



Interagency Coordinating Committee on
the Validation of Alternative Methods



ICCVAM Metrics Workgroup (MWG) Update

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MWG Co-Chair

Senior Advisor for Toxicology

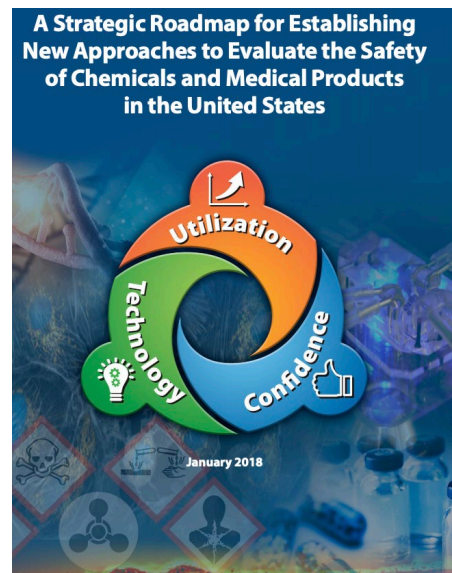
Center for Food Safety and Applied Nutrition

DHHS/FDA/CFSAN/OFVM/OCD/SSAST

Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture
Department of Defense • Department of Energy • Department of the Interior • Department of Transportation
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences
National Library of Medicine • Occupational Safety and Health Administration

ICCVAM Workgroups

- ICCVAM establishes ad hoc workgroups to perform specific tasks important for the development or validation of alternatives to animal testing. The workgroups are composed of representatives from agencies that use or require data from the topic of interest.
- Workgroups play a key role in carrying out ICCVAM activities, including implementing the goals of the ICCVAM Strategic Roadmap



Connect end users with the developers of alternative methods



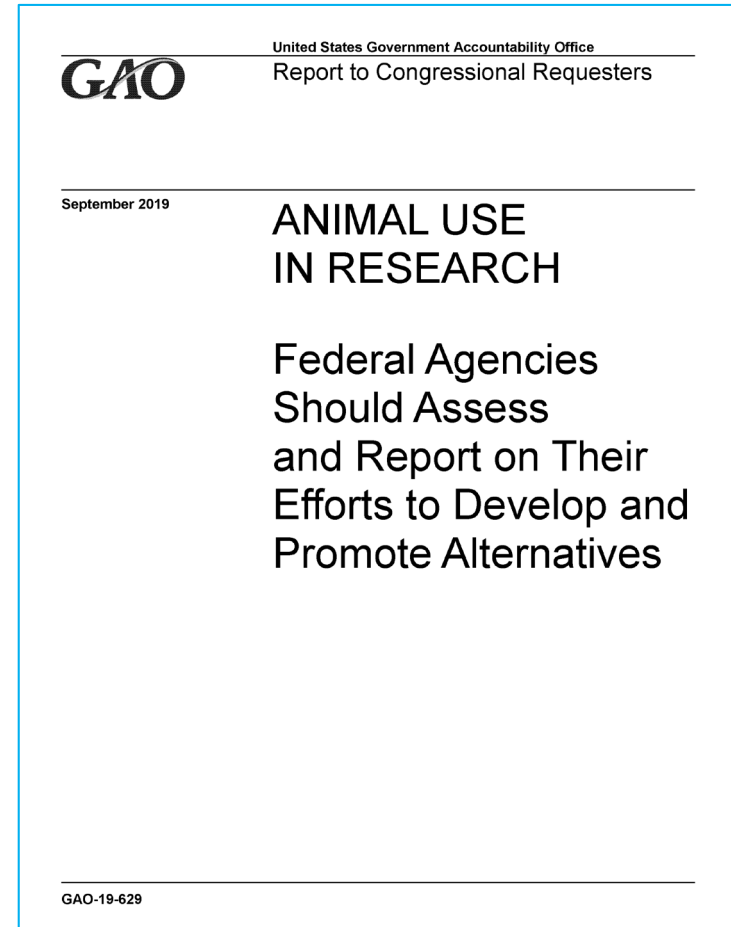
Establish new validation approaches that are more flexible and efficient



Ensure adoption and use of new methods by both regulators and industry

GAO Report on Animal use in Research

- Congress asked the General Accounting Office (GAO) how federal agencies ensure that non-animal methods are being considered and used.
- <https://www.gao.gov/products/GAO-19-629>



GAO Conclusions

- Federal agencies actively promote and enforce the use of alternative methods:
 - Modifying regulations and policies
 - Incorporating new methods into guidances
 - Inspecting research and testing facilities
 - Training researchers on the use of alternative methods
 - Developing new strategic plans to minimize the use of animals
- Federal agencies have not routinely developed or reported metrics that demonstrate how their efforts affect animal use

GAO Recommendations

Recommendations

- Federal agencies establish a workgroup to propose metrics for assessing the progress on the development and promotion of alternative methods.
- Agencies include those metrics in the ICCVAM Biennial Report published every two years.

ICCVAM Response

- In response to the GAO report, ICCVAM formed a Metrics Workgroup to help better monitor progress across the range of the committee's efforts.

ICCVAM Metrics Workgroup (MWG)

Consumer Product Safety Commission

- John Gordon, PhD

US Department of Agriculture

- Carol Clarke, DVM, DACLAM

Department of Defense

- Matthew Johnson, DVM, DACLAM
(MWG Co-Chair)
- Emily N. Reinke, PhD, DABT

Department of the Interior

- Barnett A. Rattner, PhD

Department of Transportation

- Steve Hwang, PhD

US Environmental Protection Agency

- Evisabel Craig, PhD, DABT
- Anna Lowit, PhD

US Food and Drug Administration

- Robin Levis, PhD
- Paul C. Brown, PhD
- Karen L. Davis-Bruno, PhD
- Jill Merrill, PhD, DABT
- Annabelle Crusan, DVM
- Suzanne Fitzpatrick, PhD, DABT
(MWG Co-Chair)
- Jueichuan (Connie) Kang, PhD
- Donna L. Mendrick, PhD

National Institute of Environmental Health Science

- Brian Berridge, DVM, PhD, DACVP
- Warren Casey, PhD, DABT
- Nicole Kleinstreuer, PhD

National Institutes of Health

- Harold Watson, PhD

Establishing the ICCVAM MWG (1)

- The GAO report did not differentiate between research and toxicity testing, instead using the term research to describe both activities.
- ICCVAM is legally required to work only on toxicity testing and by law its activities “do not apply to research, including research performed using biotechnology techniques, or research related to the causes, diagnosis, treatment, control, or prevention of physical or mental diseases or impairments of humans or animals.”

Establishing the ICCVAM MWG (2)

- ICCVAM Metrics Workgroup is bound to only consider test methods that use animals for toxicity testing.
- MWG charge (based on the GAO recommendation):
“Develop metrics that the agencies could use to assess the progress they have individually or collectively made toward reducing, refining, or replacing animal use in (toxicity) testing.”
- These metrics are provided as recommendations from ICCVAM to federal agencies, as ICCVAM does not have the legal authority to direct agencies to develop or report metrics.