



Interagency Coordinating Committee on the Validation of Alternative Methods

International Activities

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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

ICCVAM Participation in OECD TG Program

- April 24-27, 2018: First time that an ICCVAM representative attended the OECD WNT as an official US participant (supporting the national coordinator, Wanda Hall)
- 34 agenda items, ranging from updates to test guidelines and guidance documents, to progress reports on scientific activities, to new proposals
- The ICCVAM WNT representative position will be filled based on scientific need and contribution to the topics under discussion

OECD WNT Highlights

- 2 New TGs + Validation Report Approved on Fish Hepatic Metabolism
- 6 Updated Test Guidelines Approved
- 3 New Guidance Documents (GDs) Approved
 - Good In Vitro Methods Practices (GIVIMP)
- 4 Updated GDs Approved
 - Evaluation of Chemicals for Endocrine Disruption
- 15 New Proposals Submitted: 13 Approved, 2 Withdrawn

OECD WNT Highlights

- Simplifying TG adoption process
- Better guidance on optional endpoints
- Increase involvement in the identification and prioritization of needs for AOP development
- Workshop on ethical issues associated with the use of human derived products (e.g. serum) in *in vitro* assays
- Research project on toxicity behavior in fish (signs of moribundity)

International Harmonization

- OECD proposal co-led by US, EU, and Canada
 - Included in OECD work plan April 2017
 - Create an international performance based test guideline for non-animal skin sensitization testing strategies
 - Achieve widespread replacement of mouse test
- Evaluation framework agreed upon at special OECD session in December, 2017
 - Formed expert group on skin sensitization DAs, including subgroups on uncertainty and applicability domain
 - Expert review of simple, rule-based DAs in progress (June 2018)



Evaluation Framework

- **Structure**

- Components
- Information Provided

- **Relevance**

- Mechanistic
- Predictive Accuracy

- **Reliability**

- Reproducibility

- **Applicability**

- Technical Limitations
- Chemical Space

- **Complexity**

- Data Interpretation Procedure

- **Transparency**

- Proprietary Elements

ICCVAM Support of OECD Activities

- ICCVAM website as a resource for information on OECD activities
 - Public facing version:
 - high-level overview of projects, activities, and SPSFs
 - test guideline and guidance document status
 - participation in expert groups
 - Restricted site version:
 - lists of agency subject matter experts and points of contact to facilitate US NC communication and distribution
 - centralized repository of documents and comments

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.
- Participation in Validation Management Teams
- OECD Memorandum of Understanding with China
- October 2018: Workshop on Validation and Establishing Scientific Confidence

Other International Activities

- June 13-14: BfR and RIVM workshop: *Validation and acceptance of innovative 3R approaches in regulatory toxicology*
- June 20-21: ICCA-LRI, Health Canada, and U.S. EPA workshop: *Demonstrating 21st Century Methods and Critical Tools for Risk-Based Decisions*
- July 16-18: CAAT-Europe and EU-ToxRisk Think Tank Meeting: *Read-across in regulatory toxicology*
- Nov 6-8: OECD Validation Management Group Non-Animal (VMG-NA) Meeting in Korea
- Dec 4-6: EURL ECVAM Scientific Advisory Committee (ESAC) Meeting
- EU-ToxRisk collaboration on testing VPA analogues in alternative DevTox assays

Acknowledgments

- ICATM partners
- Wanda Hall
- EURL ECVAM/JRC
- Health Canada
- OECD Secretariat
- WNT members
- OECD TG program

