Beyond Science and Decisions: From Problem Formulation to Dose-Response – Workshop VI

Purpose

- To advance the recommendations of NAS (2009) and subsequent framework of *ARA* (Meek, 2013) on problem formulation and dose-response analysis, through review of illustrative case studies for further development of methods.

Overview of Workshop Objectives

- Build off the NAS (2009) report
  - Develop practical guidance for use by risk managers at a variety of levels
  - States, regional managers, various agencies, & industry
  - Risk assessment techniques applicable to specific problem formulations.
- Implement a multi-stakeholder approach to share information, ideas, and techniques in support of developing practical, problem-driven risk assessment guidance.

Thanks to our sponsors!

55+ sponsors and collaborators:

- 12 government agencies
- 19 industry groups
- 7 scientific societies
- 9 non-profit orgs/consortia
- 8 consulting groups

Dose-Response Advisory Committee

- Rick Becker, American Chemistry Council (ACC)
- Tiffany Bredfeldt, Texas Commission on Environmental Quality (TCEQ)
- Michael Dourson, Toxicology Excellence for Risk Assessment (TERA)
- Julie Fitzpatrick, Environmental Protection Agency (EPA)
- Roberta Grant, TCEQ
- Lynne Haber, TERA
- Lynn H. Pottenger, The Dow Chemical Company
- Jennifer Seed, EPA

ARA Steering Committee

- Anita Meyer, United States Army Corps of Engineers
- Annette Dietz, Oregon Department of Environmental Quality
- Bette Meek, University of Ottawa/Health Canada
- Edward Ohanian, United States Federal Employee
- Michael Habeck, Indiana Dept. of Environmental Mgmt.
- Michael Honeycutt, TCEQ
- Ralph Perona, Neptune & Company, Inc.
- Michael Dourson, TERA (recused)

Workshops I–III Summary

- ~100 participants for each (webcast + in-person)
- 24 Case studies evaluated by Science Panel
- Framework for linking problem formulation & methodologies was developed & refined

Workshop IV & beyond: Evergreen & Standing Science Panel

- Evergreen
  - Two meetings/year: 1 in-person, 1 web-based
  - Transition to self-supporting, sustainable effort:
    - Case studies brought to Science Panel for review/discussion
- Standing Science Panel Role:
  - Provide input on case study methods being proposed to enhance the risk framework.
  - Provide input on the utility of the case study methods to address specific problem formulations,
  - Identify areas for additional development of the case study and/or method.
  - Inclusion of a method or case study in the framework as an illustration of a technique does not imply panel acceptance of the chemical-specific outcome.

Accomplishments to Date

- Framework linking case studies to problem formulations
  - http://www.allianceforrisk.org/Workshop/Framework/ProblemFormulation.html
  - Also at http://www.chemicalriskassessment.org
  - And on NLM's Enviro-Health Links http://sis.nlm.nih.gov/enviro/toxweblinks.html (see Associations)
- Open access manuscript in press:
  - Meek et al. 2013. A Framework for Fit-for-Purpose Dose Response Assessment. Regul. Toxicol. Pharmacol. Doi: 10.1016/j.yrtph.2013.03.012
- ~30 case studies, including several award-winning ones; >20 presentations by thought leaders in risk assessment

Agenda

Day 1 (1:00 – 5:30)

Welcome and Introductions

Case Study: Endogenous Formation Implications for Formaldehyde Carcinogenicity

Adjourn 5:30; Reception (dinner portion hors d'oeuvres, 6:30 to 8:30)

Day 2 (8:30 – 5:30)

Keynote Talk – Ken Olden, Director of NCEA (8:30 to 9:30)

Invited presentations: Thomas Hartung, Bette Meek, Tim Pastoor, Ted Simon

Lunch

Case Study: Hypothesis-Driven Weight of Evidence Review for Naphthalene Carcinogenicity

Observer comments

Agenda (continued)

Day 3 (8:30 – 1:00)
Case Study: Interpretation of 24-hour Sampling Data

1:00 – 5:00
Closed panel discussion and lunch

Housekeeping

- Look around now for exits in case of fire
- Cell phone reminder....
- Mid-morning and afternoon breaks
- Lunch provided on Wednesday
- The sessions are being webcast so remember there is a second audience listening on the phone. Please be mindful of their participation:
  - **Use the mics** to facilitate listening for those on webcast
  - Only one person speaking at a time
  - Identify yourself with name & affiliation when speaking

Anti-trust Statement

- Participants in this meeting may include those who represent competing businesses. To avoid violation of anti-trust laws or any appearance of violations it is important that all participants agree to avoid any comments or actions that encourage joint action by participating firms to restrict competition, discussion of pricing or pricing policies, allocations of customers or markets, or boycotts. Competitively sensitive information should not be discussed. If at any time during the course of this meeting you think that discussions have strayed into these areas, you are required to notify the chair immediately. Please see the provided TERA anti-trust policy for further information.

Science Panel Members

Standing Panel:

- *Richard Beauchamp, Texas Dept State Health Services*
- *James S. Bus, Exponent*
- *Rory Conolly, U.S. EPA NHEERL*
- *Mike Dourson, TERA*
- *R. Jeffrey Lewis, ExxonMobil Biomedical Sciences, Inc.*
- *Bette Meek, McLaughlin Centre for Population Health Risk Assessment, University of Ottawa (Chairperson)*
- *Greg Paoli, Risk Sciences International (NAS 2009 Panel)*
- *Rita Schoeny, U.S. EPA OW (Absent)*
- *Alan Stern, New Jersey Dept of Environmental Protection*

Ad Hoc:

- *Annie Jarabek, U.S. EPA NCEA*