



Interagency Coordinating Committee on the Validation of Alternative Methods

Updated ICCVAM Goals for FY2015

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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 Library of Medicine • Occupational Safety and Health Administration

Outline

- Areas of priority and scientific focus (new or updated)
 - Acute Toxicity
 - Skin sensitization
 - Adverse outcome pathways
- International Coordination
- New Paradigms for Validation

Priority Area: Acute Toxicity Testing

- FY 2015 Goals:
 - Finalize statistical analysis of the relative contribution of data from acute oral and dermal toxicity tests to pesticide hazard classification and labeling
 - Participate on expert working groups with external stakeholders to identify and evaluate *in vitro* technologies for the assessment of acute inhalation toxicity
 - Establish expert working group, to include external stakeholders, for the evaluation of alternatives to acute oral toxicity testing
 - Develop and make public a database containing high quality data from acute toxicity studies

Priority Area: Acute Toxicity Testing

- FY 2015 Goals (cont):
 - Explore the use of zebrafish embryo and *c. elegans* models as alternatives for assessing acute oral toxicity
 - Evaluate the applicability of Tox21 data for use in an integrated approach for assessing acute oral toxicity
 - Coordinate activities to ensure synergy with EURL ECVAM upcoming strategy to avoid, reduce and refine the use of animals in the assessment of acute systemic toxicity

Priority Area: Skin Sensitization

- FY 2015 Goal:
 - Using retrospective analysis of data from validated methods, develop an integrated testing and decision strategy to meet regulatory requirements of US agencies:
 - Binary (yes/no) classification, LLNA as reference
 - Categorical, Human data as reference
 - Evaluate Tox21 / ToxCast data for use in an integrated testing and decision strategy for assessing the skin sensitization potential of chemicals

Priority Area: Adverse Outcome Pathways

- FY 2015 Goal:
 - Coordinate efforts across agencies to understand the potential utility of AOPs as a data sharing and communication tool.
 - Work on the development of an AOP for arsenic-related health effects:
 - Lung cancer
 - Ischemic heart disease

Priority Area: Alternatives to HIST Vaccines

- FY 2015 Goal:
 - Continue efforts with an international working group on implementing *in vitro* assays as alternatives to the murine histamine sensitization test (HIST) for the testing of acellular pertussis vaccines

Priority Area: Leptospira Vaccines

- FY 2015 Goal:
 - Continue to explore methods to reduce the number of hamsters used to create the virulent test material

International Coordination

- FY 2015 Goals:
 - Nominate ICCVAM agency experts to international expert working groups and validation management teams
 - Assist US test method developers in nominating methods for interlaboratory validation in the European network of testing laboratories (EU-NETVAL)

New Paradigms for Validation

- FY 2015 Goal:
 - Continue to develop & implement “Fit for Purpose” validation efforts oriented towards regulatory needs
 - Schedule a workshop to review existing approaches to test method validation and how they could be modified and/or applied differently to accelerate regulatory acceptance and improve responsiveness to on-going paradigm shifts in toxicity testing