

Creating a 3Rs Roadmap and Strategy for the United States

Background Material:

- ICCVAM Authorization Act of 2000
- A National Toxicology Program for the 21st Century – A Roadmap for the Future
- Toxicity Testing in the 21st Century: A Vision and a Strategy
- The U.S. EPA Strategic Plan for Evaluating the Toxicity of Chemicals
- Tox21: Understanding the Potential Health Risks of Chemicals
- The 3Rs Principle – Mind the Ethical Gap!

The last decade of the 20th century and the turn of the 21st century have produced dramatic technological advances in molecular biology and computer science. During this period, scientists have increasingly identified critical cellular and molecular events that lead to adverse responses to toxicants and federal agencies have developed strategies to incorporate 21st century advances into their assessments of chemical safety. The U.S. 2007 National Research Council (NRC) report, "Toxicity Testing in the 21st Century: A Vision and a Strategy," has served as the impetus for a paradigm shift in the assessment of toxicity of environmental agents, moving away from adverse health outcomes observed in experimental animals to the identification of critical perturbations of toxicity pathways. The U.S. government responded to the NRC report with the formation of the multiagency Tox21 collaboration. Initially, the main focus of Tox21 is to help prioritize chemicals for more extensive testing using traditional methods. Ultimately, it is hoped that Tox21 will develop strategies that can be used directly by regulatory agencies to regulate chemicals and reduce our current reliance on animal testing for toxicological assessments. Many additional efforts have been initiated/funded by the federal government, which aim at expanding our knowledge of the physiological, biochemical, and molecular basis of toxicity and disease. Ultimately, these efforts will also help reduce our reliance on animal-based toxicity testing.

Although considerable resources have been put into developing technologies that could reduce the need for animal-based testing, the United States does not have a clear strategy to replace, reduce, or refine (3Rs) the use of animals in toxicological tests required or conducted by federal agencies. There are numerous projects, committees, and funding mechanisms that could potentially impact the 3Rs, but there is not currently a national strategy or roadmap to help the United States realize the full potential of these investments. A discussion of 3Rs strategies will highlight existing efforts and provide examples for improved coordination of current efforts in the United States.

Charge Question to SACATM

- Is a national 3Rs strategy and roadmap needed?
- If so, what process should be considered for developing a national strategy and what government agencies, industries, NGOs and other organizations should be involved?

- What mechanisms (public-private partnerships, strategic funding, international activities, new metrics, etc.) should be considered for leveraging United States-based activities to help advance the 3Rs?