The ICCVAM Public Forum: Twelve Years of Stakeholder Engagement

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Scientific Advisory Committee on Alternative Toxicological Methods

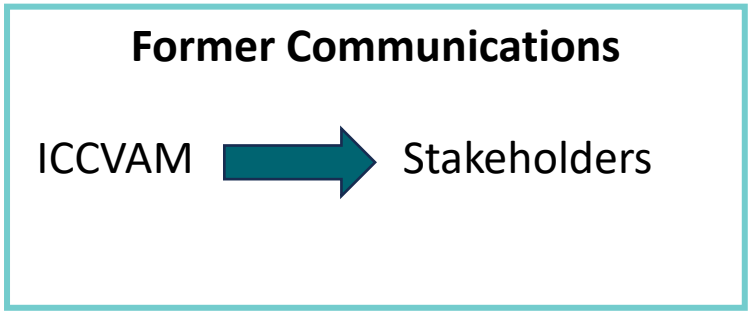
September 12, 2025

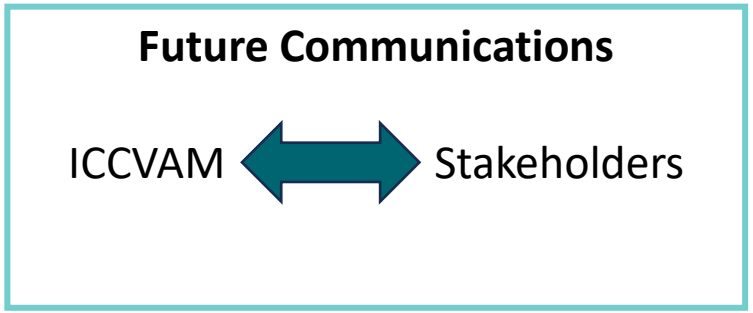
Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture • Department of Defense
Department of Energy • Department of the Interior • Department of Transportation • Department of Veterans Affairs Office of Research and Development
Environmental Protection Agency • Food and Drug Administration • National Cancer Institute • National Institute for Occupational Safety and Health
National Institute of Environmental Health Sciences • National Institute of Standards and Technology • National Center for Advancing Translational Sciences
National Institutes of Health • National Library of Medicine • Occupational Safety and Health Administration

The views expressed in this presentation are those of the author and do not necessarily reflect the views or policies of the U.S. Environmental Protection Agency.

Origin of the Public Forum

- In 2013, a new vision was proposed for ICCVAM by NIEHS director Linda Birnbaum
  - "15 Years Out: Reinventing ICCVAM" – EHP February 2013, https://doi.org/10.1289/ehp.1206292
  - Proposed an "approach to promoting the 3Rs (reduce, replace, refine)…that will be driven by regulatory agency needs while remaining responsive to the test method development community."
- Interaction with stakeholders was key to implementing this vision, requiring ICCVAM to consider new approaches to public interaction.

