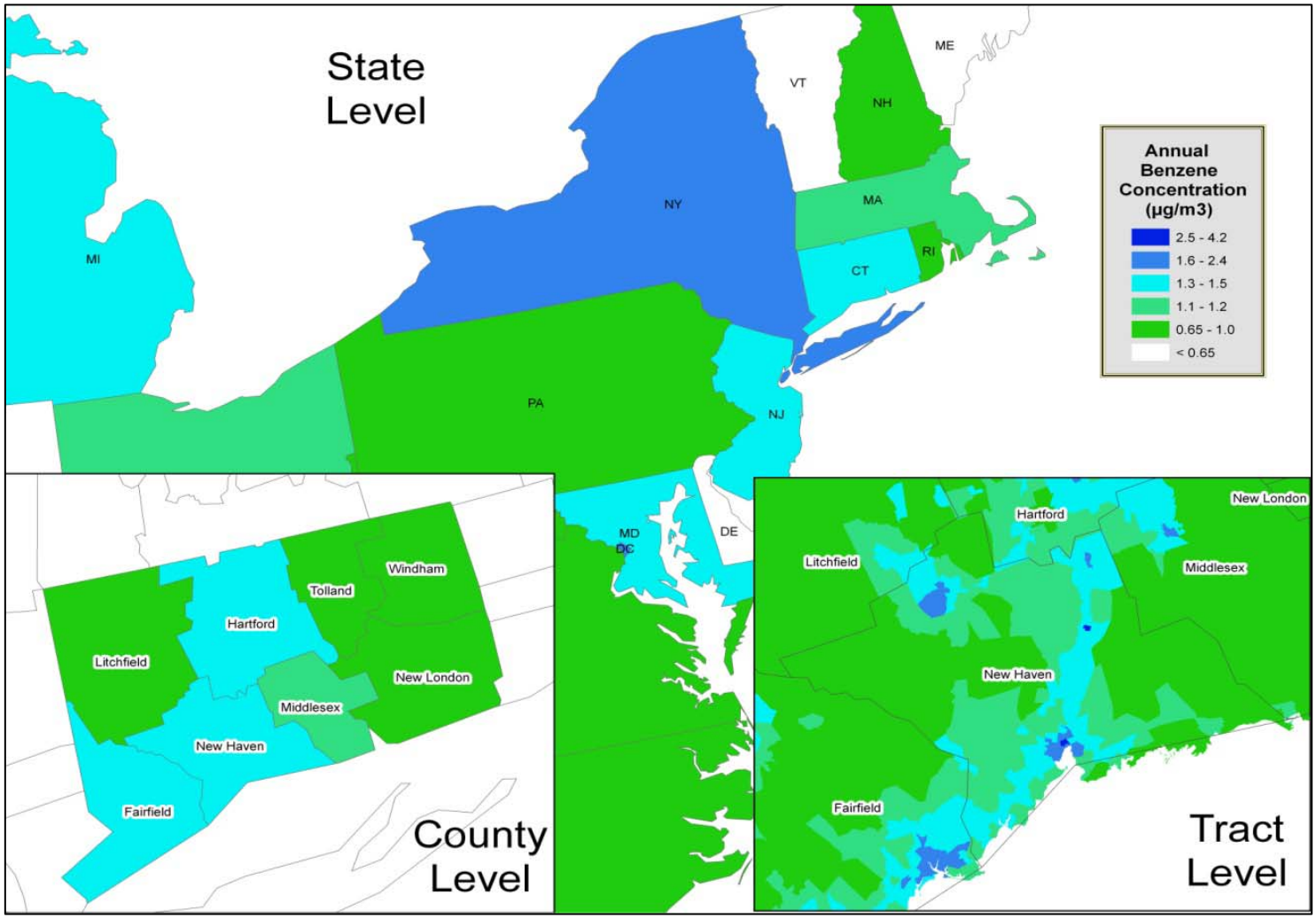


Content of the Exposure Paper (Cont.)

