

VISION: To facilitate the development and use of new approaches for evaluating the safety of chemicals and medical products in the United States that will increase confidence in alternative methods and improve their relevance to human health, while maintaining a commitment to replace, reduce, and refine animal use.

MISSION: Federal agencies, the regulated community, and interested stakeholders will work together to explore new approaches for evaluating the safety of chemicals and medical products in the United States while collaborating with international partners to facilitate global harmonization of new testing approaches. The successful development and implementation of new approaches will require integrated efforts that **(1)** help end-users (agencies and industry) guide the development of new tools to support regulatory and research needs **(2)** foster the use of timely, flexible and robust practices to establish confidence in new methods, and **(3)** encourage the adoption and use of new approaches by Federal agencies and regulated industries.

GOALS (Draft, May 25):

- 1. Help end-users (agencies and industry) guide the development of new tools that support regulatory and research needs**
- 2. Foster the use of timely, flexible and robust practices to establish confidence in new methods**
- 3. Encourage the adoption and use of new approaches by Federal agencies and regulated industries**

OBJECTIVES (Draft, May 25):

- 1. Communicate the decision contexts and needs of Federal agencies**
 - a. Clearly delineate the toxicological testing requirements and/or context of use by ICCVAM agencies
 - b. Develop and communicate cross-agency and individual agency priorities
 - c. Explore new approaches to validation and publish best practices for the development and evaluation of new methods and approaches
 - d. Adopt clear language on the acceptance of, and preference for, new methods and approaches, when applicable
- 2. Streamline processes for regulatory acceptance of new methods**
 - a. Actively solicit the submission of parallel data from animal studies and alternative methods
 - b. Establish forums to discuss best approaches for fast-track regulatory acceptance of methods already in use for in-house screening by industry

- c. Host regular interagency discussions to share ways in which successful programs at one agency can be applied at another
 - d. Explore processes to incentivize the use of new methods.
- 3. **Collaborate with international partners to facilitate global harmonization and regulatory acceptance of new methods and approaches**
 - a. Identify and prioritize key areas where efforts can increase international harmonization
- 4. **Promote communication and data sharing across product-sectors and help unify efforts to develop alternative methods**
 - a. Utilize public-private partnerships to facilitate the development, evaluation, and utilization of new test methods and approaches
 - b. Identify and make public case studies from ICCVAM agencies, the regulated community, and other stakeholders where alternative approaches have been evaluated or implemented
- 5. **Identify and promote resources that can foster the development and utilization of new or enhanced approaches**
 - a. Establish and promote training programs for personnel who conduct, recommend, or review toxicology studies, to include: hands-on training on *in vitro* or *in silico* methods, workshops and webinars, factsheets, tutorials, and videos
 - b. Identify funding sources for applied research that supports agency needs
 - c. Encourage the development of grant review processes specifically for alternative methods
 - d. Identify and collate sources of high quality human toxicological data relevant to assessment of new alternative methods
 - e. Create a centralized access point of high-quality data that is publicly available and easily accessible
- 6. **Establish appropriate metrics for prioritizing activities, monitoring progress, and measuring success**
- 7. **Develop a communication plan for transmitting and receiving information related to the Strategic Roadmap**
 - a. Ensure broad distribution of information related to the acceptance of new methods, data sharing opportunities, and other efforts.