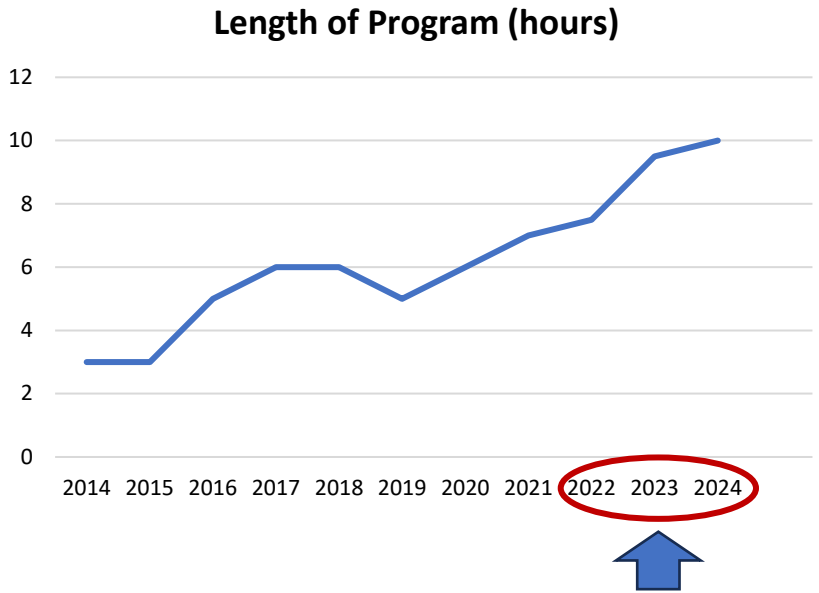


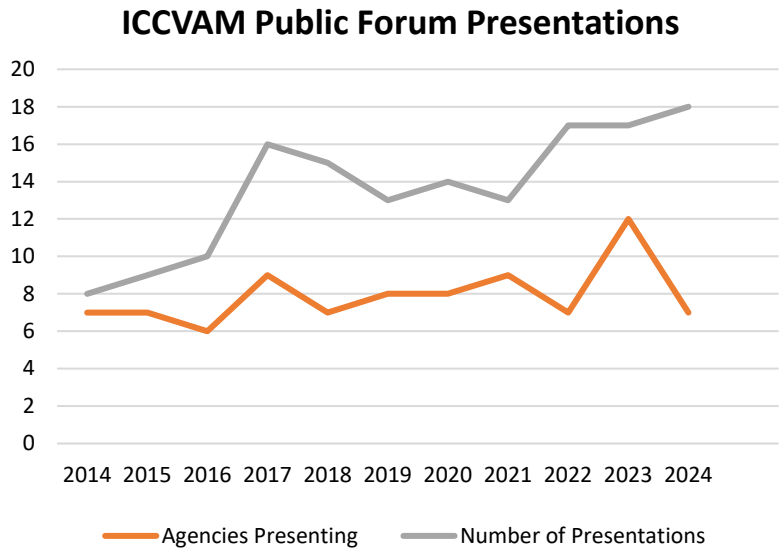


The First Public Forum

- June 25, 2014, NIH Natcher Center, 1:00-4:00 p.m.
- Presentations:
  - NICEATM and ICCVAM updates
  - General updates on skin sensitization and Tox21
  - Agency updates from FDA, EPA, Dept. of the Interior, NIH
- Public comments from PCRM, Center for Responsible Science, Johns Hopkins CAAT, White Rabbit Beauty, ARDF
- Audience: about 50 (combined in-person/online)

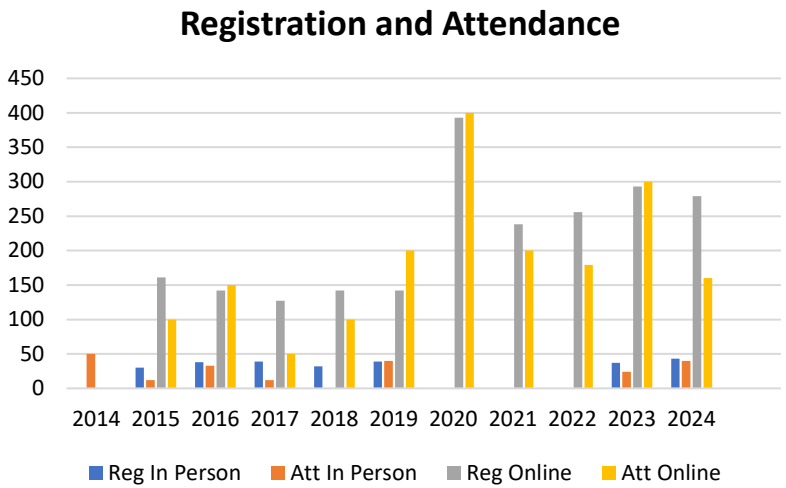
By the Numbers: Length of Program





Format Changes Over the Years

- In person vs. virtual
  - 2020 to 2022 were virtual
  - All other years have been hybrid
- Number of days
  - Multiple-day event since 2022
- Length of days
  - 1 day
  - 1.5 day – followed by a training for NICEATM tools
  - 2 day

