



# Update on ICCVAM's Vision and Strategy

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SACATM Meeting, September 27, 2016  
Research Triangle Park, NC

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

# Priority Areas of Focus

- ICCVAM is developing a strategy and roadmap to establish alternative methods for the six most commonly conducted acute toxicity tests.
- A more comprehensive US strategy and roadmap will be needed to implement the use of more human-predictive approaches for assessing complex biological processes such as developmental toxicity and carcinogenicity.

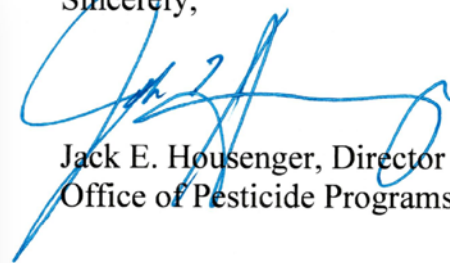
# Acute Toxicity

Excerpt for Letter to Stakeholders on OPP's Goal to Reduce Animal Testing:

*“OPP's immediate goal is to significantly reduce the use of animals in acute effects testing (the "6-pack" studies). Over 50 animals are used for a complete set of 6-pack studies. Annually, we receive over 500 acute toxicity 6-pack submissions.”*



Sincerely,

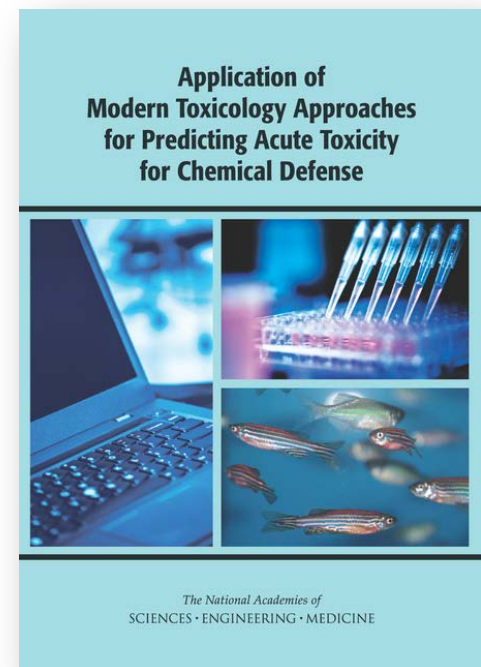


Jack E. Housenger, Director  
Office of Pesticide Programs



# Acute Toxicity

DOD asked the National Research Council to determine how DOD could use modern approaches for predicting chemical toxicity in its efforts to prevent debilitating, acute exposures to deployed personnel. This report provides an overall conceptual approach that DOD could use to develop a predictive toxicology system.



# Acute Toxicity

Study Type
Acute oral toxicity – Rat
Acute dermal toxicity – Rat /Rabbit
Acute inhalation toxicity – Rat
Primary eye irritation – Rabbit
Primary dermal irritation – Rabbit
Dermal sensitization – Guinea Pig / Mouse

Agencies that utilize data (generate, require, accept, or consider) from one or more acute toxicity tests:  
CPSC, DoD, DoT, EPA, FDA, NIEHS (NTP), OSHA

# General Approach for Each Test

- Establish ICCVAM Working Group
- Draft Scoping Document:
  - Identify all agency requirements / expectations
    - Classification & labeling system(s) (GHS, EPA, CPSC)
    - Legal framework for acceptance of alternative methods
  - Define chemical and regulatory space for each agency
  - Identify validated alternatives and status of acceptance by agency

# General Approach for Each Test

- Identification, acquisition, and curation of high quality data (in vitro and in vivo)
- Identify obstacles to implementation
- Develop validation strategy and prioritize activities based on agency needs, expected impact on animal usage, ability to mitigate obstacles, and available resources
- Coordinate efforts with international partners throughout the process



# Progress

- Database of complete “6-pack” studies from ~900 pesticide products
- Acute dermal toxicity
  - EPA draft waiver guidance
- Acute oral and inhalation toxicity
  - Defining IATAs; discussing harmonization
- Skin sensitization
  - ICCVAM IATAs published; ICATM workshop
- Skin & Eye irritation/corrosion
  - Cataloging validation status of new methods, identifying testing needs, developing IATAs