TOOLS FOR RISK-BASED DECISIONS IN OTTAWA

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Dr Rick Becker

Toxicologist

American Chemistry Council

ICCA-LRI Workshop

Co-organized with Health Canada and U.S. EPA

June 20-21, 2018 | Fairmont Château Laurier | Ottawa, Canada

Demonstrating 21st Century Methods and Critical Tools for Risk-Based Decisions

Workshop Co-Chairs:

Tara Barton-Maclaren *Health Canada*

Russell Thomas *U.S.EPA*

ICCA International Council of Chemical Associations

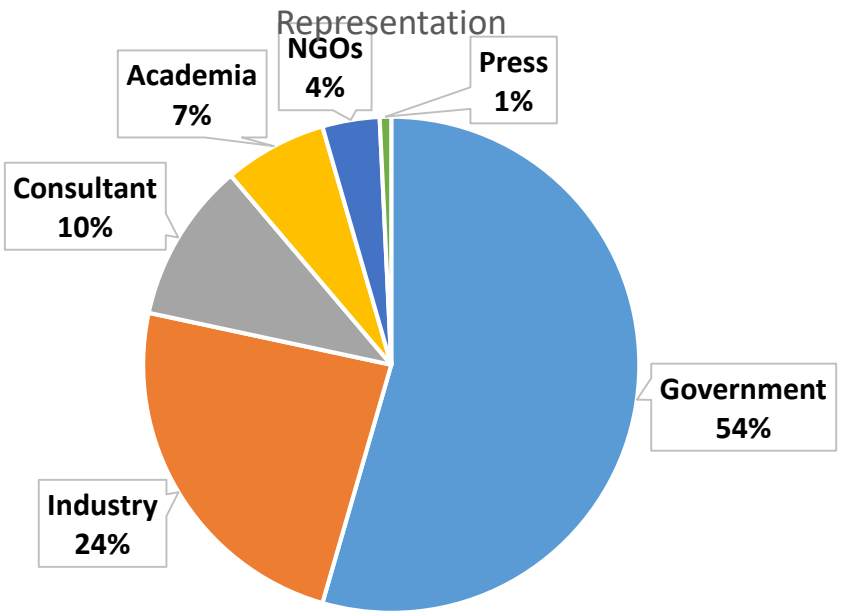
LRI Long-Range Research Initiative

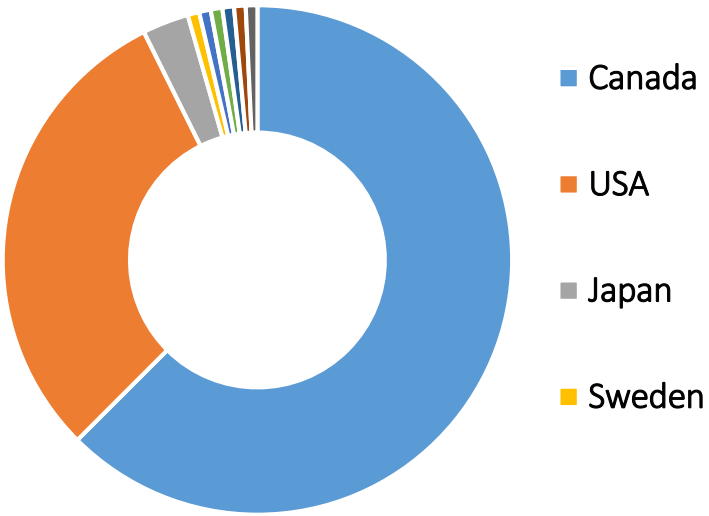
Health Canada Santé Canada

EPA United States Environmental Protection Agency

Workshop Participation

Final Attendee Count: 136





Session I: Setting the Stage

Chairs: B. Barter | *ExxonMobil Biomedical Sciences, Inc.*, L. Sweet | *The Lubrizol Company*

Discussed the changing landscape in toxicology and the challenges and opportunities that have arisen in recent years.

Session II: Toxicogenomics

Chairs: B. Hubesch | *Cefic*, F. Webster | *Health Canada*

Highlighted the novel tools and implications for toxicogenomics.

Session III: Fit-for-Purpose Tools and Methods

Chairs: M. Hanzawa | *JCIA*, P. McMullen | *ScitoVation*, and R. Skoglund | *Covestro*

Representatives described various fit-for-purpose tools and methods from regulatory agencies and private industry.

Session IV: New Approach Methods for Environmental and Ecotoxicology

Chairs: N. Basu | *McGill University*, S. Hughes | *Health Canada*

Discussed NAMs developed for environmental and ecotoxicology and analyzed their relationship with regulatory development.

Session V: International Collaborations for Applying New Approach Methods to Regulatory Decisions

Chair: R. Becker | *ACC*

Described two international collaborations for applying NAMs and elaborated upon by experts in their field.

Session VI (Panel): Establishing Scientific Confidence in New Approach Methods

Facilitator: V. Dellarco | *U.S. EPA, Retired*

Is it Time to Get Rid of the "V" (Validation) Word? If Yes, What is its Replacement? Various methods for establishing confidence in NAMs were discussed

Panelists:

T. Barton-Maclaren | *Health Canada*,
R. Becker | *ACC*,
W. Casey | *NIEHS*,
E. Haugabrooks | *Physicians Committee for Responsible Medicine*,
M. Rasenberg | *ECHA*,
K. Paul Friedman | *U.S. EPA*

Selected Points from Rapporteur Summaries

Mel Andersen, ScitoVation and Steve Maguire, McGill University

Important themes included:

- Moving from prediction to protection: A different way to do assessment.
- An avalanche of new technologies bring along challenges for data storage and data evaluation
- Triage of compounds for testing and prioritization is a key part of the risk evaluation process
- Understanding decision contexts and bringing design thinking into the development and application of toxicological knowledge, including understanding the end users
- Different understanding of uncertainty across stakeholders needs to be addressed

Discussion of Path Forward

- Collaborations and partnerships among regulators, industry, and academia are necessary – joint research and joint case studies.
- Developers of tools need to work with the end users to create accessible, effective tools.
- Prediction versus protection: need to understand the decision context and document how these different constructs can be applied in safety evaluation.
- Uncertainty will persist: there is familiarity in the status quo approach but not in new approach methods (NAMs).
  - Need to bridge this gap by demonstrating confidence in using NAMs for different kinds of safety decisions (priority setting, screening, read across, mode of action, etc.).
  - Engage multi-stakeholder groups and demonstrate the manner in which NAMs would be used

THANK YOU!