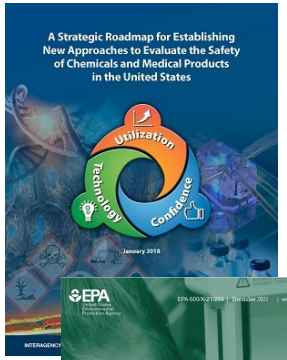


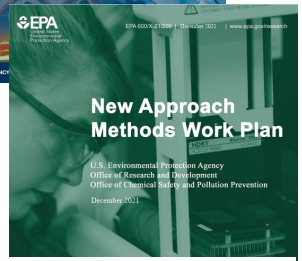
Agenda Trends Over Time

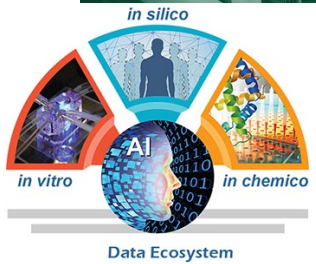
- 10-minute updates from agencies in 2015 and 2016, grew to current 15+ min. time slot in 2017
- EPA, DoD, and FDA have frequently had updates from multiple offices
- Reports on international (OECD, GHS, ICH) interactions
- Reports on Tox21 activities in early years have broadened into more comprehensive (and sometimes multiple) presentations on NIEHS activities supporting NAMs development and validation

A Venue to Announce and Discuss Projects and Initiatives

- ICCVAM Strategic Roadmap
  - Public input solicited for development in 2017; one of three opportunities provided
  - Publication and implementation plan announced in 2018, implementation plan updates 2018-2021
- Since 2021 publication of "Measuring Progress Toward Implementation of Alternative Methods," agencies have presented metrics updates at Public Forum
- CPSC announced guidance on animal use and alternatives in 2022
- In 2024, EPA discussed NAMs Work Plan, NIH outlined Complement-ARIE
- NIEHS updated on various research programs using NAMs

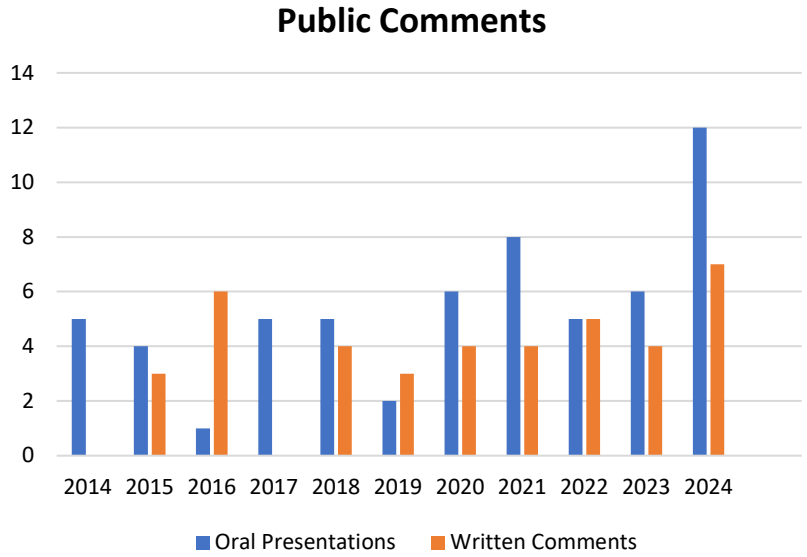






By the Numbers: Public Comments

- How the comments have evolved
  - Primarily NGO engagement
    - Development of education and training opportunities
  - Method developers started providing comments in 2023
    - Led to implementation of Method Developers Forums



2023 Agenda – Varied Topics and Many Agencies

Interagency Coordinating Committee on the Validation of Alternative Methods

ICCVAM Public Forum
Thursday, May 18, 2023 – 9:00 a.m.-3:15 p.m.
Friday, May 19, 2023 – 9:00 a.m.-12:50 p.m.
NIH Natcher Center, Bethesda, MD
Draft Agenda

