Accelerating the Pace of Chemical Risk Assessments

An International Workshop Hosted by the US EPA
September 14-15, 2016 in Washington DC

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European Commission Scientific Conference
Non-animal Approaches – The Way Forward
Brussels, Belgium 6-7 December 2016
• To bring together international regulators to discuss progress and barriers in applying new tools to prioritization, screening, and quantitative risk assessment of differing levels of complexity.

• To discuss opportunities to increase collaboration in order to accelerate the pace of chemical risk assessment.
Participants

- **United States:** EPA, California EPA, NTP, CPSC
- **Canada:** Health Canada
- **Europe:** EChA, EFSA, JRC, OECD, INERIS, RIVM
- **Asia:** Korea – Ministry of the Environment, Japan – Ministry of the Environment & Ministry of Health, Welfare and Labour, Singapore – A*STAR, Taiwan – SAHTECH
- **Australia:** NICNAS
Desired Outcomes

- Compilation of a master list of chemicals of common international interest for ongoing and future NAM application
- Identification of potential sources of NAM information and how such information could be shared and exploited
- Common understanding of current state of the science applications of New Approach Methods (NAMs), including the regulatory context and presentation of practical examples
- Commitment to development and sharing of case studies of mutual interest
• Day 1 – Setting the Stage
  – Background presentations on legislative drivers, chemicals of concern, timelines for action and expected outcomes, status of activities, acceptability of NAMs

• Day 2 – Getting to Action
  – Facilitated Discussions
    • What do regulators need to accelerate risk assessment
    • What are the chemicals of common interest internationally
    • How do we develop shared case studies to address the challenges
  – Agreement on Action Items, Timelines and Leads
Key Discussion Points

• Opportunities for progress
  – Data sharing
  – Classification systems for NAMs
  – Collaborative case studies as proof of concept for use of NAMs in chemical risk assessment

• Barriers to progress
  – Different regulatory needs
  – Inconsistent characterization of data, NAMs
  – Low confidence in new methods due to lack of understanding
Barriers to Acceptance

- The Use of Laboratory Animal Studies As the Ultimate Gold Standard
  - Limited coverage of some emerging health issues in the human population
  - Lack of concordance with evidence accumulating in population studies

- Potential Limitations of Existing Technologies
  - Metabolic capabilities, lack of more systems level models

- Benchmarking NAMs Against Laboratory Animal Studies
  - Unlikely to encounter one-to-one replacements

- Lack of Understanding and Confidence in Applying NAMs
  - Note success with emergency responses and with the US EPA EDSP

- Differing Regulatory Needs for Decision Making, with Some Requiring Specific Testing Requirements

- Current Inability to Share Information Across National Boundaries
**Action Items**

- **Foundational** – must be conducted first to take advantage of other activities.
  - Data Platforms: For chemicals of common interest, hazard data repositories.
  - Classification Systems for NAMS: There are systems for traditional toxicity data but not for NAMs.

- **Experimental**
  - Case Studies: It is necessary to explore how to make NAM case studies useful to regulators.
  - Data Generation: As we consider case studies, we need to also think about generating data that will help them achieve success.
Proposed Case Studies

- Outline for a project proposal to assess chemicals, using and developing New Approach Methodologies (NAMs)
- Revisiting and Updating Chemical Categorizations with NAMs
- Examining the Utility of In Vitro Bioactivity as a Conservative Point of Departure: A Case Study
- Triaging Exposure Data and Modeling Needs for Exogenous Chemicals
- Linking Exposure to Toxicology Using Lead as Case Study
- NAMs for Assessing Endocrine Disrupting Properties
- Application of NAMs to Chemical Category for Class of Perfluoroalkylated Substances
- Carcinogenic Potential of Aromatic Amines
Executive Summary from the workshop finalized (November 2016)

Case study proposals shared with all participants and discussed on November 22 teleconference

General Teleconference in December to discuss case study milestones and timelines

Ongoing discussions between EChA, OECD and JRC on concept of eChem Portal as data repository

OECD EAGMST discussion on value of classification systems for NAMs

Several participants offered to host a second meeting in 2017 to ensure momentum can continue to grow