Non-Animal Cosmetic Safety Assessment

Announcing a collaboration to achieve complete safety assessment of cosmetics without the use of animals

Baltimore, MD, 12 March 2019

A new collaboration between Humane Society International, industry partners and other interested groups intends to help shape future cosmetics legislation and share the decision-making approaches which are being applied to assess safety without animals. The associated investment in education and training will ensure that there is the ongoing ability to satisfy regulations which require non-animal safety approaches.

The multi-stakeholder NACSA collaboration was introduced at the 2019 Society of Toxicology Annual Meeting in a session that attracted approximately 100 attendees. This collaboration will help shape future cosmetics legislation and build global capacity in making safety decisions about cosmetics without new animal testing. Investment in education and training materials and processes will ensure that there is the ongoing ability to meet regulations which require non-animal safety approaches. At this symposium, we introduced the overall objectives of this collaboration, presented examples of non-animal safety approaches from existing partners, discussed priorities for education and training, and highlighted opportunities to join.

The collaboration has three primary objectives:

1. **Global harmonization of non-animal cosmetic safety assessment legislation** - The goal is to harmonize prohibitions of animal testing of cosmetics and cosmetic ingredients, effectively ending this practice globally by 2023. Priority regions are ASEAN (Association of Southeast Asian Nations), Australia, Brazil, Canada, Chile, Mexico, South Africa, Sri Lanka and the United States.

2. **Sharing information on decision-making approaches without new animal testing**

As non-animal testing methods and approaches develop, they can be used for many different purposes, including decision-making on the consumer safety of cosmetics. The collaboration will gather information, identify gaps, and share tools to allow confident decision-making without the need for new animal testing. Case studies will be used to demonstrate different decision contexts (e.g. different uses, products, decision-types).

3. **Education and Training** - Capacity building is necessary within both the regulated and regulatory cosmetic communities for the long-term acceptance and implementation of these new approaches. In collaboration with regulators, the regulated community, and consultants NACSA will develop curricula for critical audiences that are engaging and accessible with specific focus on the application of the data generated for safety decision making.
The Society of Toxicology Annual meeting provided a perfect venue for announcing this new collaboration that brings together a broad spectrum of stakeholders, including risk assessors from both government and industry, service providers, model and method developers, contractors, consultants and academics to develop the tools necessary for non-animal risk assessment. This project is unique in focusing not on method development or evaluation per se, but rather on the use of all types of information in safety decision-making. This introductory session focused on the experience sharing and education and training aspects of the project; the purpose was to stimulate interest and solicit partners.

Program

Welcome & Introduction - Catherine Willett, HSI
Applying ICCR Principles to Next Generation Risk Assessment (NGRA) - Paul Carmichael and Gavin Maxwell, Unilever
Cheminformatics & Toxicogenomics to Support Toxicity Assessment - George Daston, Procter & Gamble
Round table: Priorities for Education & Training - Jay Ansell, PCPC; Chris Barber, CEO, Lhasa; Warren Casey, Director, NICEATM; Rebecca Clewell, 21st Century Tox Consulting; Clive Roper, Charles River Laboratories

First two presentations available at: https://humanotoxicologyproject.org/risk-assessment/

Summary

The ICCR principles (the International Cooperation on Cosmetics Regulation, comprised of 5 member regulators: Brazil, Canada, EU, Japan, and USA; www.ICCR-cosmetics.org) was introduced as a general approach to safety decisions. The framework includes four overriding principles: the goal is a human safety risk assessment, the assessment is exposure led, hypothesis-driven and is designed to prevent harm. The assessment should be conducted following appraisal of all existing information using a tiered and iterative approach, using robust and relevant methods. Sources of uncertainty should be characterized, and the entire assessment should be transparent and documented. Next, a case study showing how Unilever applies this approach to skin sensitization was provided, followed by a read-across case study from Procter and Gamble.

Discussion & Recommendations

The panel discussion and audience participation was directed at three main topics: priorities for module development, stakeholder inclusion, and desired formats for dissemination. The audience engaged directly with panel members and also responded to questions via a live online poll. Participants stressed the importance of “community facilitated learning” rather than a more traditional “education” as well as the idea of engaging regulators as early as possible in the discussion. The importance of tailoring materials to the audience level and needs was stressed, as was the need for several specific case studies. Finally, the strong winners in terms of priorities for module development were the role of the following in decision-making: in-silico approaches, PBPK modeling, 3D tissues and organs-on-a-chip, toxicogenomics and tiered risk assessment case studies.
Interested companies are invited to join the NACSA collaboration to achieve a global end to cosmetic animal testing by 2023 through harmonized national legislation, education & capacity building in next-generation safety assessment. If interested, contact kwillett@hsi.org