Strategic Roadmap

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SACATM Meeting
September 5, 2018

- Review and evaluate new or revised or alternative test methods.
- Coordinate interagency and international 3R activities
- Facilitate and provide guidance on the development of validation criteria and processes for alternative test methods.

- 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
- National Institute for Occupational Safety and Health

- Agency for Toxic Substances and Disease Registry
- National Cancer Institute
- National Inst of Env. Health Sciences
- National Library of Medicine
- National Institutes of Health
- Department of Defense
- Department of Energy
- National Institute of Standards and Technology

- Other participants: NCATS, Tox21
ICCVM Workgroups

- Acute lethality (LD50 / IC50)
- Skin Sensitization
- Ocular / Dermal Irritation and Corrosion
- Developmental Tox
- Eco Tox
- Nano Tox
- Read Across
- IVIVE
NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM)
Strategic Roadmap: Implementation

View details of ongoing and planned activities for implementation of the Strategic Roadmap in the following areas:

- Acute Systemic Toxicity
- Skin and Eye Irritation
- Skin Sensitization

ICCVAM establishes temporary ad hoc workgroups to perform specific tasks identified by the committee as being important for the development or validation of new approach methodologies, and it is envisioned that ICCVAM workgroups will play a key role in implementing the goals of the strategic roadmap. The workgroups are chaired by representatives from agencies that use or require data from the topic of interest. The chairs are responsible for developing the group's scope and charge, which is then reviewed and approved by ICCVAM. ICCVAM member agencies and partners in the International Cooperation on Alternative Test Methods (the European Union Reference Laboratory for Alternatives to Animal Testing, the Japanese Center for the Evaluation of Alternative Methods, the Korean Center for the Evaluation of Alternative Methods, and Health Canada) are then invited to participate in the workgroup.
ICCVAM Public Forum

ICCVAM Public Forum: May 2018

May 24, 2018
William H. Natcher Conference Center
National Institutes of Health
Bethesda, Maryland, USA

Read a summary of the Public Forum in the July 2018 NIEHS Environmental Factor newsletter

Final agenda

Videocast recording on NIH VideoCasting and Podcasting website
Approximately 4 hrs 30 min – requires Adobe Flash installed and Java Script enabled
The International Cooperation on Alternative Test Methods (ICATM)

• Promote international cooperation in the areas of:
  – validation studies,
  – independent peer review, and
  – development of harmonized test methods and recommendations.
Interagency Coordinating Committee on the Validation of Alternative Methods

The Organisation for Economic Co-operation and Development (OECD)

Quick facts

- **History**: established in 1961
- **Headquarters**: Paris, France
- **Membership**: 36 countries
- **Budget**: EUR 374 million
- **OECD Secretary-General**: Angel Gurría
- **Secretariat staff**: 2,500
- **Publications**: 250 new titles/year
- **Annual report**
- **OECD Observer**
- **OECD Yearbook**
NAM

New Alternative Methodologies
U.S. agencies and stakeholders will work together to build a new framework to develop, establish confidence in, and encourage use of new approaches to toxicity testing that improve human health relevance and reduce or eliminate testing in animals.

- Published Jan 30, 2018
- https://ntp.niehs.nih.gov/go/natl-strategy
A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States
Interagency Coordinating Committee on the Validation of Alternative Methods

Develop Technology → Validate → Reg. Acceptance & Industry Use
Each “toxicity test” has MANY potential purposes
Interagency Coordinating Committee on the Validation of Alternative Methods
Every body perseveres in its state of being at rest or of moving uniformly straight forward, except insofar as it is compelled to change its state by forces impressed.

Isaac Newton
Interagency Coordinating Committee on the Validation of Alternative Methods

Connecting End-Users with Developers of NAMs

Encourage the adoption and use of new methods and approaches by federal agencies and regulated industries

Foster the use of efficient, flexible, and robust practices to establish confidence in new methods.
Connecting End-Users with Developers of NAMs

- Identify anticipated testing requirements
- Encourage the establishment of grant review criteria tailored to the development of NAMs
- Develop mechanisms to improve communication between end users and researchers
Connecting End-Users with Developers of NAMs

- **Identify anticipated testing requirements**

  Agencies and industry stakeholders need to work together to identify and communicate their anticipated science and technology needs for safe product development and registration.
Connecting End-Users with Developers of NAMs

- Identify anticipated testing requirements
  - Technology: Microphysiological Systems
  - Approaches: Read Across
  - Endpoints: Cancer
Connecting End-Users with Developers of NAMs

• **Identify anticipated testing requirements**

Agencies and industry stakeholders need to work together to identify and communicate their anticipated science and technology needs for safe product development and registration.
Connecting End-Users with Developers of NAMs

• Encourage the establishment of grant review criteria tailored to the development of NAMs

Funding development of NAMs should begin as early in the research and development process as possible. However, most current grant review processes are tailored to reward research involving animal models. To better support NAM development, processes for influencing the distribution of funding to NAMs by the federal government should be explored.
Connecting End-Users with Developers of NAMs

• Encourage the establishment of grant review criteria tailored to the development of NAMs
  – NIH Notice Number: NOT-TR-18-027

Notice of Availability of Administrative Supplements for Tissue Chip Consortium Awardees: Development of Tissue Chips to Model Nociception, Opioid Addiction and Overdose
Connecting End-Users with Developers of NAMs

- Develop mechanisms to improve communication between end users and researchers

One of the most cost-effective and impactful actions that can be taken immediately is to foster efforts that improve the dialog between end users and test-method developers. Federal agencies and industry stakeholders should collaborate to develop programs and processes that encourage an open dialog between test-method developers and end users.
Connecting End-Users with Developers of NAMs

• Develop mechanisms to improve communication between end users and researchers
  – Communities of Practice Webinar: January, 2019
  – Exhibitor Hosted Session, SOT: March 2019
  – Public Forum: May, 2019
Clarifying Questions?