Interagency Coordinating Committee on the Validation of Alternative Methods

ICCVAM Workgroup Update

ICCVAM Public Forum

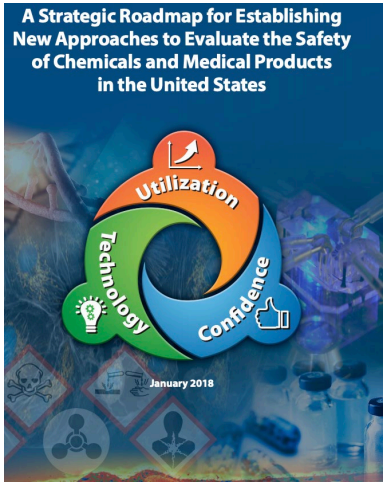
May 27, 2022

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 Energy
Department of Veterans Affairs Office of Research and Development • 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 Workgroups

- ICCVAM establishes ad hoc workgroups to perform specific tasks important for the development or validation of alternatives to animal testing. The workgroups are composed of representatives from agencies that use or require data from the topic of interest.

- Workgroups play a key role in carrying out ICCVAM activities, including implementing the goals of the ICCVAM Strategic Roadmap



Connect end users with the developers of alternative methods

Establish new validation approaches that are more flexible and efficient

Ensure adoption and use of new methods by both regulators and industry

ICCVAM Workgroups

- Draft a scoping document to identify U.S. agency requirements and decision contexts for toxicity testing data
- Coordinate efforts with stakeholders
- Identify, acquire, and curate high quality data from reference test methods and other relevant sources
- Identify and evaluate new approach methodologies (NAMs)
- Facilitate regulatory acceptance of NAMs

Current ICCVAM Workgroups

- Acute Toxicity Workgroup
- Consideration of Alternative Methods Workgroup
- Ecotoxicology Workgroup
- In Vitro to In Vivo Extrapolation Workgroup
- Read Across Workgroup
- Validation Workgroup
- ICCVAM Expert Groups

https://ntp.niehs.nih.gov/go/iccvam-wg

ICCVAM Expert Groups

ICCVAM also establishes expert groups to facilitate communication among agencies on a specific area of interest. Expert groups can be established from workgroups that have completed their charge tasks, or by agency representatives that share interest in a topic for which no specific activity has been identified. ICCVAM currently has expert groups in the areas of developmental and reproductive toxicity, developmental immunotoxicity, FAIR data standards, metrics, microphysiological systems, ocular and dermal irritation, and skin sensitization.

Acute Toxicity Workgroup (ATWG) Charges

ICCVAM Sponsor Agencies: EPA, DoD

- Evaluate the usefulness of acute oral LD50 data for classifying dermal systemic hazard of potential toxicants such as pesticides, industrial chemicals, chemical warfare agents, and household chemicals
  - Complete – for pesticide formulations and active ingredients; EPA published waiver guidance for formulations in 2016 and for technical chemicals in 2020
- Evaluate in vitro/in silico approaches for predicting acute systemic *toxicity*
  - *Modeling workshop convened – workshop report published (Kleinstreuer et al. 2018)*
  - Acute oral toxicity in silico models – CATMoS (Mansouri et al. 2021); model predictions for ICCVAM agencies
  - Variability analysis of the in vivo oral test method (Karmaus et al. 2022)
  - Acute inhalation toxicity – evaluating suitability of available acute inhalation toxicity data for modeling
- GHS additivity formula evaluation for acute systemic toxicity tests
  - Hamm et al. 2021
- Publish a scoping document that outlines the current requirements and testing needs for U.S. and international regulatory authorities
  - Complete for U.S. (Strickland et al. 2018)


