

Update on ICCVAM's Vision and Strategy / ICCVAM Roadmap for Skin Sensitization Testing

Background Material:

- 15 Years Out: Reinventing ICCVAM. Birnbaum L. *Env Health Perspect* 121(2) 2013
- NRC Report on Toxicity Testing in the 21st Century
- A New Vision and Direction for ICCVAM

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In an *Environmental Health Perspectives* editorial, National Institute of Environmental Health Science (NIEHS) and National Toxicology Program (NTP) Director Linda Birnbaum announced that NIEHS would move forward with a different philosophy toward the Interagency Coordinating Committee on Alternative Toxicological Methods (ICCVAM) whereby the partner regulatory agencies would drive ICCVAM's activities. In addition, Dr. Birnbaum sought to better align ICCVAM and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) with the vision laid out by the National Academy of Sciences in the 2007 National Research Council (NRC) *Report on Toxicity Testing in the 21st Century* as ICCVAM fulfilled its mission to implement the 3Rs of toxicity testing. In response to Dr Birnbaum's updated vision for ICCVAM, the committee developed the draft document titled *A New Vision and Direction for ICCVAM*. The document presented ICCVAM's

- Areas of priority and scientific focus for immediate resource investment
- Plans for improved communications with stakeholders and the public
- Interest in exploring new paradigms for the validation and utilization of alternative toxicologic methods

ICCVAM actively sought comment on the draft document from SACATM and the public and has begun developing strategies to replace the use of animals in six acute toxicity tests that currently account for ~50% of all animals used for toxicity testing worldwide: acute lethality (oral, dermal, inhalation), skin sensitization, and eye irritation. An overview of ICCVAM's current and planned activities will be presented.

ICCVAM is developing a U.S. roadmap for replacement of animal testing for skin sensitization. To set the stage, the presentation on the roadmap will summarize the current regulatory statutes of federal agencies (and chemical sectors) that either require or consider skin sensitization data, the concordance between data from existing animal test methods and human results, and the reproducibility of the animal tests. This background will provide a basis for comparison and subsequently be followed by a review of non-animal test methods, strategies to combine them, and evaluations of their performance against the animal data and the human data.

Current chemical space coverage of non-animal test methods for skin sensitization is confined largely to cosmetics ingredients, and efforts are underway to generate *in vitro* data to expand and assess the applicability domain of the non-animal test methods, *e.g.*, for pesticides and agrochemicals. Multiple non-animal testing strategies have been identified with equivalent or superior performance to current animal tests, and strategies for their adoption in the US and internationally will be presented.