

# What Will Work? Application of New Approaches for Chemical Safety Assessment

Overview of ICCA-LRI and US EPA Workshop.  
New Orleans, June 16-17, 2015

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# Workshop Driver

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ICCA-LRI and  
US EPA Workshop

New Orleans, LA  
June 16-17, 2015

Sheraton New Orleans Hotel



## What Will Work? Application of New Approaches for Chemical Safety Assessment

Recent advancements in new technologies for chemical safety assessment have catalyzed the development of pilot applications. If sufficient scientific confidence can be established through these pilot applications, the new technologies offer considerable promise for their use to assess chemical safety.

This workshop will critically review outcomes from ongoing pilot applications as the foundation for a discussion of future approaches and their potential value for advancing chemical evaluations. These sessions will lead to a discussion on linking current knowledge with future thinking and on increasing confidence in the use of the new technologies and their data streams for chemical safety assessment and for decision making.

The International Council of Chemical Associations' Long-Range Research Initiative (ICCA-LRI) in collaboration with the United States Environmental Protection Agency (US EPA) invites you to attend this year's workshop.

The annual ICCA-LRI workshops bring together international representatives from industry, academia, and governmental and non-governmental organizations to address issues of mutual interest in chemical safety. The workshop agenda will include plenary speakers, panel discussions, and a poster session highlighting relevant research.

This workshop, which builds upon themes from two previous workshops, will include the following sessions:

- ▶ **What is Working?** Case studies and lessons learned from application of new approaches for chemical safety assessment and their relevance for decision making
- ▶ **What Will Work?** Discussion of future approaches and technologies for evaluating chemical safety
- ▶ **Bridging the Gap.** Consideration of next steps to increase confidence in the use of current and future approaches for decision making about chemicals



New Orleans, Louisiana, USA – A unique and timeless city, New Orleans is steeped in European traditions and Caribbean influences. The Big Easy combines the sweet sounds of jazz and the enchanting aroma of savory spices. New Orleans is a culturally rich haven with *lagniappe* – a little something extra – that will stay with you long after you leave.

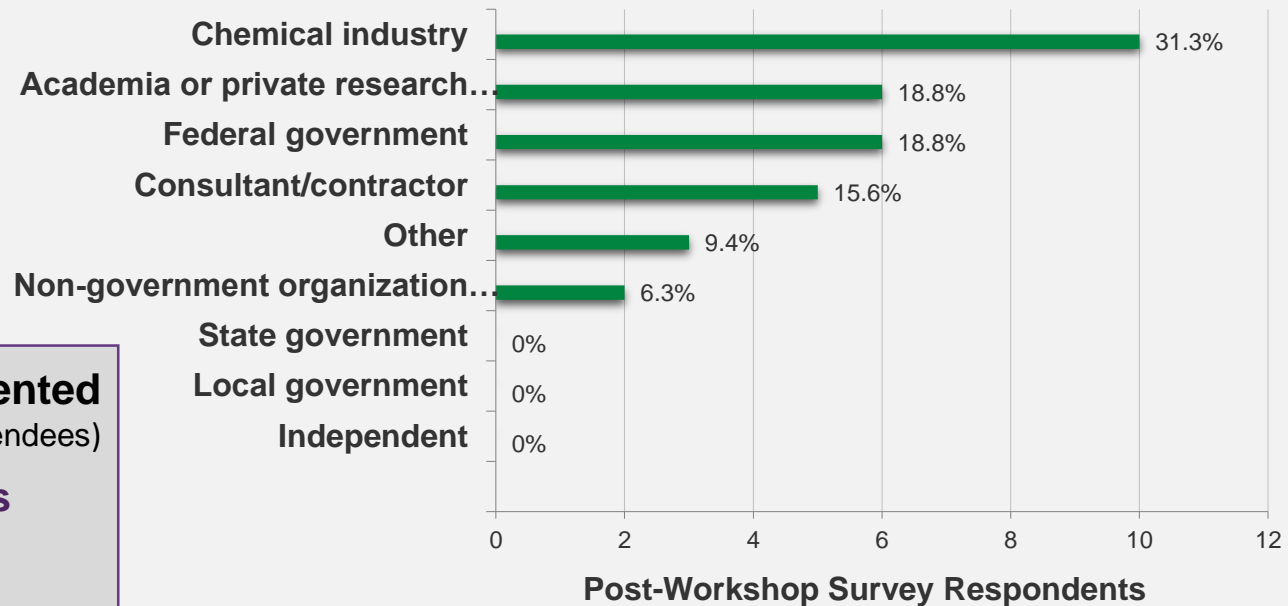
*To actualize the promise of new technologies to rapidly and cost-effectively provide data for assessing the safety of chemicals, scientific confidence needs to be built to underpin reliance on these methods for regulatory and product stewardship decision making.*