Computational Toxicology 8 (2018) 21–24

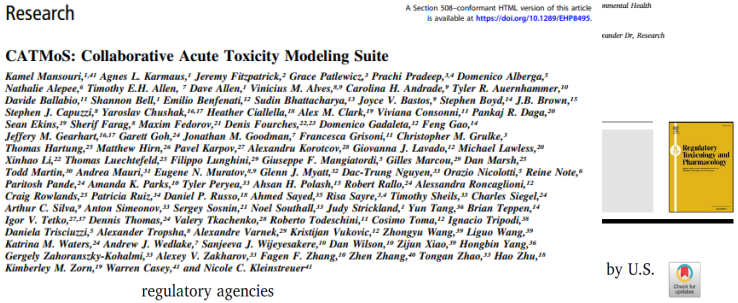
Contents lists available at ScienceDirect

Computational Toxicology

journal homepage: www.elsevier.com/locate/comtox

Predictive models for acute oral systemic toxicity: A workshop to bridge the gap from research to regulation

Nicole C. Kleinstreuer[a], Agnes L. Karmaus[b], Kamel Mansouri[b], David G. Allen[b], Jeremy M. Fitzpatrick[c], Grace Patlewicz[c,*]


Research

A Section 508–conformant HTML version of this article is available at https://doi.org/10.1289/EHP8495.

CATMoS: Collaborative Acute Toxicity Modeling Suite

Kamel Mansouri,[1,41] Agnes L. Karmaus,[1] Jeremy Fitzpatrick,[2] Grace Patlewicz,[3] Prachi Pradeep,[3,4] Domenico Alberga,[5] Nathalie Alepee,[6] Timothy E.H. Allen,[7] Dave Allen,[1] Vinicius M. Alves,[8,9] Carolina H. Andrade,[9] Tyler R. Auernhammer,[10] Davide Ballabio,[11] Shannon Bell,[1] Emilio Benfenati,[12] Sudin Bhattacharya,[13] Joyce V. Bastos,[9] Stephen Boyd,[14] J.B. Brown,[15] Stephen J. Capuzzi,[8] Yaroslav Chushak,[16,17] Heather Ciallella,[18] Alex M. Clark,[19] Viviana Consonni,[11] Pankaj R. Daga,[20] Sean Ekins,[19] Sherif Farag,[8] Maxim Fedorov,[21] Denis Fourches,[22,23] Domenico Gadaleta,[12] Feng Gao,[14] Jeffery M. Gearhart,[16,17] Garett Goh,[24] Jonathan M. Goodman,[7] Francesca Grisoni,[11] Christopher M. Grulke,[1] Thomas Hartung,[25] Matthew Hirn,[26] Pavel Karpov,[27] Alexandru Korotcov,[28] Giovanna J. Lavado,[12] Michael Lawless,[20] Xinhao Li,[22] Thomas Luechtefeld,[25] Filippo Lunghini,[29] Giuseppe F. Mangiatordi,[5] Gilles Marcou,[29] Dan Marsh,[25] Todd Martin,[30] Andrea Mauri,[31] Eugene N. Muratov,[8,9] Glenn J. Myatt,[32] Dac-Trung Nguyen,[33] Orazio Nicolotti,[5] Reine Note,[6] Paritosh Pande,[24] Amanda K. Parks,[16] Tyler Peryea,[33] Ahsan H. Polash,[13] Robert Rallo,[34] Alessandra Roncaglioni,[12] Craig Rowlands,[25] Patricia Ruiz,[34] Daniel P. Russo,[18] Ahmed Sayed,[35] Risa Sayre,[3,4] Timothy Sheils,[33] Charles Siegel,[34] Arthur C. Silva,[9] Anton Simeonov,[33] Sergey Sosnin,[21] Noel Southall,[33] Judy Strickland,[1] Yun Tang,[36] Brian Teppen,[14] Igor V. Tetko,[27,37] Dennis Thomas,[34] Valery Tkachenko,[28] Roberto Todeschini,[11] Cosimo Toma,[12] Ignacio Tripodi,[38] Daniela Trisciuzzi,[5] Alexander Tropsha,[8] Alexandre Varnek,[29] Kristjan Vukovic,[12] Zhongyu Wang,[39] Liguo Wang,[39] Katrina M. Waters,[34] Andrew J. Wedlake,[7] Sanjeeva J. Wijeyesakere,[40] Dan Wilson,[19] Zijun Xiao,[36] Hongbin Yang,[36] Gergely Zahoranszky-Kohalmi,[33] Alexey V. Zakharov,[33] Fagen F. Zhang,[36] Zhen Zhang,[36] Tongan Zhao,[33] Hao Zhu,[18] Kimberley M. Zorn,[19] Warren Casey,[41] and Nicole C. Kleinstreuer[41]

