Alliance for Risk Assessment Workshop

By Michael Dourson and Patricia M. McGinnis — December 17, 2019

The next Beyond Science and Decisions Workshop XI will be held on February 18-20, 2020 in Cincinnati, Ohio, at the Taft Auditorium of the National Institute for Occupational Safety and Health (NIOSH).

Alliance for Risk Assessment (ARA) Presents: Beyond Science and Decisions: from Problem Formulation to Comprehensive Risk Assessment

Toxicology Excellence for Risk Assessment (TERA)

Risk assessment problems can be complex and often cross organizational boundaries. Moreover, individual groups often do not have sufficient resources to address these problems in a timely manner. This reality led to the creation of the Alliance for Risk Assessment (ARA); see https://tera.org/Alliance%20for%20Risk/index.htm [2]. The ARA is now in its 12th year. Its longest running program, and some say most successful, is a workshop series entitled “Beyond Science and Decisions: from Problem Formulation to Comprehensive Risk Assessment.”

Background of the Workshop Series

The Alliance for Risk Assessment (ARA) has sponsored a series of workshops 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), ten workshops have been conducted to date that brought
together a number of organizations seeking to clarify and advance the NAS recommendations (see: https://tera.org/Alliance%20for%20Risk/ARA_Dose-Response.htm). A total of 40 or more research case studies have been presented at these workshops, which provided a real-time compendium of practical, problem-driven approaches for “fit for purpose” risk assessments. Specifically, the compendium links novel and evolving scientific methods and approaches with specific problems faced by risk assessors and risk managers in a variety of organizations (e.g., local, regional and federal governments, academia, and private sector).

Objectives of the Workshops

The seven objectives for the ARA workshops are as follows:

- Improve the risk assessment process by developing an updated and ongoing compendium of practical, problem-driven approaches for “fit for purpose” risk assessments, linking methods with specific problem formulations (e.g., prioritization, screening, and in-depth assessment) for use by risk assessors and managers at a variety of levels (e.g., states, regional managers, people in a variety of agencies, and in the private sector).
- Implement a multi-stakeholder approach to share information, ideas, and techniques in support of developing practical problem-driven risk assessment methods.
- Identify effective and meaningful problem formulation, and useful hazard identification, dose-response, exposure assessment, and risk characterization techniques for specific issues, including consideration of relevant data, description of assumptions, strengths, and limitations, and how the techniques address key considerations in risk assessment and decision-making. These techniques should appropriately reflect the relevant biology (including the biology of thresholds), mode of action information, and exposure variability at a level of appropriate detail.
- Provide methods to explicitly address human variability in assessments, including explicit consideration of underlying disease processes and exposure conditions, as appropriate for the relevant risk assessment context.
- Identify methods for calculating the probability of response for noncancer endpoints, as appropriate for the relevant risk assessment context.
- Identify useful decision-making approaches that incorporate risk information and uncertainty analysis.
- Develop a risk methods compendium that will serve as a resource for regulators and scientists on key considerations for applying selected dose-response or exposure assessment techniques for various problem formulations, with suggested techniques and resources.

Committees of the Alliance

Much of the work of the Alliance is accomplished by its various committees. These committees include:

- The Alliance for Risk Assessment Steering Committee (SC) provides guidance and oversight of the workshop series and research case study selection. The Steering Committee has the final decision on charge questions after consultation with the Risk Assessment
Advisory Committee, as well as the final decision on members of the Expert Panel after a review of all nominations. The SC consists of state, tribal, and federal governments, academia, and environmental non-governmental organizations (NGO). See: https://tera.org/Alliance%20for%20Risk/ARA_Steering_Committee.htm [4].

- The Risk Assessment Advisory Committee (RAAC) is composed of state, federal, industry, and NGO representatives. This group represents the various sponsors in the development of workshop structure, charge questions, development of Panel nominations, and the recruitment of presenters. The RAAC has the final decision on workshop structure, presenters, and content, after consultation with the ARASC. See: https://tera.org/Alliance%20for%20Risk/raac.html [5].

- The Beyond Science and Decisions Science Panel (SP) provides input on research case study methods being proposed to enhance the risk framework. Panel members also provide input on the utility of the research case study methods to address specific problem formulations, and identify areas for additional development of the research case study and/or method. Inclusion of a method or research case study in the framework as an illustration of a useful technique does not imply panel acceptance of the chemical-specific outcome, however. Core panel members serve for two to three years; ad hoc members may be added to the standing panel to ensure expertise on specific topics. See: https://tera.org/Alliance%20for%20Risk/Workshop/Panel.htm [6].

The most recent workshop was held at the offices of the Texas Commission on Environmental Quality (TCE) in February of 2019. Dr. Michael Honeycutt of the TCEQ gave the Keynote Talk entitled “Risk Assessment in the Trenches: The Importance of Getting it Right.”

Several research case studies were presented, including:

- Wastewater Cleaning: A preliminary method adapted from the trenches by Mr. Kelly Houston of AEI, LLC.
- Data-Derived Extrapolation Factors for Developmental Toxicity: A Case Study with PFOA by Drs. Bernard Gadagbui and Michael Dourson of TERA.
- Physiologically-based pharmacokinetic (PBPK) modeling of inhaled aerosol by Drs. Aditya Reddy Kolli, Florian Martin, Arkadiusz Kuczaj of PMI Research and Development.

Cutting edge research presented, included:

- Weight of Evidence Methodology by Dr. Bette Meek of the University of Ottawa
- Bayesian Benchmark Dose Analysis for Probabilistic Risk Assessment – Another Revolution in Dose-Response by Dr. Kan Shao of Indiana University.
- Fetal Cardiac Findings in Rats Exposed to TCE in Drinking Water by Dr. James Bus of Exponent.
- Going beyond basic QSARs to support Pre-Manufacturing Notices by Dr. Alexandra Maertens of the Consortium for Environmental Risk Management
- Probabilistic exposure models for industrial hygiene applications by Dr. Tom Armstrong of
The next Beyond Science and Decisions Workshop XI will be held on February 18, 19 and 20 in 2020 at the Taft Auditorium of the National Institute for Occupational Safety and Health (NIOSH) in Cincinnati, Ohio. On deck for presentation will be research case studies from NIOSH on Occupational Exposure Banding 2.0: Characterizing Risks for Chemicals with Limited Data, and from the Texas Commission for Environmental Quality on Applying Hypothesis-Testing Methods to Help Inform Causality Conclusions from Epidemiology Studies. The RAAC is soliciting additional research case studies, nomination for a keynote talk, and several additional presentations highlighting risk method updates. The current draft agenda can be found at: https://tera.org/Alliance%20for%20Risk/Workshop%20XI/Feb_2020/Draft_Agenda.pdf [7]