- 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
  - Describe what models, data, approaches (e.g., screening level, probabilistic, tiered) were used/selected for each case study, why and how the results were integrated into the risk assessment
  - Examine whether there were differences in the outcome of a risk assessment in cases where approaches/methods differed
- Discussion
  - Commonalities, differences among approaches and tools used by the three jurisdictions, limitations, and lessons learned
  - Effectively communicating results and limitations to risk assessors and managers
  - Recommended next steps to address the challenges identified:
    - harmonizing methods (i.e., when and how)
    - data sharing
    - biomonitoring considerations,
    - hands-on modeling training
    - future collaborative case studies

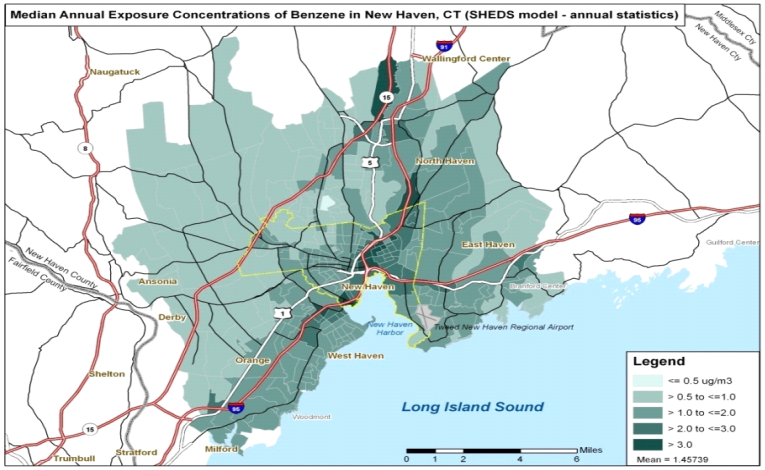
Benzene Case Study Example from the US

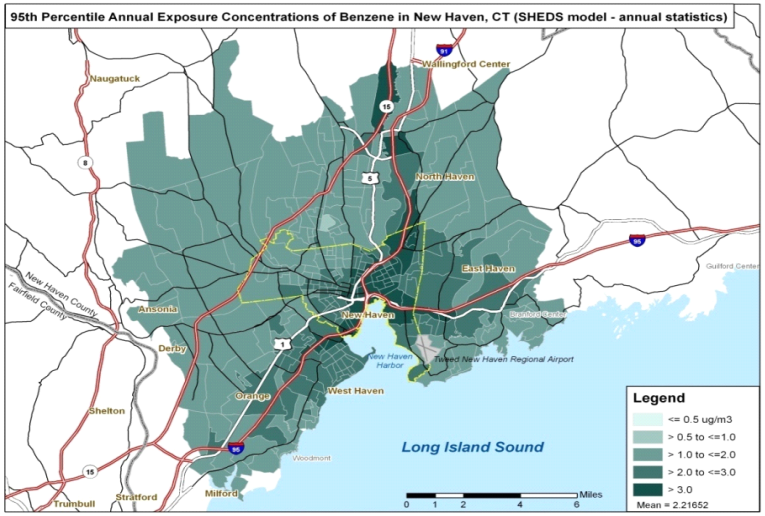
2005 NATA – Average Benzene Concentrations at different Geographic Scales in the Northeastern United States.



Benzene Case Study Example from the US

SHEDS Modeled Annual Average Benzene Exposures (μg/m^3) for Census Block Groups in New Haven, CT: (a) Median value, (b) 95th percentile value.





Planned EAWG Product # 2 (Biomonitoring Guidelines Document)

- Product
  - international biomonitoring guidance document

- Goal
  - to improve and harmonize 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

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 exposure/risk case studies

- Discuss (during the Exposure Breakout Session) 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

Plans for the Exposure Breakout Session

- (~1 hr) Product #1: Discussing ideas and next steps
- (~1 hr) Product #2: Discussing ideas and next steps
- (~1 hr) Product #3: Discussing ideas and next steps
- (0.5 hr) Wrap-up and group report-out preparation