regulatory agencies

Judy Strickland[b,*], Amy J. Clippinger[b], Jeffrey I

by U.S.


Regulatory Toxicology and Pharmacology 125 (2021) 105007

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Performance of the GHS Mixtures Equation for Predicting Acute Oral Toxicity

Jon Hamm[a,*], David Allen[a], Patricia Ceger[a], Tara Flint[b], Anna Lowit[b], Lindsay O'Dell[b], Jenny Tao[b], Nicole Kleinstreuer[c]

[a] ILS, P.O. Box 13501, Research Triangle Park, NC, 27709, USA
[b] Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave, NW, Washington, DC, 20460, USA


ACCEPTED MANUSCRIPT

Evaluation of Variability across Rat Acute Oral Systemic Toxicity Studies

Agnes L Karmaus, Kamel Mansouri, Kimberly T To, Bevin Blake, Jeremy Fitzpatrick, Judy Strickland, Grace Patlewicz, David Allen, Warren Casey, Nicole Kleinstreuer

Author Notes

Toxicological Sciences, kfac042, https://doi.org/10.1093/toxsci/kfac042

Published: 15 April 2022

Cite Permissions Share

ntal Health Sciences, P.O. Box

ATWG Roster

- Xinrong Chen (CPSC)
- John Gordon (CPSC)
- Joanna Matheson (CPSC)
- Donald Cronce (DoD, Co-chair)
- Natalia Garcia-Reyero (DoD)
- Tyler Goralski (DoD)
- Matthew Grogg (DoD)
- David Mattie (DoD)
- Akeisha Owens(DoD)
- Heather Pangburn (DoD)
- Brian Pate (DoD)
- Marc Williams (DoD)
- Aiguo Wu (DoD)
- Ryan Vierling (DOT)
- Anna Lowit (EPA, OPP)
- Grace Patlewicz (EPA, ORD, Co-chair)
- Elissa Reaves (EPA, OPP)
- Jenny Tao (EPA, OPP)
- Warren Casey (NIEHS)
- Nicole Kleinstreuer (NIEHS)
- Deana Holmes (OSHA)

ICATM Liaison Members

- Pilar Prieto Peraita (EURL ECVAM)

NICEATM Support Staff (ILS)

- Judy Strickland
- Agnes Karmaus
- David Allen

ICCVAM Consideration of Alternative Methods Workgroup (CAMWG) Charges

ICCVAM Sponsor Agencies: USDA, NIEHS, DOD

- Work with stakeholders to publish a white paper on approaches that could potentially be used to foster the consideration and use of NAMs to replace or reduce live animal use in painful/distressful procedures or refine the work so it is less painful/distressful by organizations currently using animals for testing.
- Foster collaborations with authorities outside of the U.S. to share ideas and progress to promote greater harmonization for considering NAMs.
- Refer the community to available grants devoted to the development of alternatives to live animal use.
- Identify/improve communication efforts/opportunities that help promote the use of NAMs.
- Where appropriate and feasible, encourage agencies to promote avenues where NAMs can be better considered and leveraged (i.e., suggestions to encourage consideration, adoption, and best practices regarding NAMs).

