

International Activities, Opportunities, and Challenges

Background Material:

- International Cooperation on Alternative Test Methods

International collaboration, harmonization, and adoption of alternative test methods are high priorities for ICCVAM, given the economic importance of international trade to industries such as cosmetics, industrial and agricultural chemicals, and pharmaceutical products.

The globalization of markets has resulted in the urgent need for international coordination of alternative method development and validation. In the absence of such coordination, unilateral efforts on the part of the U.S. to reduce animal usage will be largely negated by compulsory animal-based testing in other countries. Conversely, animal testing bans enacted by U.S. trading partners (European Union, India, Israel, Norway – and soon Korea, Brazil and Association of Southeast Asian Nations [ASEAN] member states) prohibit the importation, sale, or marketing of cosmetics that have been tested on animals, thereby dividing the global market into countries that require versus those that prohibit animal-testing.

These animal-free testing policies not only create a challenge to commerce, they may also pose a significant threat to public health unless validated alternatives are developed and internationally accepted. The Organisation for Economic Co-operation and Development (OECD), via the Test Guidelines program, provides a mechanism for the international evaluation and adoption of alternative methods by its 34 member countries. The International Cooperation on Alternative Test Methods (ICATM) provides another means to coordinate 3Rs (replacement, reduction, or refinement of animal use) activities among its member countries: United States, Canada, Europe Union, Japan, and Korea. ICATM was established with the goal of promoting international cooperation in the critical areas of validation studies, independent peer review, and development of harmonized recommendations in order to ensure worldwide acceptance of alternative methods and strategies.

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a European Union (EU) regulation that addresses the production and use of chemical substances, and their potential impacts on both human health and the environment. REACH is the strictest law to date regulating chemical substances, and will affect industries throughout the world, requiring all companies manufacturing or importing chemical substances into the European Union in quantities of one ton or more per year to register these substances with European Chemicals Agency (ECHA). A chemical safety assessment is one component of the registration process and is estimated to result in the use of ~40 million animals. This animal testing will take many years to complete and will cost billions of dollars, which will in turn raise consumer prices while creating a barrier for small US businesses seeking to enter the global market. REACH also poses a legal dilemma for manufactures of cosmetic products, which are required to abide by the animal-testing ban while also being obligated to register (and test) raw materials under REACH. Other countries (i.e., Korea) have also enacted similar legislation and the US is considering the modernization of its Toxic Substances Control Act (TSCA), underscoring the need to expedite the international validation and harmonization of non-animal methods for safety testing.

Examples of technical and policy-related challenges in 3Rs implementation will be identified and discussed.

Charge Question for SACATM:

- Please suggest strategies to accelerate the international adoption of 3Rs methods.