Day 1: Thursday, May 18

Time	Agenda Item	Presenter
9:00 a.m.	**1. Welcome & Introductions**	**Anna Lowit**
	2. Consumer Product Safety Commission • CPSC Guidance on NAMs	John Gordon
	3. EPA Office of Pesticide Programs • Update from EPA Office of Pesticide Programs	Monique Perron
	4. EPA Office of Pollution Prevention and Toxics • Update from EPA Office of Pollution Prevention and Toxics	Anna Lowit
10:05 a.m.	**Break**	
	5. FDA Center for Food Safety and Applied Nutrition • Update on Advancing Alternatives for Regulatory Use	Suzanne Fitzpatrick
	6. Occupational Safety and Health Administration • Update on GHS Non-Animal Testing	Deana Holmes
	7. Department of Veterans Affairs (VA) Office of Research and Development • Update on NAMs Efforts at VA	George Lathrop
11:20 a.m.-1:20 p.m.	**LUNCH**	
	8. Update on OECD and Other International Activities	Charles Kovatch
	9. Department of the Interior	Jessica Leet
	10. National Institute of Standards and Technology	Elijah Petersen
2:20 p.m.	**Break**	
	11. National Cancer Institute • In Vitro Co-culture Assays to Assess Safety of CAR-T Cell Therapies	Shari Price
	12. NICEATM Computational Tools Update	Kamel Mansouri
	13. Day 1 Wrap-Up	Nicole Kleinstreuer
3:15 p.m.	**ADJOURN DAY 1**	

Interagency Coordinating Committee on the Validation of Alternative Methods

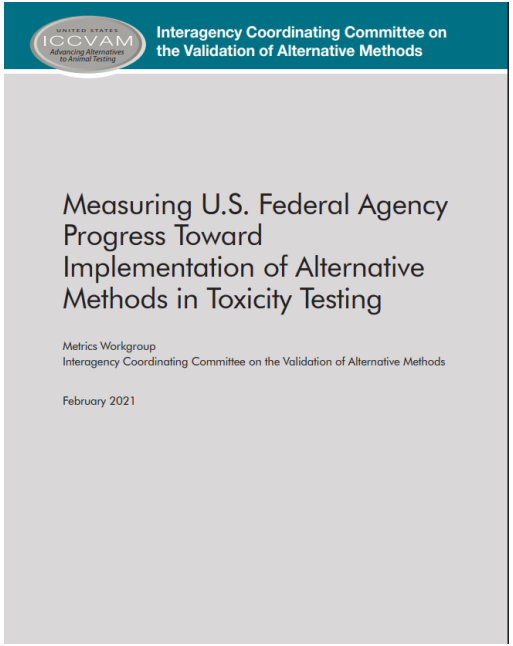
Day 2: Friday, May 19

Time	Agenda Item	Presenter
9:00 a.m.	**14. Welcome & Introductions**	**John Gordon**
	15. Summary of Written Public Statements	Nicole Kleinstreuer
	16. Oral Public Statements (7 minutes + 3 minutes Q&A each) • Amy Kyle, University of California Berkeley (retired) • Jesse Salk, TwinStrand Biosciences • Amy Clippinger, PETA Science Consortium International • Elizabeth Baker, Physicians Committee for Responsible Medicine • Frank Barile, Humane Society of the United States • Randolph Ashton, Neurosetta LLC	
	17. National Institute of Environmental Health Sciences – NTP Interagency Center for the Evaluation of Alternative Toxicological Methods • NICEATM and NIEHS Update	Nicole Kleinstreuer
	18. ICCVAM Workgroup Updates	Dave Allen
11:00 a.m.	**Break**	
	19. U.S. Department of Agriculture – Animal Welfare Information Center	Jessie Carder
	20. FDA Center for Tobacco Products	Luis Valerio
	21. Department of Defense • Soldier-on-a-chip: Interrogating the Effects of Chemical and Biological Threat Agent Exposure Using a Multi-organ MPS	Tyler Goralski
	22. NIH National Center for Advancing Translational Sciences • Tissue Chip for Drug Screening Program	Danilo Tagle
	23. Additional questions and comments	Nicole Kleinstreuer
12:50 p.m.	**ADJOURN DAY 2**	