Recent ICCVAM CAMWG Meetings

Milestone	Description	Date
Workgroup Teleconference	Workgroup members discussed ideas for a workshop (e.g., workshop format, topics, and identification of key stakeholders to participate).	21 January 2022
Workgroup Teleconference	Workgroup members continued discussion regarding the proposed workshop.	23 February 2022
Workgroup Teleconference	Presentation by Dr. Sue Marty (Dow Chemicals) on the use of animal metrics to determine how NAMs are contributing to reduced animal use.	18 March 2022
Stakeholder Discussions	Targeted small-group discussions with various stakeholder groups to provide their perspectives on how alternatives to traditional animal tests are considered in the development of their organization's toxicology testing programs.	May-June 2022

CAMWG Roster

- John Gordon (CPSC)
- Patrice Klein (USDA)
- Jessie Carder (Co-Chair, USDA)
- Matthew Johnson (Co-Chair, DOD)
- Alexandra Miller (DOD)
- Christopher Bever (VA ORD)
- Holly Krull (VA ORD)
- Nakissa Sadrieh (FDA/CDER)
- Suzanne Fitzpatrick (FDA/CFSAN)
- Brian Cholewa (NCI)
- Ron Johnson (NCI)
- Warren Casey (NIEHS)
- Dori Germolec (NIEHS)
- Helena Hogberg-Durdock (NIEHS)
- Nicole Kleinstreuer (NIEHS)
- Nicolette Petervary (NIH)

NICEATM Support Staff (ILS)

- David Allen
- Amber Daniel
- Oluwakemi Oyetade

Ecotoxicity Workgroup (EcoWG) Charges

ICCVAM Sponsor Agencies: DOI, EPA

- Identify ecotoxicological test data requirements as they relate to agency/ departmental registration and regulation of chemicals and their use (Manuscript in progress)
- Identify ecotoxicological research and monitoring activities as they relate to agency/departmental mission and programmatic goals (Same as above)
- Identify endpoints needed by each federal agency and commonalities and differences between agencies (Same as above)
- Identify one or more New Alternative Methods (NAMs) that can potentially be used alone or in combination to reduce, refine, or replace the acute fish toxicity test (Manuscript in progress)
- Characterize the identified methods (Same as above)
- Determine criteria that are important to regulatory agencies when considering replacement methods for acute fish toxicity (Same as above)

Timeline for manuscript completion: Agency Needs for Ecotoxicity Testing

Milestone	Date
Article accepted, with minor revisions	11 April 2022
Revised manuscript submitted to journal	19 May 2022
Journal acceptance (Reg Tox Pharmacol)	25 May 2022
Published online	Depends on journal

Timeline for manuscript completion: Prioritizing Alternatives for Acute Fish Toxicity

Milestone	Date
Compile second draft - circulate to workgroup	June 2022
Workgroup meeting to discuss draft	TBD
Deliver final draft to ICCVAM agencies for review and clearance	TBD
Manuscript submitted to journal	TBD
Journal review comments received	Depends on journal
Revised manuscript submitted to journal	1 month after comments received
Journal acceptance	Depends on journal
Galley proof received	Depends on journal

EcoWG Roster – May 2022

- Kristina M. Adams (USDA)
- Katherine Horak (USDA)
- Patrice Klein (USDA)
- Jim Warren (USDA)
- Natalia Garcia-Reyero (DOD)
- Kurt A. Gust (DOD)
- Edward Perkins (DOD)
- Marc Williams (DOD)
- Paula F. P. Henry (DOI)
- Jessica K. Leet (DOI)
- Barnett A Rattner (DOI)
- William Eckel (EPA/OPP)
- Tara Flint (EPA/OPP)
- Douglas Harwood (EPA/OPP)
- Michael Lowit (EPA/OPP)
- Scott Lynn (EPA/OPP)
- Jennifer Brennan (EPA/OPPT)
- Karen Eisenreich (EPA/OPPT)
- Kellie Fay (EPA/OPPT)
- Kara Koehrn (EPA/OPPT)
- Carlie Lalone (EPA/ORD)
- Michael Elias (EPA/OW)
- Laura Phillips (EPA/OW)
- Amy Bergdale (EPA/Region 3)
- James Laurenson (FDA, CDER)
- Sarah Winfield (FDA, CFSAN)
- Shannon Hanna (FDA, CTP)
- Wesley Hunter (FDA, CVM)
- Nicole Kleinstreuer (NIEHS)
- Elijah Petersen (NIST)

