RISK Assessment for the 21st Century Exposure Subteam Update

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RISK21: Realizing the Future of Risk Assessment

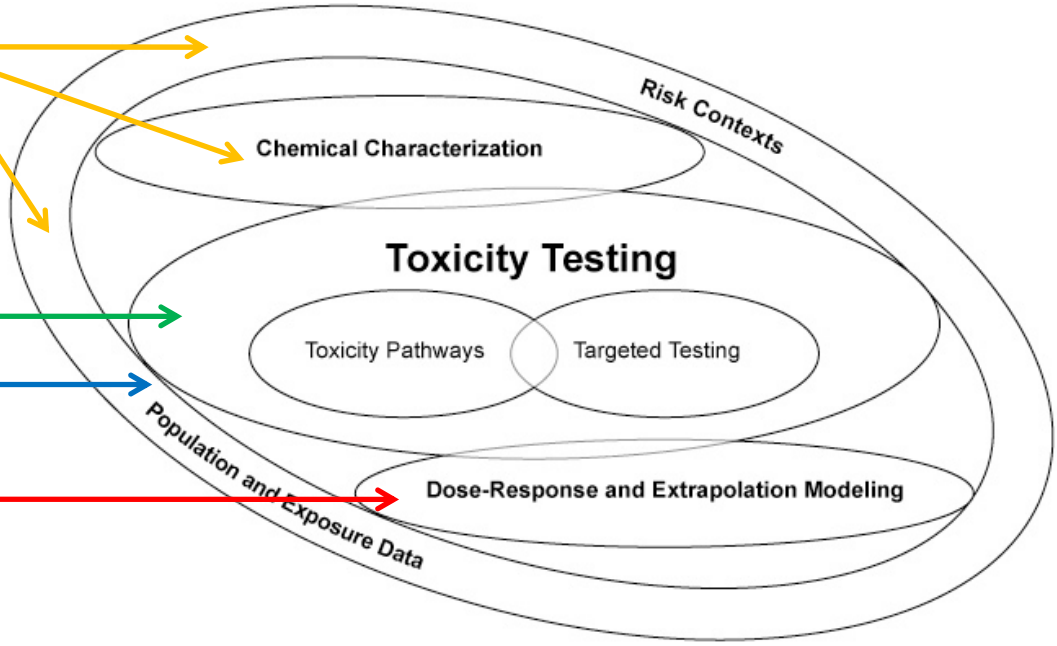
Key Areas of Focus

Exposure Science

Dose-response

Tiered (Integrated) Testing

Cumulative Risk



Exposure Science

- Co-Chairs:
  - Dana Sargent *(Arysta LifeSciences)*
  - Mike Dellarco *(NIH/NICHD)*

Mission:

- Propose approaches for using new technologies to improve characterization of real-world exposures and provide the data-driven, evidence base for 21st Century exposure measurement, modeling and risk assessment

Exposure Science Sub-Team Roster

Global, multi-sector representation
n=24 scientists, 22 affiliations

- Academia (n=5; 5 institutions)
  - Emory University
  - Radboud University Nijmegen
  - University of Aarhus
  - University of Michigan
  - University of Toronto
- Industry (n=10; 9 companies)
  - Arysta LifeSciences
  - BASF
  - Bayer CropScience
  - Dow AgroSciences
  - Dow Chemical
  - DuPont
  - ExxonMobil
  - Procter & Gamble
  - Syngenta
- Government (n=9; 8 agencies)
  - Consumer Product Safety Commission
  - Health Canada
  - National Institutes of Health (NIH)
  - Pacific Northwest National Laboratory (PNNL)
  - RIVM
  - US Department of Agriculture
  - US Environmental Protection Agency
  - US Food and Drug Administration

Exposure Science –Objectives

- Define exposure to address current and emerging needs for risk assessment
- Improve the quality of exposure data for use in risk assessment
- Apply exposure science to reduce uncertainty in risk assessment
- Establish links between lab/in vitro exposure and real-world human exposures
- Propose approaches for interpreting and applying exposure data to inform testing, to support dose-response, and to facilitate cumulative risk
- Explore how new technologies can be harnessed to better characterize exposure (e.g. incorporation of time, space and scale; and relevant dynamics and kinetics).
- Provide exposure information of value in a forum and context that can better inform the public

Exposure Science – Initial Output

- Develop a "Report-card for Exposure"
  - Expert commentary that provides a critical examination of the field
  - Discussion of best practices & provide recommendations
  - Illustrate the importance of measured data
  - Highlight examples to illustrate key points
  - Draw from a range of other examples to apply lessons learned (e.g., lead, dioxin, etc.)
    - What should have been done? What was done right or wrong?
- Best Practices for Exposure Assessment - Emerging Compounds
  - Using nanomaterials as an example, discuss how you would go about doing exposures assessment "right"
    - Where would you start?
    - What information do you need?
    - What information do you ask for?
    - What does this expert group recommend?

Exposure Science – Report Card

- Report-card format
  - Topic title
  - Brief description
  - Strength of effort & value of research to the field
  - Limitations or omissions
  - "Grade" with suggestions for improvement
  - An annotated bibliography for the various areas

Exposure Science – Report Card

- Draft topic list
  - Biological monitoring
  - Biomarkers
  - Environmental sample analysis
  - Environmental sample collection
  - Exposure models
  - Exposure monitoring studies
  - Personal exposure monitoring methods
  - Populations exposed
  - Sources identification
  - Technology
  - Terminology
  - Time Activity Patterns
  - Source to disease model

Best Practices for Exposure - Nanomaterials

- Using nanomaterials as an example, discuss how you would go about doing exposures assessment "right"
  - Review the work of the National Nanotechnology Initiative (NNI) Human and Environmental Exposure Assessment report as a starting point on how best to measure and incorporate exposure data into risk assessment of novel technologies.
  - Produce a case example looking at critical exposure questions
    - Focus on a specific nanomaterial
  - How can the lessons from the past be used to provide a roadmap for future work
    - Recommendations for exposure studies to meet identified data gaps
    - What were the barriers that existed in the past to exposure research for other compounds
      - How can these barriers be addressed for nanomaterials

Exposure Science – Potential Impact

- Capture perspectives and needs of both researchers, modelers and regulators/decision makers
- Develop a framework for the consistent application of new technologies for exposure measurement and assessment
- Use of available information to facilitate cross-talk (researchers, modelers and risk assessors) and inform future data collection
- Identification of exposure information required to inform toxicity testing design
- Integration of exposure information to better inform the risk assessment decision making processes
- Standards for exposure data representation (including minimum elements necessary to efficiently collect, store and link exposure data)