Workshop XIII Agenda & Purpose

To advance the recommendations in the NAS (2009) report concerning issue identification (problem formulation) and all aspects of risk assessment and management, through selection of illustrative research case studies for further development

Day 1: Tuesday, February15th, 2022

Chair: **Mark S. Johnson,** U.S. Army Public Health Center

Welcome: (1:00 to 1:15)

- **Wendelyn Jones,** Institute for the Advancement of Food and Nutrition Sciences
- **Michael Dourson,** Toxicology Excellence for Risk Assessment

Keynote Talk: New approach methodologies (NAMs) (1:15 to 2:00)

- **Russell Thomas,** U.S. Environmental Protection Agency

Research Case Study 1: Developing Confidence in NAMs data for risk assessment: *C elegans* as a case study (2:00 to 3:00)

- **Piper Hunt and Suzanne Fitzpatrick,** U.S. Food and Drug Administration
- Discussion by the Science Panel
- Comments from Observers

Afternoon Break (3:00 to 3:30)

Research Case Study 1: continued (3:30 to 5:00)

- Discussion by the Science Panel
- Comments from Observers
- Chair's Summary

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Social TBD-open to all attendees
(dinner portion hors d'oeuvres, 6:00 to 8:00)

Day 2: Wednesday, February 16th

Chair: **Neeraja Erraguntla,** American Chemistry Council

Research Case Study 2: Biological Effect Action Level (BEAL) Versus Biological Exposure Index (BEI) (8:30 to 10:00)

- **Michael Taylor,** NiPERA
- Discussion by the Science Panel
- Comments from Observers

Morning Break (10:00 to 10:30)

Research Case Study 2: continued (10:30 to noon)

- Discussion by the Science Panel
- Comments from Observers
- Chair's Summary

Lunch (noon to 1:00)

Ongoing Activities (1:00 to 2:30)

- Using NAMs to derive a risk assessment decision on coumarin
    - **Maria Baltazar,** Unilever
- Use of multiple novel in vitro culture assays to assess the human relevance of spermatotoxicity
    - **Rebecca Clewell,** 21CT
- Mechanistic data in hazard characterization: key characteristics and mode of action/adverse outcome pathways in context
    - **Bette Meek,** University of Ottawa

Afternoon Break (2:30 to 3:00)

Ongoing Activities: continued (3:00 to 4:30)

- ToxCalc! Automate routine calculations and reduce errors
    - **Reena Sandhu,** SafeDose
- Next-generation Drug Safety Assessment with Organ-Chip Technology
    - **Lorna Ewart,** Emulate
- Evidence-Based Risk Assessment of Potential Dietary Carcinogens
    - **Andy Maier and Christopher Bates,** Cardno ChemRisk

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Dinner on your own

Day 3: Thursday, February 17th

Chair: **Suzanne Fitzpatrick,** U.S. Food and Drug Administration

Research Case Study 3: Use of Molecular Dosimetry to Identify Points of Departure for Potential Carcinogens with Both Endogenous and Exogenous Exposures (8:30 to 10:00)

- **Jim Sherman,** Celanese; **Rita Schoeny**, EPA retired; **Rory Conolly**, Ramboll US consulting, Inc; and **Kun Lu**, University of North Carolina
- Discussion by the Science Panel
- Comments from Observers

Morning Break (10:00 to 10:30)

Research Case Study 3 continued: (10:30 to noon)

- Discussion by the Science Panel
- Comments from Observers
- Chair's Summary

Lunch (noon to 1:00)

Research Case Study 4: Cancer Risk Assessment for 1,3-Butadiene Based on New Data and Methods (1:00 to 2:30)

- **Christopher Kirman,** Summit Toxicology
- Discussion by the Science Panel
- Comments from Observers

Afternoon Break (2:30 to 3:00)

Research Case Study 4: continued (3:00 to 4:30)

- Discussion by the Science Panel
- Comments from Observers
- Chair's Summary

Summary of the Workshop (4:30 to 5:00)

- **Mark S. Johnson,** U.S. Army Public Health Center
- **Neeraja Erraguntla,** American Chemistry Council
- **Suzanne Fitzpatrick,** U.S. Food and Drug Administration