NICEATM Support Staff (Inotiv)

- Patricia Ceger
- Jon Hamm
- David Allen

In Vitro to In Vivo Extrapolation Workgroup (IVIVE-WG) Charges

ICCVAM Sponsor Agencies: ATSDR, EPA

- Conduct literature searches for current IVIVE methods, models, and case studies; catalog open source and commercially available IVIVE models, case studies and software tools (Complete; included in the recently published manuscript)
  - *Chang X, Tan Y-M, Allen DG, Bell S, Paul BC, Browning L, Ceger P, Gearhart J, Hakkinen PJ, Kabadi SV, Kleinstreuer NC, Lumen A, Matheson J, Paini A, Pangburn HA, Petersen EJ, Reinke EN, Ribeiro AJS, Sipes N, Sweeney LM, Wambaugh JF, Wange R, Wetmore BA, Mumtaz M. IVIVE: facilitating the use of in vitro toxicity data in risk assessment and decision making. Toxics 10(5):232. 2022. https://doi.org/10.3390/toxics10050232*
- Determine specific risk assessment purposes that can be achieved with the currently available approaches, and identify gaps (Same as above)
- Determine best practices for IVIVE analyses and approaches/models/tools to implement them (Same as above)
- Identify case studies to demonstrate utility and applicability of IVIVE to the needs of risk assessors (Same as above)
- Ensure international harmonization on the use and application of IVIVE through ICATM (Ongoing collaboration with OECD)
- Future Directions: WG will discuss obstacles/challenges and based on the experience gained in the manuscript preparation propose new ideas and timelines for activities (ongoing and proposed).

IVIVE-WG Roster

- Moiz Mumtaz (ATSDR, co-chair)
- Michael Babich (CPSC)
- John Gordon (CPSC)
- Eric Hooker (CPSC)
- Joanna Matheson (CPSC)
- William Eck (DOD)
- Christy Foran (DOD)
- Natalia Garcia-Reyero (DOD)
- Jeffrey Gearhart (DOD)
- Saber Hussain (DOD)
- Heather Pangburn (DOD)
- Lisa Sweeney (DOD)
- Chris Brinkerhoff (EPA, OCSPP)
- Daniel Chang (EPA, OCSPP)
- Martin Phillips (EPA, OCSPP)
- Anna Lowit (EPA, OPP)
- Cecilia Tan (EPA, OPP, co-chair)
- John Wambaugh (EPA, ORD)
- Barbara Wetmore (EPA, ORD)
- Paul Brown (FDA, CDER)
- Ronald Wange (FDA, CDER)
- Suzanne Fitzpatrick (FDA, CFSAN)
- Brenna Flannery (FDA, CFSAN)
- Shruti Kabadi (FDA, CFSAN)
- Annie Lumen (FDA, NCTR)
- Tracy Chen (FDA, OCS)
- Warren Casey (NIEHS)
- Nicole Kleinstreuer (NIEHS)
- Elijah Petersen (NIST)
- Pertti (Bert) Hakkinen (NLM)

ICATM Liaison Members
- Yuji Ishii (JaCVAM)
- Fumiaki Shono (JaCVAM)

