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Mary Wolfe, Ph.D.
Director, Office of Policy, Review, and Outreach
Division of Translational Toxicology
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Dear Dr. Wolfe and SACATM members,

Thank you for the opportunity to comment on activities to advance the development, regulatory acceptance, and use of non-animal test methods that will be discussed at the meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM).

Session I: Updates, Roadmaps, and Collaboration

We commend the establishment of the National Institutes of Health (NIH) Office of Research Innovation, Validation, and Application (ORIVA) and its mission to prioritize human-relevant research. We also welcome the publication of the Food and Drug Administration's (FDA's) "Roadmap to Reducing Animal Testing in Preclinical Safety Studies," and we look forward to seeing measurable progress. In addition to preclinical safety testing of monoclonal antibodies (as outlined in the roadmap), there is an urgent need to apply more reliable and relevant non-animal methods across other areas under FDA's jurisdiction—including skin irritation testing for medical devices, shellfish biotoxin assessment, sunscreen safety evaluation, pyrogenicity testing, and anticaries testing of fluoridated over-the-counter products.

We are pleased to see the FDA Human Foods Program (HFP) is launching a pilot program to qualify new approach methodologies (NAMs) for food safety use, which will join the Center for Devices and Radiological Health's (CDRH's) Medical Device Development Tools (MDDT) Program and the Center for Drug Evaluation and Research's (CDER's) Innovative Science and Technology Approaches to New Drugs (iSTAND) Program. However, we caution that there needs to be consistent standards and NAMs-trained staff involved in these programs to be successful. CDRH's MDDT program was a welcome addition in 2014, promising to overcome roadblocks to the timely qualification of new tools to better protect public health. Yet, a decade later, the program has ended up far from meeting expectations. The number of MDDT submissions is unknown as it is not public information; however, there has yet to be an *in vitro* method approved to replace an animal test and submissions have been fraught with different reviewers with inconsistent feedback, endless quests for data, and ever higher bars to reach. We encourage staff from all three of these programs to share best practices and lessons learned and to utilize the ORIVA team's expertise in vetting new testing approaches.

To evaluate progress towards agency roadmaps, qualification programs, and other initiatives, we encourage agencies to collect and transparently report quantitative metrics on both animal and non-animal test method submissions as well as internal use of these methods.

Entities:
- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Switzerland
- PETA Netherlands
- PETA Foundation (U.K.)

Session II: Data Standards, Validation, and Qualification

In 2024, ICCVAM published the report "Validation, Qualification, and Regulatory Acceptance of New Approach Methodologies" describing a framework for the consistent assessment of new methods based on their fitness for purpose, relevance on human biology, and ability to reliably provide information that leads to health protective decisions, rather than solely comparing testing results with those from tests in animals. Contrary to the concepts outlined in the ICCVAM report, some agency staff still place undue emphasis on a direct comparison of data from new approach methods to animal data, an outdated practice that delays the adoption of non-animal methods that are more scientifically robust than the traditional methods. To avoid this misstep, any new initiatives should align with the principles and evaluation strategies detailed in the ICCVAM publication.

Session III: Computational Resources

Following the recent Organisation for Economic Co-operation and Development (OECD) acceptance of SARA-ICE for skin sensitization hazard and potency assessment, we encourage agencies to evaluate the application of this tool in regulatory programs. We also look forward to the launch of Collection of Alternative Methods for Regulatory Application (CAMERA), which is expected to serve as a helpful resource for those seeking information on data, study reports, protocols, and regulatory guidance supporting methods. We encourage continued development of CAMERA to enhance its capabilities.

Session IV: ICCVAM Public Outreach and Education

Training and dedicated staff are essential to achieve ICCVAM's goals, including connecting end users with the developers of new approach methods; fostering the use of efficient, flexible, and robust practices to establish confidence in new methods; and encouraging the adoption and use of new methods and approaches by federal agencies and regulated industries. Without training both users and regulatory reviewers, new methods cannot be effectively implemented. One valuable training resource is the hands-on course provided three times per year by the Institute for In Vitro Sciences. Many have attended this course, including scientists and regulators from ICCVAM agencies, and have found it to be fundamental to their understanding of and ability to adopt non-animal approaches. Managers must prioritize time for their staff to attend these types of trainings.

Opportunities provided by the Communities of Practice webinars and the ICCVAM Public Forum are also valuable options, and we encourage the continuation of these educational efforts. Importantly, we urge the ICCVAM Public Forum to return to a hybrid format that includes in-person interactions. Networking during the ICCVAM Public Forum is a unique opportunity to forge connections between agencies and across agencies and stakeholders. The success of these meetings relies on agency leadership providing support to their ICCVAM representative and other agency staff to participate. We also recommend incorporating a panel discussion into the Forum to enable stakeholder engagement and foster interactive dialogue, enhancing the format beyond the non-interactive public comment period.

Thank you for the opportunity to provide comments.

Sincerely,

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