A Strategic Roadmap to Establish New Approaches for Toxicity Testing in the United States

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It is difficult for evolving institutional practices to keep pace with revolutionary advances in science and technology.
One size fits all: OECD GD 34
International Cooperation on Alternative Test Methods (ICATM)

Validation of Alternative Methods: The “VAMs”

ICCVAM EURL-ECVAM KoCVAM CCVAM BraCVAM JaCVAM ChiCVAM
AGENCIES ARE ALIGNED

NEW APPROACHES

collaboration

relevance

quality

innovation

innovative

working cooperatively

risk management

decision-making

scientific tools

cost effective

best science

solutions

increase capacity

transform understanding

diverse partners

encourage adoption

overcome bottlenecks

regulatory science

specificity

promote health

early identification

technology transfer

share resources

sustainability

share expertise

improvements

comparative tools

competitiveness

global adoption

new information

science

participation

valid tools

better predict

across agencies

modernize toxicology

National leadership

efficient
“3Cs”

COMMUNICATION

COLLABORATION

COMMITMENT
“FIT FOR PURPOSE”

“CONTEXT OF USE”
WORDS MATTER
“To expedite the use of 21st Century science to protect public health and the environment, Federal agencies and stakeholders must work together to establish new approaches for the development, evaluation, and utilization of toxicological tests that are more human-relevant and that reduce or eliminate the need for testing in animals.”
Method Development → Validation → Regulatory Acceptance → Industry Adoption
MUST START HERE!!
Encourage the adoption and use of new methods and approaches by federal agencies and regulated industries

Help end-users guide the development of the new tools needed to support their needs

Foster the use of efficient, flexible, and robust practices to establish confidence in new methods
HOW IS THIS DIFFERENT?

- Driven by Federal agencies ("Top down" vs "Bottom up")
- Includes both chemicals and medical products
- Protecting public health and Improving human relevance are key drivers
- Paired with implementation plans will be tracked and publically reported
The U.S. strategic roadmap is intended as a resource to help guide the efforts of federal agencies and stakeholders seeking to adopt new approaches for use in safety and risk assessment.

The document was developed by representatives from 16 federal agencies and multiple interagency workgroups. As such, it represents a consensus perspective, does not necessarily reflect opinions or policy of any specific agency or workgroup, and should not be taken as a commitment by any federal agency.
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THANK YOU!