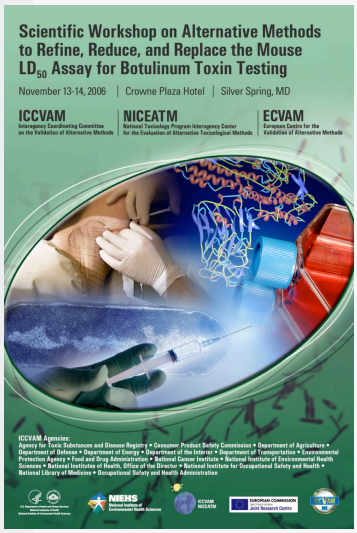
NICEATM — *National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods*

ICCVAM — *Interagency Coordinating Committee on the Validation of Alternative Methods*



Overview of ICCVAM and NICEATM

Leonard M. Schechtman, Ph.D.

Chairman, ICCVAM

Deputy Director
National Center for Toxicological Research
Washington Operations
U.S. Food and Drug Administration

November 13-14, 2006
Crowne Plaza Hotel
Silver Spring, MD

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

Genesis & Evolution of ICCVAM

- 1994: Assembled as an *ad hoc* committee in response to the NIH Revitalization Act of 1993 (P.L. 103-43)
- 1997: Established as a standing committee
- 2000: Congressional passage of the ICCVAM Authorization Act established ICCVAM as a permanent interagency committee composed of the heads of 15 Federal regulatory & research agencies, or their designees
- ICCVAM Authorization Act of 2000 (P.L. 106-545)
  - *an Act to establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised scientifically valid toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness*

ICCVAM Member Agencies

Regulatory/Research

Consumer Product Safety Commission

Department of Agriculture

Department of the Interior

Department of Transportation

Environmental Protection Agency

Food and Drug Administration

Occupational Safety and Health Administration

Non-Regulatory/Research

Agency for Toxic Substances and Disease Registry

Department of Defense

Department of Energy

National Cancer Institute

National Institute of Environmental Health Sciences

National Institute for Occupational Safety and Health

National Library of Medicine

National Institutes of Health, OD

ICCVAM Mission

ICCVAM's mission is to facilitate development, validation and regulatory acceptance of new and revised regulatory test methods that reduce[1], refine[2], and replace[3] the use of animals in testing while maintaining and promoting scientific quality and the protection of human health, animal health, and the environment.

[1]Reduction alternative: New or modified test method(s) that reduce(s) the number of animals required for a test method, while remaining consistent with sound scientific practices necessary to obtain valid results.

[2]Refinement alternative: New or modified test method(s) that refine(s) procedures to lessen or eliminate pain or distress in animals or enhances animal well-being.

[3]Replacement alternative: New or modified test method(s) that replace(s) animals with non-animal systems or replace(s) an animal species with a phylogenetically lower species.

ICCVAM Duties (P.L. 106-545)

- Facilitate and provide guidance on test method development, validation criteria, and validation processes
- Facilitate acceptance of scientifically valid test methods
  - Consider petitions from the public for review and evaluation of test methods
  - Review and evaluate new,revised, and alternative test methods applicable to regulatory testing
  - Submit test recommendations to Federal agencies
- Facilitate interagency and international harmonization of test methods

NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)

- Located at NIEHS
  - Research Triangle Park, North Carolina
- Functions:
  - Administers ICCVAM
  - Provides scientific and operational support for ICCVAM activities
  - Organize test method peer reviews,expert panel meetings, and workshops
  - Communicates and partners with stakeholders
  - Conducts independent validation studies
- http://iccvam.niehs.nih.gov

ICCVAM Agency Representatives

ATSDR	Moiz Mumtaz
CPSC	Marilyn Wind (Vice-chair) Patricia Bittner Kristina Hatlelid
USDA	Jodie Kulpa-Eddy Elizabeth Goldentyer
DOD	Robert E. Foster Patty Decot Harry Salem
DOE	Michael Kuperberg Marvin Stodolsky
DOI	Barnett Rattner Sarah Gerould
DOT	George Cushmac Steve Hwang
EPA	Karen Hamernik, OSCP Julian Preston, ORD Suzanne McMaster, ORD Jerry Smrchek, OECD TGP Amy Rispin, OPP Deborah McCall, OPP
FDA	Leonard Schechtman, NCTR (Chair) Suzanne Fitzpatrick, OS Abigail Jacobs, CDER Raju Kammula, CDRH Melvin Stratmeyer, CDRH Richard McFarland, CBER Ying Huang, CBER David Hattan, CFSAN Robert Bronaugh, CFSAN Devaraya Jagannath, CVM M. Cecilia Auguila, CVM William Allaben, NCTR Lawrence D'Hoostelaere, ORA
NCI	Alan Poland T. Kevin Howcroft
NIEHS	William Stokes John Bucher Rajendra Chhabra Jerrold Heindel
NIOSH	Paul Nicolaysen K. Murali Rao
NIH	Margaret Snyder
NLM	Vera Hudson Jeanne Goshorn
OSHA	Surrender Ahir