



## Interagency Coordinating Committee on the Validation of Alternative Methods

# Consideration of Alternative Methods Workgroup (CAMWG) Update

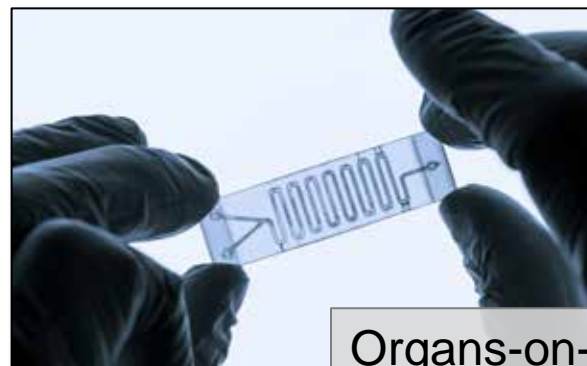
SACATM

September 21 – 22, 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

# CAMWG Background

- Currently, there is little incentive for investigators who have long used specific in-vivo models and well-established protocols to work toward validating an alternative approach.
- Moving to new approach methodologies (NAMs) could alter traditional and established methods of toxicology testing and research. Without incentives, investigators may be less likely to actively seek out, validate, or research NAMs.
- This workgroup is exploring opportunities to encourage scientists to pursue potential NAMs that could contribute to the goals of replacing, reducing, or refining their use of live animals.



Organs-on-chips



Computational models



Zebrafish embryos

# CAMWG Scope

- Work with stakeholders to develop a catalog of incentives that could be used to encourage proposals for NAMs in conjunction with existing in-vivo test methods.
- Review current requirements for the consideration of NAMs, and how those might be modified/expanded upon to foster additional consideration by stakeholders.
- While the efforts are focused on toxicology testing, it could have broader applications to other areas of animal research and testing that involve animal use.



# CAMWG Charges

1. Work with stakeholders to publish a white paper on approaches to the use of NAMs.
2. Foster collaborations with authorities outside of the U.S. to share ideas and progress to promote greater harmonization for considering NAMs.
3. Refer the community to available grants devoted to the development of alternatives to live animal use.
4. Identify and improve communication efforts and opportunities that help promote the use of NAMs.
5. Encourage agencies to promote avenues where NAMs can be better considered and leveraged.





# Recent 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	<p>Presentation by Sue Marty (Dow Chemicals) on the use of animal metrics to determine how NAMs are contributing to reducing animal use.</p> <p>Marty MS, Andrus AK, Groff KA. Animal metrics: Tracking contributions of new approach methods to reduced animal use. ALTEX. 2022;39(1):95-112. doi:<a href="https://doi.org/10.14573/altex.2107211">10.14573/altex.2107211</a>. Epub 2021 Oct 22. PMID: 34676883.</p>	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-September 2022



# Stakeholder Discussion Questions

1. Barriers to implementing NAM's?
2. Suggestions to overcome those barriers?
3. Areas to use NAMs that are currently unavailable?
4. Areas where NAMs are used but are inappropriate?
5. Funding opportunities to research/validate NAMs?
6. Does your group consider or employ the use of NAMs?
7. Methods to prescreen drug or substance candidates for development? Examples?
8. Thoughts on the availability of NAMs (in Academia, Pharma, etc.)?
9. Thoughts on the current state of NAMs in toxicology testing?
10. Examples of successful use of an alternative approach?
11. Suggestions on communication efforts that would promote the use of NAMs?



# CAMWG Next Steps

Milestone	Description	Date
Stakeholder Discussions	Continue discussion with remaining stakeholders (e.g., pharma, academia, regulatory agencies, etc.)	September – December 2022
Compile All Feedback	Compile and organize all information and feedback from stakeholder discussions and distribute to the WG	January – March 2023
Draft White paper/Review article	Draft white paper with suggestions to incentivize the consideration and use of NAMs	March – June 2023
Publish White paper/review article	Review, edit and distribute white paper to stakeholders to implement recommendations	August 2023



# CAMWG Roster

- John Gordon (CPSC)
  - Patrice Klein (USDA)
  - Jessie Carder (Co-Chair, USDA)
  - Shannon Marko (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 (Inotiv-RTP)
- David Allen
  - Amber Daniel
  - Oluwakemi Oyetade