NICEATM Support Staff (ILS)
- David Allen
- Patricia Ceger
- Xiaoqing Chang

Nanomaterials Workgroup (NanoWG) Charges

ICCVAM Sponsor Agencies: CPSC, NIST

- Identify agency requirements and needs for nanomaterial toxicology testing (Requirements collated; Manuscript is accepted and published by ALTEX)
- Identify other Federal and International efforts in this area (Same as above)
- Work with ICATM partners to identify international regulatory requirements for nanomaterial toxicity testing (Same as above)
- Identify the extent to which agencies accept alternatives to animal testing (i.e., in vitro, physicochemical, nanomaterial grouping) to fulfill regulatory requirements for nanomaterial toxicity testing and if agencies require modifications to standard toxicological methods for use with nanomaterials (Same as above)
- **The NanoWG has recently transitioned to an Expert Group after the manuscript publication.**
  - *Petersen E. J. et al. (2022) "U.S. federal agency interests and key considerations for new approach methodologies for nanomaterials", ALTEX, 39(2), pp. 183–206. doi: 10.14573/altex.2105041*

NanoWG Roster

- John Gordon (CPSC)
- Joanna Matheson (CPSC)
- Natalia Garcia-Reyero (DOD)
- Alan Kennedy (DOD)
- Laura Stolle (DOD)
- Danielle McShan (EPA, OPP)
- Abhilash Sasidharan (EPA, OPPT)
- Katherine Tyner (FDA, CDER)
- Rakhi M. Dalal-Panguluri (FDA, CDRH)
- Peter Goering (FDA, CDRH)
- Penelope Rice (FDA, CFSAN)
- Anil Patri (FDA, NCTR)
- Raymond Derk (NIOSH, HELD)
- Liying Rojanasakul (NIOSH, HELD)
- Warren Casey (NIEHS)
- William Gwinn (NIEHS)
- Nicole Kleinstreuer (NIEHS)
- Srikanth Nadadur (NIEHS)
- Nigel Walker (NIEHS)
- Bryant Nelson (NIST)
- Elijah Petersen (NIST, chair)
- Vytas Reipa (NIST)

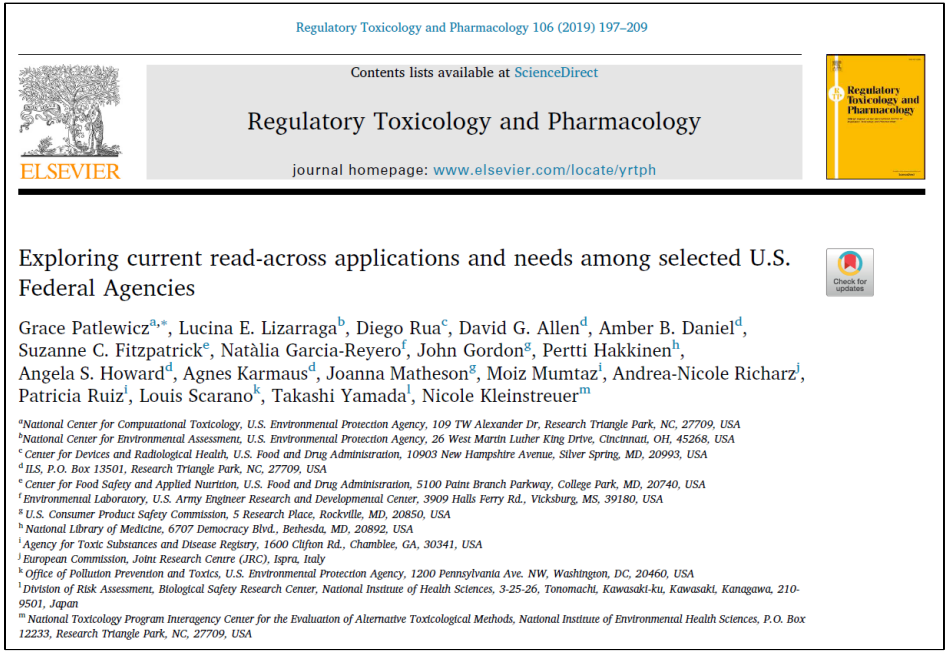
NICEATM Support Staff (ILS)

