AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Submitted via email to ICCVAMquestions@niehs.nih.gov

Dear Dr. Casey,

On behalf of People for the Ethical Treatment of Animals (PETA), we thank the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) for the opportunity to comment on its goals and activities to advance the development, regulatory acceptance, and use of non-animal test methods that protect human health and the environment. This year's Forum is particularly timely as new leadership within agencies is leading to renewed and new commitments to reduce and replace testing on animals. For example, the creation of the National Institutes of Health (NIH) Office of Research Innovation, Validation, and Application (ORIVA) is a particularly promising development, and we look forward to seeing measurable progress.

Delivering on commitments to reduce and replace animal use in testing would be facilitated by guidance on non-animal testing (including, as appropriate, new guidance on the acceptance of non-animal approaches and removing or updating outdated guidance). The Environmental Protection Agency (EPA) Office of Pollution Prevention and Toxics' publication of its decision framework for identifying eye irritation or corrosion hazards for new chemicals is an excellent example of clear and effective guidance that was much needed.[i] New, similar notices issued by the EPA would foster a clear understanding of the acceptance of non-animal data by industry and among agency personnel at all levels. This type of intentional, coordinated guidance provides internal alignment (which translates to consistency among reviewers) and empowers companies to adopt modern, human-relevant tools. New or updated guidance or policies are also needed at other agencies, including the Food and Drug Administration (FDA). There are dozens—if not hundreds—of existing FDA-issued guidance documents that overlap and occasionally conflict with one another. Companies have noted that, when these inconsistencies apply to questions about whether specific instances of animal use are required, recommended, or even accepted by the FDA, it is simpler to conduct testing on animals than it is to seek clarity from the agency itself. For example, the FDA could immediately issue new guidance to support the use of non-animal methods for skin irritation testing for medical devices, shellfish biotoxin assessment, sunscreen safety evaluation, pyrogenicity testing, and anticaries testing of fluoridated over-the-counter products. In parallel, the FDA could delete obsolete guidance on these matters that have been replaced by updated approaches.

In addition, it is vital to strengthen IT infrastructure. Improved databases are critical for organizing existing data, enabling retrospective analyses, and supporting read-across approaches.

To evaluate progress and identify gaps in need of further work, agencies must collect and transparently report metrics on both animal and non-animal test method submissions as well as internal use of animals and non-animal tests. As the European Commission has noted, "it is crucial to understand where, how and why animals are still required to be used for scientific purposes."[ii] While the EPA has taken steps toward reporting, more comprehensive information is needed from the EPA as well as other agencies.[iii] The FDA's April 2025 *Roadmap to Reducing Animal Testing in Preclinical*

Safety Studies identifies the need to "track efficiency gains (e.g., reduction in drug development time, fewer animals used)" as a measure of success.[iv] Such tracking requires the collection of quantitative data. We also encourage the exploration of artificial intelligence to support this effort.

To achieve these goals, training and staff dedicated to understanding non-animal testing are essential. Regular, mandated training for agency staff on non-animal methods and policies will help ensure consistent feedback to industry and reduce delays or denials of non-animal testing strategies. Dedicated offices focused on non-animal methods, such as ORIVA, would further support advancements.

We look forward to collaborating with ICCVAM and its member agencies to advance non-animal testing approaches. PETA's scientists bring decades of experience working collaboratively with agencies and industry to implement reliable and relevant non-animal testing approaches that enhance human health and environmental protections, and we welcome opportunities to assist in these efforts.

Sincerely,

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[i] Environmental Protection Agency. Framework to assess eye irritation or corrosion in new chemicals. Accessed July 11, 2025. Available at www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/framework-assess-eye-irritation-or.
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