

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, February 15th, 2022

RAAC Chair 1: Pamela Williams

Welcome (1:00 to 1:15)

- **TBD**, US FDA
- **Mark S. Johnson**, Member of the Risk Assessment Advisory Committee
- **TBD**, Member of the Science Panel

Keynote Talk (1:15 to 1:45)

- New approach methodologies (NAMs)
TBD, U.S. Environmental Protection Agency (invited)

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

(1:45 to 3:00)

- **Suzanne Fitzpatrick, US FDA**
- 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, 5:30 to 8:00)**

Day 2: Wednesday, February 16th

RAAC Chair 2: Suzanne Fitzpatrick

Research Case Study 2: Risk Assessment of chemical substances with background endogenous levels: A weight of the scientific evidence workshop (8:30 to 10:00)

- **TBA**
- Discussion by the Science Panel

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
 - **Paul Carmichael, Unilever (confirmed)**
- Use of multiple novel in vitro culture assays to assess the human relevance of spermatotoxicity
 - **Rebecca Clewell of Ramboll (confirmed)**
- Mechanistic data in hazard characterization: key characteristics and mode of action/adverse outcome pathways in context
 - **Bette Meek of the University of Ottawa (invited)**

Afternoon Break (2:30 to 3:00)

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

- ToxCalc! Automate routine calculations and reduce errors
 - **Reena Sandhu of SafeDose (confirmed)**
- **TBD**

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Dinner on your own

Day 3: Thursday, February 17th

RAAC Chair 3: Neeraja Erraguntla

Research Case Study 3: (8:30 to 10:00)

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

Morning Break (10:00 to 10:30)

Research Case Study 4 continued: (10:30 to noon)

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

Summary of the Workshop (noon)

- **Pamela Williams, Suzanne Fitzpatrick, and Neeraja Erraguntla**