



**Beyond Science and Decisions:
From Problem Formulation to Risk Assessment**

February 26 & 27, 2019
Texas Commission on Environmental Quality
Austin, TX

Workshop Co-Chairs:

Mark S. Johnson, US Army Public Health Center

Kimberly White, American Chemistry Council

Workshop Coordinators:

Angela Curry, TCEQ

Valerie Ayers, TERA

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Workshop Information and Sponsors

Workshop X Title Beyond Science and Decisions: From Problem Formulation to Comprehensive Risk Assessment

Workshop X Site Texas Commission on Environmental Quality,
Room 191 Building D, 12118 N IH-35, Austin, TX

Workshop X Dates February 26 & 27, 2019

A number of organizations have sponsored this workshop series through in kind donations or grants. See: https://tera.org/Alliance%20for%20Risk/ARA_Dose-Response_Sponsors.htm.

Sponsors: (currently being confirmed)

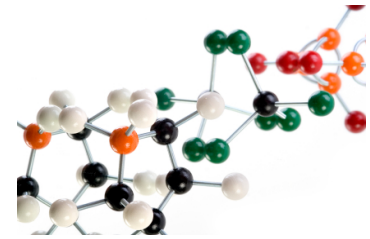
- Academy of Toxicological Sciences
- Agency for Toxic Substances & Disease Registry
- American Chemistry Council Center for Advancing Risk Assessment Science and Policy
- American Cleaning Institute
- American Petroleum Institute
- American Water Works Association
- Center for Food Safety and Applied Nutrition of the US Food and Drug Administration
- Council of Producers & Distributors of Agrotechnology
- Chemical Specialty Products Association
- Consortium for Environmental Risk Management LLC (CERM)
- CropLife America
- Dose Response Specialty Group (Society for Risk Analysis)
- Electric Power Research Institute (EPRI)
- Environ
- Environmental Protection Agency
- Ethylene Oxide Panel of the American Chemistry Council
- Georgia Department of Natural Resources (EPD)
- Georgia Pacific
- Gradient
- Grocery Manufacturers Association
- Hawai'i State Department of Health; Hazard Evaluation and Emergency Response
- Human Toxicology Project Consortium
- Illinois Environmental Protection Agency
- Indiana Department of Environmental Management
- International Copper Association
- Industrial Economics, Incorporated
- International Society of Regulatory Toxicology and Pharmacology
- The LifeLine Group

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- Minnesota Pollution Control Agency
- The Naphthalene Council
- National Center for Toxicological Research of the US Food and Drug Administration
- NIEHS
- Mixtures SS SOT
- New Zealand Ministry of Health
- Nickel Producers Environmental Research Association
- Noblis
- NSF International
- Ohio Environmental Protection Agency
- Ontario Ministry of the Environment
- Pastor, Behling & Wheeler, LLC
- Personal Care Products Council
- Regulatory and Safety Evaluation Specialty Section (Society of Toxicology)
- Risk Assessment Specialty Section of (Society of Toxicology)
- SC Johnson & Son
- Society of Chemical Manufacturers and Affiliates, Inc.
- Society for Risk Analysis
- Society of Toxicology
- Summit Toxicology
- Styrene Information and Research Center
- Ted Simon Toxicology
- Texas Association of Business
- Texas Chemical Council
- Texas Commission on Environmental Quality
- Texas Industry Project
- Toxicology Excellence for Risk Assessment (TERA)
- United States Environmental Protection Agency

Sponsors Emeritus:

- The Hamner Institute for Health Sciences
- The Mickey Leland National Urban Air Toxics Research Center
- The Sapphire Group



Background & Purpose

Background

The Alliance for Risk Assessment (*ARA*) sponsors 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' *Science & Decisions: Advancing Risk Assessment* (2009), nine workshops were conducted from 2010 to 2015 that brought together over 60 organizations seeking to clarify and advance the NAS recommendations (see: https://tera.org/Alliance%20for%20Risk/ARA_Dose-Response.htm). A total of 40 research case studies were 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, private sector).

Purpose

Due to continued demand for the types of work products achieved by these workshops, the workshop series is continuing in 2019 and will expand upon the discussion set forth by *Science and Decisions: Advancement of Risk Assessment* (NAS, 2009). These workshops will be conducted under the aegis of the Alliance for Risk Assessment (*ARA*), a broad-based coalition (see: <https://tera.org/Alliance%20for%20Risk/index.htm>).

Workshop Objectives

- 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.

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- 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.

Listing of Research Case Studies

The recommended framework for the workshops and research case studies is currently being restructured. For access to any of the prior research case studies, please see

<https://tera.org/Alliance%20for%20Risk/Workshop/Framework/ProblemFormulation.html>, or contact Michael Dourson with Toxicology Excellence for Risk Assessment (TERA) at dourson@tera.org.

COMMITTEES ASSOCIATED WITH THE ALLIANCE FOR RISK ASSESSMENT

- The Alliance for Risk Assessment **Steering Committee** (SC) will provide guidance and oversight of the workshop series and research case study selection. The Steering Committee will have the final decision on charge questions after consultation with the Risk Assessment Advisory Committee, and will have the final decision on members of the Expert Panel after a review of all nominations. The SC consists of representatives of state, tribal, and federal government, academia, and environmental NGOs. Members include:
 - Anita Meyer, United States Army Corps of Engineers
 - Annette Dietz, Portland State University
 - Michael Dourson, Toxicology Excellence for Risk Assessment
 - Michael Honeycutt, Texas Commission on Environmental Quality
 - Moiz Mumtaz, Agency for Toxic Substance & Disease Registry
 - Ralph Perona, Neptune & Company, Inc. [representing tribal interests]

