May 9, 2019

Dr. Warren Casey
Director, NICEATM
P.O. Box 12233
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Dear Dr. Casey,

The following comments are submitted on behalf of People for the Ethical Treatment of Animals (PETA) in response to the April 12th Federal Register notice by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM).

The Strategic Roadmap and the 3 C's

We congratulate ICCVAM on the progress that has been made in implementing "A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States". Over the past year, several examples of communication, collaboration, and commitment to reducing and replacing animal testing (the 3 C's) are evident, including the US Environmental Protection Agency's (EPA) "PEP" webinars, the recent collaborative publication "Evaluation of the avian acute oral and sub-acute dietary toxicity test for pesticide registration", and the December EPA FIFRA Inhalation Scientific Advisory Panel meeting. As evident in these examples, the EPA is demonstrably working towards the goals of the roadmap, and we hope the transparent and collaborative nature of the EPA will serve as a model for agencies that have not yet adopted a similar approach.

Similarly, we applaud the collaborative nature of the US Food and Drug Administration Center for Devices and Radiological Health's Medical Device Development Tools (MDDT) program. Fulfilling the goals outlined in ICCVAM's roadmap will require input from different stakeholders, and the MDDT program is an example of how to foster cross-sector partnerships for sharing knowledge, experience, and data in order to most efficiently advance test method development and evaluation. We hope to see similar programs established by other FDA divisions, such as the Center for Drug Evaluation and Research and Center for Tobacco Products.

Publicizing agency-specific mechanisms for monitoring progress and measuring success in the use and acceptance of non-animal test methods is also aligned with the 3 C's. At last year's ICCVAM Public Forum, the US EPA outlined how they are tracking implementation of animal-free methods, and we hope to see other agencies share their tracking information.

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Identification of Testing Needs and Goals

As indicated in ICCVAM's roadmap, it is essential that agencies identify and communicate their testing needs and the context in which data are used. This information is imperative for many reasons, including to help prioritize new method development and validation. This year, the EPA Office of Pollution Prevention and Toxics plans to retrospectively and prospectively identify and evaluate studies requested and submitted under the amended Toxic Substances Control Act, and make this analysis publicly available. The collection of similar information by other ICCVAM member agencies would be beneficial to support the development of new test methods.

The identification of testing needs will also help to inform ICCVAM workgroup efforts, and we are supportive of the formation of workgroups to address roadmap goals. We see significant potential for these groups to advance new methods, and we hope that these workgroups will be open to the public or to external advisors to ensure timely and effective implementation of activities to meet the roadmap's goals.

Skin sensitization

We congratulate the EPA on releasing its Draft Policy to Reduce Animal Testing for Skin Sensitization. We hope to see ICCVAM agencies continue to be involved in expanding the applicability domain covered under this policy, and for additional agencies to examine how they may apply these testing approaches. Further, when there is a non-animal approach that can be used, we encourage all agencies to note a preference, if not requirement, to use the non-animal methods.

Antibodies

As we highlighted in previous ICCVAM Public Forum comments, the use of non-animal antibodies should be prioritized within ICCVAM member agencies. Last year, the EURL ECVAM Scientific Advisory Committee (ESAC) reviewed the scientific validity of animal-free antibodies, and it is planning to soon publish a report on its findings. We hope that ICCVAM member agencies will identify how antibodies are used internally in their work and how antibodies are used in product or data submissions and that a workshop will be held in the US building on the ESAC's discussions and determining how the recommendations can be implemented within US agencies. Considering PETA's work in this area, we are happy to assist with such as workshop.

Thank you for considering our comments, and we look forward to continuing to collaborate with NICEATM and ICCVAM agencies to achieve our common goals.

Sincerely,

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