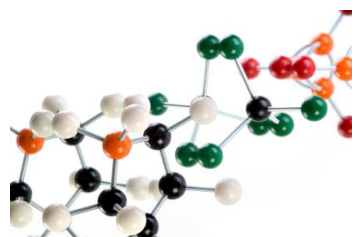


Workshop Series: Beyond Science and Decisions XIII

**Location: U.S. Food and Drug Administration- Wiley Auditorium
5001 Campus Drive, College Park, MD 20740**

Dates: February 15, 16 and 17, 2022



SUMMARY

Since 2010, the Alliance for Risk Assessment (ARA: see [here](#)) has sponsored a workshop series titled *Beyond Science & Decisions: From Problem Formulation to Comprehensive Risk Assessment*. Building on the ideas of the National Academy of Sciences' (NAS) *Science & Decisions: Advancing Risk Assessment* (2009), twelve previous workshops brought together over 60 organizations seeking to advance the NAS recommendations (see [here](#)).

Over 50 presented case studies have thus far contributed to an expanding compendium of practical, problem-driven approaches for “fit for purpose” risk assessments. As a resource for regulators and scientists, the compendium details key considerations for applying relevant dose-response or exposure assessment methods, whether novel or evolving, and links these methods to specific problems faced by risk assessors and risk managers in a variety of organizations (e.g., local, regional and federal governments, academia, private sector).

WORKSHOP XIII OBJECTIVES

- Use a multi-stakeholder approach to share information supporting the development of practical problem-driven risk assessment methods
- Highlight effective and meaningful context-specific problem formulation approaches that apply an appropriate level of detail
- Promote hazard identification, dose-response, exposure assessment, and risk characterization methods, such as those that:
 - Reflect relevant biology (including dose-dependent transitions) and mode of action
 - Describe assumptions, strengths, and limitations of relevant data and address key considerations in risk assessment and decision-making
 - Use new approaches to advance the 3’Rs (replace, reduce, and refine animal use in research)
 - Consider population and human variability, including underlying disease and exposure conditions
 - Quantitative or qualitative uncertainty analysis.

- **Celebrate the Success-** Occurring 13 years after Workshop I in 2010, Workshop XIII will highlight successes from previous case studies, such as (but not limited to) the:
 - Regulatory impact of a state-of-the-science method
 - Harmonization of risk values or methodology
 - Engagement of stakeholders in informing policy
 - Advancement of the 3’Rs
 - Contact the Alliance for Risk Assessment at ARA@tera.org with the Subject: ARA Success Story, if you have a success story from a previous case study to share.

SPONSORS AND RELEVANT COMMITTEES

Numerous organizations have sponsored this workshop series through in-kind donations or grants (see [here](#)) and three committees shepherd the workshop series:

- The Alliance for Risk Assessment Steering Committee (see [here](#))
- The Beyond Science and Decisions Science Panel (see [here](#))
- The Risk Assessment Advisory Committee, which includes state, federal, industry, and NGO representatives.

CASE STUDIES

The agenda, speakers, and case studies for Workshop XIII are under development.

Case studies can range in complexity from Qualitative → Quantitative Screening → In-depth Assessments. See examples [here](#).

WORKSHOP XIII REGISTRATION

Click [here](#) to register.

Contact Michael Dourson of TERA at dourson@tera.org for more information.

WE WELCOME YOUR THOUGHTS!

Please use [this link](#) to complete a <5-minute survey and share your thoughts (anonymously, if desired) on past or future Workshops.