Humane World for Animals
Humane World Action Fund

Formerly called the Humane Society of the United States and Humane Society Legislative Fund

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Helena Hogberg, PhD
Acting Director, NICEATM
National Institute of Environmental Health Sciences
P.O. Box 12233, K2–16
Research Triangle Park, NC USA 27709

RE: Interagency Coordinating Committee on the Validation of Alternative Methods Public Forum

Dear Dr. Hogberg,

On behalf of Humane World for Animals and Humane World Action Fund, formerly called the Humane Society of the United States and Humane Society Legislative Fund, and our members and supporters, thank you for the opportunity to comment on the important ongoing work of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). Our organizations strongly support the continued efforts of ICCVAM, its member agencies and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) to carry out the goals of the January 2018 publication, *A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States* as well as more recent commitments made by several agencies that acknowledge the importance of moving toward better, more human-relevant science.[1,2,3]

In order to achieve the ambitious goals put forward by ICCVAM agencies to replace animal studies with non-animal new approach methodologies (NAMs), Humane World for Animals and Humane World Action Fund encourage ICCVAM and its member agencies to increase efforts on the suggested areas below.

NAMs training for staff

While scientific advances are rapidly moving away from traditional animal studies and toward non-animal approaches, such as advanced in vitro models and artificial intelligence, it is important that agency staff who are tasked with reviewing product submissions, approving new chemicals or making decisions about which research projects should receive funding obtain appropriate training to be able to fully understand and interpret results from NAMs.

In the April 2025 *FDA Roadmap for Reducing Animal Testing in Preclinical Safety Studies,* it clearly articulates the importance of ensuring that agency scientists are "well-versed in NAM technologies and

[1] Food and Drug Administration. (2025, April 10). FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs. Retrieved from: https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs

[2] National Institutes of Health. (2025, April 29). NIH to prioritize human-based research technologies. Retrieved from: https://www.nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies

[3] Dinan, Stephen. (2025, April 10). Zeldin to pursue new ban on animal testing at EPA. Retrieved from: https://www.washingtontimes.com/news/2025/apr/10/epa-chief-lee-zeldin-eyes-ban-animal-testing

open to novel types of evidence."[4] We appreciate the commitment FDA made in this document to provide training for review staff specifically to "increase comfort and consistency in reviewing NAM-based submissions."[5]

FDA and other ICCVAM agencies would be well-served to look at the Environmental Protection Agency's website as a model for compiling a list of available NAMs training and providing opportunities for learning about new technologies.[6] For example, later this month, EPA is providing two free training opportunities. The first is on the agency's latest iteration of the Chemical and Product Database, which can be used to create an exposure assessment for chemical ingredients,[7] and the second on its httk R Package, which fills data gaps from traditional toxicokinetic models with in vitro data.[8] All ICCVAM agencies should prioritize the delivery of relevant and ongoing training opportunities for their staff as they move toward new non-animal methods.

Clear and consistent communication with stakeholders

Humane World for Animals and Humane World Action Fund also urge NICEATM and all ICCVAM member agencies to clearly and consistently communicate with stakeholders to eliminate unnecessary animal testing and ensure early adoption of NAMs by regulated industries. All stakeholders should be able to obtain current information from NICEATM and ICCVAM agencies on accepted NAMs including in workshops, webinars, meetings and website updates. Discussions of ways to avoid unnecessary animal testing and incorporate NAMs into testing plans should become a regular part of agency interactions with regulated industries. We also encourage ICCVAM member agencies to consider opportunities for incentivizing NAMs use and data submission for their regulated industries.

In August 2024, ICCVAM launched its first ever Method Developers Forum on carcinogenicity. This webinar brought together various scientists working to develop alternative approaches to assess the potential for chemicals to cause cancer and how they may be used in a regulatory context.[9] This was an innovative approach for ICCVAM agencies and NAMs developers to work together to address a specific endpoint with a focus on the regulatory needs of the agencies. As ICCVAM works to plan its next Method Developers Forum, we hope additional time will be built into the agenda for greater collaboration and discussion and ideally that there may be an opportunity for follow-up meetings, so that efforts to replace more complex endpoints can continue to progress well after the initial meetings are complete.

