



**THE HUMANE SOCIETY
OF THE UNITED STATES**



HUMANE SOCIETY
LEGISLATIVE FUND™

May 10, 2019

Warren Casey, PhD
Director, NICEATM
National Institute of Environmental Health Sciences
P.O. Box 12233
Durham, NC USA 27709

RE: ICCVAM; Notice of Public Meeting; Request for Public Input

Dear Dr. Casey,

On behalf of the Humane Society of the United States (HSUS), Humane Society Legislative Fund (HSLF), and our members and supporters, we appreciate the opportunity to provide comments on the Interagency Coordinating Committee on the Validation of Alternative Methods' (ICCVAM's) recent activities as well as its future direction. HSUS and HSLF commend ICCVAM on its continued implementation of plans outlined in the January 2018 publication, *A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States*. The "Roadmap" has served as an important catalyst for agency efforts toward a more human-relevant, predictive, and economical approach to chemical safety evaluation while reducing animal use.

HSUS and HSLF are pleased that the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) continues to demonstrate leadership in providing stakeholders with information about new approach methodologies (NAMs). We encourage NICEATM and member agencies to continue to provide opportunities for regulators, industry, and other stakeholders to share news and discuss forward-thinking approaches in risk assessment and safety testing such as those listed below:

- The Converging on Cancer Workshop held on April 29-30, 2019, organized by National Toxicology Program (NTP) addressed the need to better understand how chemical exposure may lead to cancer and how to incorporate knowledge of systems biology and mechanistic data into cancer risk assessment as well as the development of new cancer therapeutics.
- The January 2019 ICCVAM Communities of Practice Webinar about non-animal approaches to assess inhalation toxicity.

- The October 2018 workshop *Implementing Nonanimal Approaches to Human and Veterinary Vaccine Testing: Achieving Scientific and Regulatory Success for Rabies and Beyond*, which brought together experts to develop recommendations to advance alternative testing strategies for rabies vaccines.

HSUS and HSLF are also happy to see that NICEATM staff are continuing to review and compile information about data needs for federal and international regulatory agencies so that NAM development will address those specific requirements. We also encourage NICEATM to continue its work comparing results from animal data and non-animal testing strategies such as those recently published on skin sensitization¹ and acute oral toxicity². In reviewing the specific information needs of different agencies, we hope that ICCVAM will also consider impact on animal use when prioritizing areas of focus.

While HSUS and HSLF are excited to see the enormous amount of activity surrounding NAM development, acceptance, and use, we encourage ICCVAM to focus efforts on a few needs to ensure successful implementation of the Roadmap.

Increase Agency Engagement: ICCVAM member agencies have an important role to play in ensuring that the Roadmap's goals are realized. HSUS supports the work of the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) to create and release their own roadmaps. We urge these agencies to continue to publicize their efforts in NAM development and acceptance to inform their respective regulated industries as well as the public. HSUS and HSLF would be pleased to work with NICEATM or any agency to assist with their efforts to develop and encourage the use of NAMs.

Increase International Harmonization: HSUS and HSLF are excited about the progress agencies in the United States are making in NAM acceptance, but in order to make a true impact on industry uptake and thus animal lives, global acceptance and harmonization of testing methods and requirements will need to be considered. We strongly encourage ICCVAM and its federal member agencies to increase involvement with OECD and the International Cooperation on Alternative Test Methods (ICATM), whenever possible. NAMs implementation would benefit from the committed participation of all ICCVAM members.

NAM Funding: In order to speed the expansion of NAMs, stakeholders need to invest significant time and money into their development. As ICCVAM's Roadmap points out, one way to facilitate funding of NAMs is to modify grant review criteria. As ICCVAM is housed within an NIH

¹ Kleinstreuer, Nicole et.al (2018): Non-animal methods to predict skin sensitization (II): an assessment of defined approaches, *Critical Reviews in Toxicology*, DOI: 10.1080/10408444.2018.1429386

² Kleinstreuer, Nicole et.al (2018): Predictive models for acute oral systemic toxicity: A workshop to bridge the gap from research to regulation, *Computational Toxicology*, DOI: 10.1016/j.comtox.2018.08.002

institute, it could also encourage the issuance of specific grant opportunities for development of NAMs. NICEATM might also play a larger role in influencing approaches taken by NTP more generally, which could, when successful, influence the investment in NAMs by other institutes. ICCVAM should explore additional approaches for funding NAMs.

HSUS and HSLF are eager to help ICCVAM in further dissemination and uptake of NAMs in the United States and globally, whether in the form of webinars, agency trainings, outreach to international partners, or in organizing further workshops.

Sincerely,



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