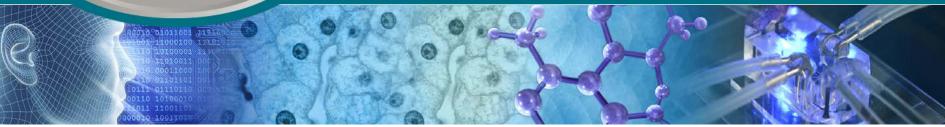


Interagency Coordinating Committee on the Validation of Alternative Methods



New Approaches to Validation and Characterizing Performance of NAMs

Warren Casey, PhD, DABT Director, NICEATM

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

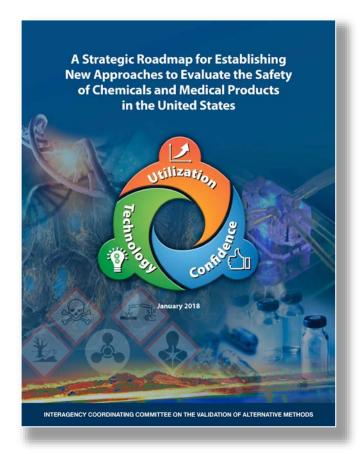
National Institute of Standards and Technology • National Institutes of Health • National Cancer Institute • National Library of Medicine

National Institute of Environmental Health Sciences • Occupational Safety and Health Administration

Interagency Coordinating Committee on the Validation of Alternative Methods







U.S. agencies and stakeholders will work together to build a <u>new framework</u> to develop, establish confidence in, and encourage use of new approaches to toxicity testing that <u>improve human</u> <u>health relevance</u> and <u>reduce or eliminate testing in animals</u>.

- Published 2018
- https://ntp.niehs.nih.gov/go/natl-strategy
- Google

ICCVAM roadmap

Interagency Coordinating Committee on the Validation of Alternative Methods





Must START with the end in mind!





EPA Acute 6-Pack Studies

- Acute Dermal Lethality > Retrospective Evaluation of Data
- Skin sensitization > Defined Approaches using In vitro methods
- Acute Oral Lethality > QSAR models currently being evaluated

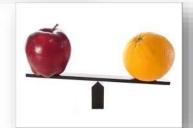




Institutional Resistance to Change



Animal Data as the Reference for Validation



Harmonization





From

- Centralized ("VAMs")
- One Size Fits All
- Binary Status (Validated / Not)
- Stand Alone

TRANSITION



Towards

- Decentralized (End Users)
- Fit for Purpose
- Evolving Confidence

Integrative



Questions / Comments?