Prioritization of resources

The replacement of animal tests with NAMs necessitates shifting federal funding and resources toward the development and acceptance of non-animal approaches. We encourage all ICCVAM member agencies to prioritize the transition of agency resources, including the need for dedicated staff, to make this shift a reality. Agency staff need to be provided with the time and resources necessary to invest in NAMs work. One key component is the need to have staff devoted to updating guidance and other policy documents that will clearly communicate to industry stakeholders about both acceptance and preferred

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[4] Food and Drug Administration. (2025). FDA Roadmap for Reducing Animal Testing in Preclinical Safety Studies. Retrieved from: roadmap_to_reducing_animal_testing_in_preclinical_safety_studies.pdf

[5] Ibid.

[6] Environmental Protection Agency. (2025). New Approach Methods (NAMs) Training. Retrieved from: https://www.epa.gov/chemical-research/new-approach-methods-nams-training

[7] Environmental Protection Agency. (2025). EPA Computational Toxicology and Exposure Communities of Practice: EPA's Chemical and Products Database (CPDat) 4.0: New and Expanded Chemical Use Data for Support of Exposure Assessment. Retrieved from: https://usepa.zoomgov.com/meeting/register/hxZIBsZDRq6LgPBXm6THvA#/registration

[8] Environmental Protection Agency. (2025). EPA New Approach Methods (NAMs) Virtual Training: httk R Package. Retrieved from: https://us02web.zoom.us/webinar/register/WN_dxWr0ZjPTuipvmkg4ty3uA#/registration

[9] National Toxicology Program. (2024). Method Developers Forum: New Approaches for Carcinogenicity Testing. https://ntp.niehs.nih.gov/whatwestudy/niceatm/resources-for-test-method-developers/method-developers-forums

use of non-animal data. In addition, outdated guidance documents and references to animal tests that can be replaced should be promptly removed to avoid confusion and prevent unnecessary animal testing.

The recent creation of the National Institutes of Health's Office of Research Innovation, Validation and Application (ORIVA) is a perfect example of demonstrating the agency's commitment to ensuring a shift toward non-animal approaches. ORIVA has been charged with coordinating "NIH-wide efforts to develop, validate and scale the use of non-animal approaches across the agency's biomedical research portfolio and serve as a hub for interagency coordination and regulatory translation for public health protection."[10] ORIVA has also been tasked with increasing funding for and training in NAMs.

Finally, ICCVAM member agencies should be given the time and resources needed to participate in international efforts to seek alignment with regulatory schemes in other countries, while also taking advantage of an opportunity to showcase the leadership of the United States in advancing NAMs. It is imperative that the leadership at NICETAM and the member agencies of ICCVAM regularly dialogue with regulatory agencies outside of the U.S. and continue to participate in international organizations such as the Organisation for Economic Co-operation and Development, International Cooperation on Alternative Test Methods, and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Consistent communication with regulators in other countries will allow sharing of lessons learned and ensure global harmonization across product sectors, therefore maximizing efforts to reduce animal use worldwide.

Conclusion

Humane World for Animals and Humane World Action Fund welcome the opportunity to work with NICEATM or any ICCVAM agency to help achieve the common goal of replacing animals with human-relevant test methods and strategies.

Thank you for your consideration of our comments.

Sincerely,

[redacted]

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Humane World for Animals

Naomi Maxwell
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Humane World Action Fund

[10] National Institutes of Health. (2025). NIH To Prioritize Human-based Research Technologies. Retrieved from: https://nihrecord.nih.gov/2025/07/04/nih-prioritize-human-based-research-technologies