



December 9, 2013

NICEATM, NIEHS
P.O. Box 12233
Mail Stop: K2-16
Research Triangle Park, NC 27709

RE: Request for Information on Alternative Skin Sensitization Test Methods and Testing Strategies and for Comment on ICCVAM's Proposed Activities; FR Doc. 2013-27095

Submitted via email to niceatm@niehs.nih.gov

Dear Docket Officer,

These comments to NICEATM are submitted on behalf of the PETA International Science Consortium (PISC), Ltd. and the Physicians Committee for Responsible Medicine (PCRM). PCRM, and PISC represent the interests of more than 3 million supporters worldwide who are concerned about the use of animals in laboratory experiments.

In FR Doc. 2013-27095, it is noted that ICCVAM is aware of the significant international efforts to replace the use of animals in skin sensitization testing including the work of the Organisation for Economic Cooperation and Development (OECD), the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) and Cosmetic Europe (formerly COLIPA). The OECD is currently drafting three test guidelines: the KeratinoSens Assay, the Direct Peptide Reactivity Assay (DRPA) and the Human Cell Line Activation Test (hCLAT). EURL ECVAM recently released a strategy on assessing skin sensitization without the use of animals.¹ These non-animal methods have the potential to better predict human skin sensitizers than the animal methods, especially when a combination of assays is used.^{2,3,4} In addition, Cosmetics Europe has organized a skin sensitization task force to further evaluate various alternative skin sensitization tests. In light of these substantial international efforts, we encourage ICCVAM and its agency representatives to remain involved in these efforts and make recommendations to U.S. agencies on the use of these methods

¹ Casati *et al.*, 2013. EURL ECVAM Strategy for Replacement of Animal Testing for Skin Sensitisation Hazard Identification and Classification. European Commission JRC79446.

<http://publications.jrc.ec.europa.eu/repository/handle/111111111/27708>

² Bauch *et al.*, 2011. *Toxicology in Vitro*. 25: 1162-1168, <http://www.ncbi.nlm.nih.gov/pubmed/21669280>

³ Bauch *et al.*, 2012. *Regulatory Toxicology and Pharmacology*. 63: 489-504, <http://www.ncbi.nlm.nih.gov/pubmed/22659254>.

⁴ ICCVAM, "Interagency Coordinating Committee on the Validation of Alternative Methods. The Murine Local Lymph Node Assay: a test method for assessing the allergic contact dermatitis potential of chemicals/compounds. The results of an independent peer review evaluation coordinated by the ICCVAM and the NICEATM," National Institute of Environmental Health Sciences, NIH Publication no. 99-4494, <http://www.iccvam.niehs.nih.gov/>.

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in a timely manner in order to minimize additional testing and time needed to implement similar methods and testing strategies in the U.S. Specifically, as we have suggested before, it is important to determine that the *in vitro* methods being currently considered at OECD have been adequately assessed and can meet the specific data needs of the ICCVAM member agencies *now*, so that any deficiencies can be addressed during the test guideline development process.

We hope that ICCVAM member agencies and industry will respond to this current request with useful data for these efforts. We have shared this request widely and hope others have done so as well.

With regard to outreach to industry groups, we suggest, for this topic in particular, ICCVAM reach out to CropLife America⁵ and other crop protection industry representatives. It may be useful to address CLA's HAR committee regarding the need for industry to participate in the validation and implementation processes of these *in vitro* methods.

We were pleased to see mention of NICEATM's collaboration with industry scientists to develop an open-source Bayesian network as a framework for an integrated testing strategy. We support ICCVAM's continued pursuit of the development of this network for public use.

We encourage ICCVAM to also be involved with the OECD QSAR Toolbox (www.qsartoolbox.org). There are already QSARs to predict a substance's potential to cause skin sensitization and further efforts in the development of, and training on the use of, these methods would be valuable.

Specifically addressing the "ICCVAM proposed plans," we support them. We wonder, however, whether guidance written by ICCVAM will be useful given differing member agency data needs. Perhaps the guidance would address these differing needs and how non-animal test methods might meet them?

Educational workshops on how to interpret the data from these methods, addressed specifically to member agency risk and hazard assessors, is a major need.

We appreciate the opportunity to comment on ICCVAM's proposed activities related to alternative skin sensitization test methods and look forward to the swift implementation of alternative skin sensitization tests in the U.S. Please feel free to contact us if you have any questions.

Sincerely,

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⁵ <http://www.croplifeamerica.org>

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