# Workshop Goals

- Examine current and future advancements in technologies for generating bioactivity, hazard, and exposure data and predictions.
- Critically review outcomes from ongoing pilot studies of these technologies as the basis for establishing scientific confidence in the utilization of these methods for chemical safety assessments.
- Discuss challenges and opportunities for potential uses of these technologies and their data streams in decision making, priority setting, screening, and chemical safety determinations.

# Workshop Participants

## Sectors Represented



## Countries Represented

(In order of number of attendees)

- United States
- Japan
- Canada
- Germany
- United Kingdom
- Belgium
- Netherlands
- Finland

# Workshop Session 1: Use & Applicability of Technology Advances

- **Advances in hazard and exposure assessment for chemical safety in North America, Europe, and Japan:**
  - **North America:** Incorporation of technological advancements and data from both hazard and exposure assessments for risk-based approaches.
  - **Europe:** Increased use of *in vitro* testing and read-across methods for hazard-based approaches for classification and labelling.
  - **Japan:** Consideration of both exposure information and quantitative structure activity relationship (QSAR) for chemical safety determinations.
- **Current innovative approaches in chemical safety assessment:**
  - **U.S. EPA's Endocrine Disruptor Screening Program:** Agency's first effort to use high-throughput screening results to make regulatory decisions on chemicals; challenges include distinguishing specific responses and establishing predictive model performance.
  - **Current application of read-across and QSAR approaches:** Application for untested chemicals and chemicals with limited data sets; challenges include difficulties in developing consistent opinions by experts for read-across assessments for complex toxicities, especially for substances with limited datasets.

# Workshop Session 2: Assessing Confidence in Technology Advances

- **Adverse outcome pathways (AOPs):**
  - The goal is for AOPs, a conceptual framework for linking initial molecular interactions to an adverse outcome in an individual or population, to be used for regulatory applications such as category formation, read-across, hazard evaluation, and risk assessment.
- **Predictive exposure modeling for estimating human and ecological exposures:**
  - Research to improve exposure predictions is accelerating, and information from different modeling approaches can be combined to both verify and add power to the predicted exposure estimates.
- **Challenges of integrating pathway and exposure information for risk-based evaluations:**
  - Comparison of data from fruit and vegetable extracts with data from chemicals obtained using the same assay system provided a real world context for the data and an impetus for thoughtful future interpretation of high-throughput *in vitro* data.
- **Scientific confidence in chemical evaluations:**
  - Effective communication to the general public regarding scientific confidence in chemical evaluations based on these advanced approaches is needed.

## Workshop Session 3: Promise and Challenges of Technology Advances

- Highlighted both the promises offered and the challenges faced by the new technologies for advancing chemical safety assessment.
- Demonstrated that new technologies are already being successfully applied for chemical screening and prioritization and are catalyzing the transition away from traditional animal toxicity testing.
- Additional research and communication will ensure stakeholders have confidence in the use of new approaches for chemical safety assessment applications in regulatory decision making.

# CEFIC LRI Workshop November 19<sup>th</sup> 2015

Thank you for your attention