- Xiaoqing Chang
- Patricia Ceger
- David Allen

ICCVAM Read Across Workgroup (RAWG) Charges

ICCVAM Sponsor Agencies: CPSC, NIST

- Develop and implement a plan for ICCVAM members to build capacity in the development and application of “read-across” approaches
- Create a catalog of ongoing read-across experiences and needs across the different Agencies to highlight the different decision contexts of interest. (Patlewicz et al. 2019)
- Create a catalog of existing read-across resources (including existing technical guidance and software tools). (Patlewicz et al. 2019)
- Develop a compendium of member agency read-across case studies and use it as a basis to inform guiding principles for different read-across decision contexts. (in progress)
- Demonstrate impact of the guiding principles identified by facilitating the initiation and completion of a read-across case study presented in an internal agency document. (Complete, feedback on CPSC draft plan for OFR class-based Risk Assessment)



Regulatory Toxicology and Pharmacology 106 (2019) 197–209

Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Exploring current read-across applications and needs among selected U.S. Federal Agencies

Grace Patlewicz[a,*], Lucina E. Lizarraga[b], Diego Rua[c], David G. Allen[d], Amber B. Daniel[d], Suzanne C. Fitzpatrick[e], Natàlia Garcia-Reyero[f], John Gordon[g], Pertti Hakkinen[h], Angela S. Howard[d], Agnes Karmaus[d], Joanna Matheson[g], Moiz Mumtaz[i], Andrea-Nicole Richarz[j], Patricia Ruiz[i], Louis Scarano[k], Takashi Yamada[l], Nicole Kleinstreuer[m]

[a] National Center for Computational Toxicology, U.S. Environmental Protection Agency, 109 TW Alexander Dr, Research Triangle Park, NC, 27709, USA
[b] National Center for Environmental Assessment, U.S. Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, OH, 45268, USA
[c] Center for Devices and Radiological Health, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD, 20993, USA
[d] ILS, P.O. Box 13501, Research Triangle Park, NC, 27709, USA
[e] Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD, 20740, USA
[f] Environmental Laboratory, U.S. Army Engineer Research and Developmental Center, 3909 Halls Ferry Rd., Vicksburg, MS, 39180, USA
[g] U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD, 20850, USA
[h] National Library of Medicine, 6707 Democracy Blvd., Bethesda, MD, 20892, USA
[i] Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd., Chamblee, GA, 30341, USA
[j] European Commission, Joint Research Centre (JRC), Ispra, Italy
[k] Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC, 20460, USA
[l] Division of Risk Assessment, Biological Safety Research Center, National Institute of Health Sciences, 3-25-26, Tonomachi, Kawasaki-ku, Kawasaki, Kanagawa, 210-9501, Japan
[m] National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC, 27709, USA

ICCVAM Read Across WG Case Studies

- Case Study Submitted by FDA “Updates to the Cramer et al. Decision Tree and the Threshold of Toxicological Concern: the Expanded Decision Tree and Its Use as a Read-Across Tool” Szabina Stice
- Case Study Submitted by “EPA Revisiting and updating chemical groupings with new approach methodologies” Dan Chang
- CPSC: Draft Plan “Assessing the Risks of Organohalogen Flame Retardants (OFRs): A Class Approach” Mike Babich

RAWG Roster

- Moiz Mumtaz (ATSDR)
- Patricia Ruiz (ATSDR)
- Michael (Mike) Babich (CPSC)
- John Gordon (CPSC)
- Joanna Matheson (CPSC)
- Natalia Garcia-Reyero (DOD)
- Louis (Gino) Scarano (EPA/OPPT)
- Lucina Lizarraga (EPA/ORD)
- Grace Patlewicz (EPA/ORD – chair)
- Diego Rua (FDA/CDRH)
- Tyna Dao (FDA/CFSAN)
- Suzanne Fitzpatrick (FDA/CFSAN)
- Brenna Flannery (FDA/CFSAN)
- Patra Volarath (FDA/CFSAN)
- Warren Casey (NIEHS)
- Helena Hogberg-Durdock (NIEHS)
- Nicole Kleinstreuer (NIEHS)
- Pertti (Bert) Hakkinen (NLM)