- The **Risk Assessment Advisory Committee** (RAAC) will be composed of state, federal, industry, and NGO representatives. This group will represent the various sponsors in the development of workshop structure, charge questions, development of Panel nominations, and the recruitment of presenters. The RAAC will have the final decision on workshop structure, presenters, and content, after consultation with the *ARA* Steering Committee. Members include:
 - James Bus, Exponent
 - Danielle Carlin, NIEHS
 - Michael Dourson, TERA
 - Suzanne Fitzpatrick, FDA
 - Mark S. Johnson, US ARMY
 - Sabine Lange, TCEQ
 - Kimberly White, ACC
 - Pamela Williams, E Risk Sciences, LLP

- 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. Core panel members will serve for 2-3 years; members may be added to the standing panel to ensure expertise on specific topics. Panel members are selected from a diversity of affiliations and areas of expertise, particularly biology/toxicology, exposure assessment, epidemiology, risk assessment, and statistical/modeling. Members include:
 - James Bus, Exponent
 - Chris Chaisson, The Lifeline Group
 - Michael Dourson, TERA
 - Annie Jarabek, U.S. EPA
 - Judy LaKind, LaKind Associates LLC
 - Bette Meek, University of Ottawa
 - Greg Paoli, Risk Sciences International

Workshop X 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 26th

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

Welcome (8:30 to 8:45)

- **Commissioner Emily Lindley**, Texas Commission on Environmental Quality
- **Dr. Pamela Williams**, E Risk Sciences, LLP, Member of the Risk Assessment Advisory Committee
- **Dr. Danielle Carlin**, NIEHS, Member of the Risk Assessment Advisory Committee

Keynote Talk (8:45 to 9:15)

- **Dr. Michael Honeycutt**, Texas Commission on Environmental Quality

Wastewater Cleaning: A preliminary method adapted from the trenches (9:15 to 10:15)

- **Mr. Kelly Houston**, AEI, LLC
- Discussion by the Science Panel
- Comments from Observers

Morning Break (10:15 to 10:45)

Assessing Influence of Confounding Variables in Low Dose Lead Dose Response (10:45 to noon)

- **Cynthia Van Landingham and Rosalind Schoof**, Ramboll
- Discussion by the Science Panel
- Comments from Observers

Lunch (noon to 1:00)

Data Derive Extrapolation Factors for Developmental Toxicity: A Case Study with PFOA (1:00 to 3:00)

- **Bernard Gadagbui**, TERA; **Ray York**, York and Associates
- Discussion by the Science Panel

Afternoon Break (3:00 to 3:30)

Data Derive Extrapolation Factor Case Study Continued (3:30 to 5:00)

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

Social TBA-open to all attendees (dinner portion hors d'oeuvres, 6:30 to 9:00)

Day 2: Wednesday, February 27th

Chair: **Dr. Kimberly White**, American Chemistry Council

Physiologically based pharmacokinetic (PBPK) modeling of inhaled aerosol (8:30 to 10:00)

- **Drs. Aditya Reddy Kolli, Florian Martin, Arkadiusz Kuczaj** of PMI Research and Development
- Discussion by the Science Panel

Morning Break (10:00 to 10:30)

PBPK Research Case Study continued (10:30 to 12:30)

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

Lunch (12:30 to 1:30)

Ongoing Activities (1:30 to 3:00)

Weight of Evidence Methodology

- **Dr. Bette Meek**, University of Ottawa

Bayesian Benchmark Dose Analysis for Probabilistic Risk Assessment – Another Revolution in Dose-Response

- **Dr. Kan Shao**, Indiana University, Bloomington, Indiana.

Fetal Cardiac Findings in Rats Exposed to TCE in Drinking Water

- **Dr. James Bus**, Exponent, Midland, Michigan.

Afternoon Break (3:00 to 3:30)

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

Going beyond basic QSARs to support Pre-Manufacturing Notices

- **Alexandra Maertens**, Consortium for Environmental Risk Management

Probabilistic exposure models for industrial hygiene applications

- **Dr. Tom Armstrong**, TWA8HR Occupational Hygiene Consulting, LLC

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

- **Drs. Kimberly White and Mark S. Johnson**

Adjourn (5:00)

Presentations

Presentations will be available at the Workshop.

Biographical Sketches of Workshop Co-Chairs and Coordinators

To be developed

Biographical Sketches of Speakers and Workshop Presenters

Thomas W. Armstrong, PhD, CIH, FAIHA is the Principal Investigator at his sole proprietor consulting company, TWA8HR Occupational Hygiene Consulting, LLC established in 2008. Tom has his Bachelor of Science in Chemistry, Master of Science in Environmental Health, and PhD in Environmental Engineering, all from Drexel University, Philadelphia, PA. He is certified in the comprehensive practice of industrial hygiene (CIH), and is a Fellow of the American Industrial Hygiene Association. Tom is a longtime member of the American Industrial Hygiene Association and the Society for Risk Analysis. Before he retired from ExxonMobil Biomedical Sciences in 2008, he was a Senior Scientific Associate in Exposure Sciences. His career in anticipating, recognizing, evaluating, controlling and confirming control of occupational health risks spans over 40 years in multiple industries. His ongoing activities include exposure assessment for epidemiology studies, mathematical methods to estimate exposures to chemicals, quantitative risk assessments for Legionella and Legionnaires' disease and risk assessments for other hazards. He has over 30 peer reviewed publications, and has published chapters in books on exposure assessment strategies, mathematical modeling to estimate exposures, and risk assessment approaches. He has been the lead instructor for American Industrial Hygiene Association (AIHA) professional development courses on mathematical modeling to assess chemical exposures, and Monte Carlo Simulation techniques in exposure assessment.