Products of Public Forum Engagement

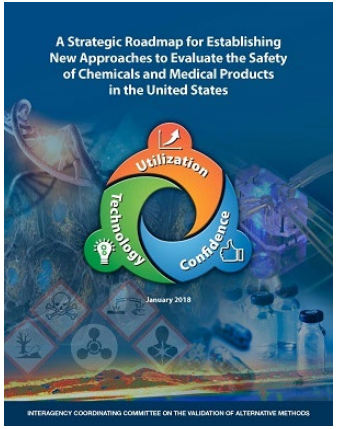
Measuring Animal Use and Implementation of NAMs

- Early Public Forum comments requested detailed tracking of numbers of animals used for testing
  - Not possible under current U.S. regulations
- Publication of Metrics Workgroup document (2021) and subsequent agency-specific activities to develop other measures of success have been recognized by stakeholders and prompted a more nuanced and constructive dialogue on this topic



Engagement with Method Developers (1)

- Many Public Forum comments have encouraged agencies to engage with method developers more proactively to ensure validated methods meet agency needs
- Goal #1 of 2018 Strategic Roadmap:
  "…regulatory agencies and the regulated industries who will ultimately be using new technologies should engage early with test-method developers and stay engaged through the development of the technologies."
- In 2022, FDA began an Alternative Methods Forum webinar series, providing method developers to present new method directly to FDA scientists
  - 29 webinars presented in 2022-2023



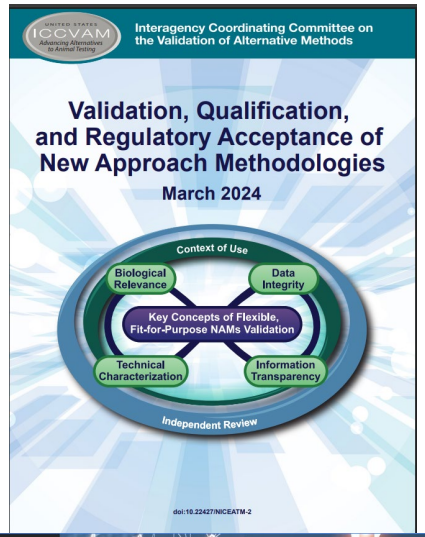
FDA's Alternative Methods Forum Series

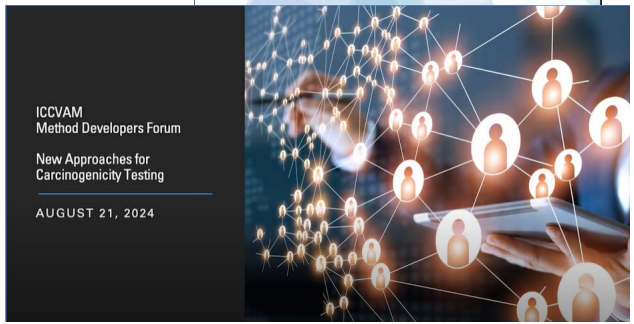
Promoting cutting-edge technologies for disease modeling, efficacy, and safety

An Opportunity for Developers and FDA Scientists

Engagement with Method Developers (2)

- Public Forum comments in 2020, 2021, 2023, and 2024 included presentations by test method developers on specific methods in development
- Validation Workgroup document published in 2024
- Evident need for a forum for developers to present new methods and the availability of a framework for structuring presentations led to development of ICCVAM Method Developers Forums
  - First MDF on carcinogenicity testing in August 2024
  - Information on future forums available at https://ntp.niehs.nih.gov/go/developers-forums





ICCVAM Public Forum Conclusion

- The public forum has increased in engagement from both the public and representative agencies over time
- The format has continuously morphed to meet the current needs of participants over the years and will continue to do so
- Topics are not pre-planned and are presented at the behest of participating agencies
- Multiple successful projects and collaborations across sectors have come out of the Public Forum