



Interagency Coordinating Committee on the Validation of Alternative Methods

ICCVAM Update

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Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture
Department of Defense • Department of Energy • Department of the Interior • Department of Transportation
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences
National Institute of Standards and Technology • National Library of Medicine • Occupational Safety and Health Administration

15 Years Out: Reinventing ICCVAM

February 1, 2013 Editorials Comments Off

Linda S. Birnbaum

Director, NIEHS and NTP, National Institutes of Health, Department of Health and Human Services, Research Triangle Park, North

2013 A New Vision and Direction for ICCVAM

- Agenda driven by member agencies
- Emphasize “fit for purpose” approach to validation
- Improve communications with stakeholders and the public
- Increase productivity of international collaborations
- Identified projects where there is a reasonable likelihood of success with a reasonable timeframe (1-5 years)
 - *Leptospira* vaccine potency
 - Oral-dermal acute lethality
 - Skin sensitization



Current ICCVAM Working Groups

- Acute Toxicity
 - Skin Sensitization
 - Ocular and Dermal Irritation
 - Reference Chemicals
- Working groups include international partners

ICCVAM Acute Toxicity Working Group

ICCVAM Sponsor Agencies: EPA, DOD

23 Members/8 Agencies: CPSC, DOD (AFRL, AIPH, USAF, DTRA, ERDC), DOT, EPA (OPP, ORD), NIEHS, NLM, OSHA, ICATM Liaisons (EURL-ECVAM, KoCVAM)

- Identify and publish current requirements and testing needs for U.S. and international regulatory authorities
- Acquire and curate and make public high quality data (*in vitro* and *in vivo*)
- Develop and evaluate *in vitro* and *in silico* approaches for predicting acute oral, dermal and/or inhalation systemic toxicity
- Draft ICCVAM strategy and roadmap on using *in vitro* and *in silico* approaches to replace or reduce animal use in acute systemic toxicity testing

Webinar Series: Acute Inhalation Toxicity Testing



National Toxicology Program
 U.S. Department of Health and Human Services

Alternative Approaches for Acute Inhalation Toxicity to Address Global Regulatory and Non-regulatory Data Requirements



WEBINAR SERIES
21st Century Testing Approaches
 Dan Huh, Ph.D.
 University of Pennsylvania
 Kelly Bérubé, Ph.D.
 Cardiff University

Thursday, Sept. 8, 2016 • 11:00 a.m. – 12:30 p.m.

This webinar is the last in a series of six webinars that will be presented through September 2016. Please visit <http://ntp.niehs.nih.gov/inhalation-2016> for more information.



PETA INTERNATIONAL SCIENCE CONSORTIUM LTD.

- Regulatory guidelines - when and how acute inhalation systemic toxicity data are used for assessing hazard potential
- Existing alternative approaches (in vitro and in silico)
- Mechanisms of acute toxicity that may constitute key events in an AOP for acute inhalation toxicity
- Provided background information for in person workshop

Acute Inhalation Toxicity Testing: Ongoing Efforts

- WORKING GROUP 1: Develop a database of existing acute systemic toxicity data
- WORKING GROUP 2: Prepare a state-of-the-science review on mechanisms and non-animal (*in vitro* and *in silico*) assays for acute inhalation toxicity
- WORKING GROUP 3: Develop an *in silico* decision tree
- WORKING GROUP 4: Design and conduct an *in vitro* proof-of-concept

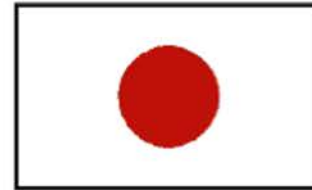


Scientists from industry, academia, NGOs, and government

New ICCVAM Working Groups 2017

- Developmental and Reproductive Toxicology
 - *In Vitro* to *In Vivo* Extrapolation
 - Read Across
- Working groups will include international partners & begin to interface with private sector groups

International Cooperation on Alternative Test Methods (ICATM)



OECD

- Organisation for Economic Co-operation and Development



- Provide input on US position
- Lead/Co-lead new projects
- Participate in expert consultations

ICCVAM Communications

- **ICCVAM Public Forum**

- ICCVAM Agency updates relevant to 3Rs; opportunities for public comment; in-person or remote attendance

- **ICCVAM Communities of Practice Webinars**

- 2017: *Incorporating Chemical Information: Resources, Limitations, and Characterizing the Domain of Applicability for 21st Century Toxicity Testing*
- 2016: *Fundamentals of Using Quantitative Structure-Activity Relationship Models and Read-across Techniques in Predictive Toxicology*
- 2015: *Reverse Toxicokinetics: Using In Vitro Data to Estimate Exposures that Could Be Associated with Adverse Effects In Vivo*

ICCVAM Communications

- Society of Toxicology 2017
 - Exhibitor Hosted Sessions
 - Developing an Implementation Strategy for Toxicity Testing in the 21st Century
 - ICCVAM Tools for Validation and Regulatory Application of Alternative Methods
- SACATM - September 18-19, 2017, Bethesda
 - 3Rs Strategic Roadmap
 - Opportunities for public comment; in-person or remote attendance

NIST Joins ICCVAM as 16th Agency

NIST **National Institute of
Standards and Technology**
U.S. Department of Commerce

Questions?