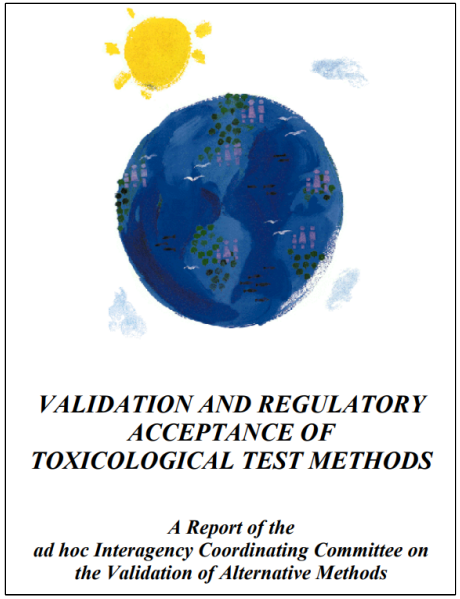
ICATM Liaisons
- Takashi Yamada (JaCVAM)

NICEATM Support Staff (ILS)
- Amber Daniel
- Agnes Karmaus
- David Allen

ICCVAM Validation Workgroup (VWG) Charges

ICCVAM Sponsor Agencies: CPSC, NIST, FDA

- Update ICCVAM report on development and validation of alternative methods (i.e., “VALIDATION AND REGULATORY ACCEPTANCE OF TOXICOLOGICAL TEST METHODS” originally published in 1997).
  - This process will include but is not limited to:
    - Developing and evaluating flexible practices that consider context of use to build confidence in new methods.
    - Seeking to align validation approaches to support international harmonization.
    - Pointing to other well-established validation documents for more context-specific information regarding validation (e.g., GIVIMP, OECD GD34, GD69 on QSAR Validation, FDA Guidance for Industry).
    - Evaluating guidance document(s) outlining best practices.
    - Examining best practices for quality and quality systems development.
  - Case studies may be included as a mechanism to demonstrate fit for purpose validation depending on context of use.



VWG Current Status

Timeline for completion of Document

Milestone	Date
Define section headers and scope of document	Complete
Identify agency representatives to lead writing of sections	Complete
Compile first draft	Complete
Circulate first draft to workgroup for comments	Complete
Section writers review comments and incorporate feedback	In Progress
Workgroup meeting(s) to discuss revised draft	In Progress
Document circulated to workgroup for final review/comments	Fall 2022
Final draft of document to agency authors for clearance	Late 2022
Document published online	Early 2023
Develop case studies	TBD after document publication
Transition to an expert group*	TBD after case study development

*The expert group will convene ad hoc to identify and address revisions necessary to keep the document up to date.

VWG Roster

- Moiz Mumtaz (ATSDR)
- John Gordon (CPSC, co-chair)
- Donald Cronce (DOD)
- Natalia Garcia-Reyero (DOD)
- Matthew Johnson (DOD)
- George Lathrop, Jr. (VA ORD)
- Anna Lowit (EPA/OPP)
- Scott Lynn (EPA/OPP)
- Monique Perron (EPA/OPP)
- Stephanie Padilla (EPA/ORD)
- Nisha Sipes (EPA/ORD)
- Paul Brown (FDA/CDER)
- Jennifer Goode (FDA/CDRH)
- Suzanne Fitzpatrick (FDA/CFSAN, co-chair)
- Anneliese Striz (FDA/CFSAN)
- Connie Kang (FDA/CTP)
- Tracy Chen (FDA/OCS)
- Warren Casey (NIEHS)
- Helena Hogberg-Durdock (NIEHS)
- Nicole Kleinstreuer (NIEHS)
- Elijah Petersen (NIST, co-chair)
- Janet Carter (OSHA)

NICEATM Support Staff (ILS)

- Agnes Karmaus
- Amber Daniel
- David Allen

Questions?