

IIVS News & Views

Dermal Absorption Workshop

In May of this year, IIVS and the Physicians Committee for Responsible Medicine (PCRM) hosted a cadre of international scientific and North American regulatory experts in dermal absorption, for a workshop intended to pave the way for the adoption of an *in vitro* method for pesticide risk assessment. Despite the adoption of OECD Test Guideline 428 on *in vitro* dermal absorption techniques in 2004, pesticide regulators in North America often do not accept data generated by using human skin *in vitro* — a technology that is commonly used to evaluate the dermal absorption of ingredients in personal care products. Regulators cite the inconsistency of experimental protocols historically submitted for regulatory review, as a major reason behind the lack of acceptance of *in vitro* data. There are several key protocol elements that can vary within the accepted guidance, such as the skin thickness, species, and preparation procedures, receptor fluid composition, and tape stripping or other post-exposure procedures.

Steering group members from the IIVS, PCRM, the California Environment Protection Agency (EPA), and the Canadian Pest Management Regulatory Agency (PMRA) planned the workshop to ensure that discussion of these and other key variables would be supported by data collected in top laboratories and agrochemical companies. The workshop participants then discussed each variable, and made several recommendations for 'best practices' for the conduct of *in vitro* dermal absorption studies. The workshop also determined reporting guidelines, to ensure that companies provide enough detail for regulators to be able to interpret the *in vitro* studies submitted to them. While the recommendations are not binding, the participants agreed that studies conducted according to them will improve the acceptability and comparability of the data across studies and laboratories, soon paving the way for broad acceptance of the *in vitro* method. Finally, the participants encouraged the conduct of a meta-analysis of existing *in vitro* and *in vivo* dermal absorption data with agrochemicals. A workshop report detailing the recommendations and reporting guidelines is being prepared.

Workshop for Russian Delegates

Furthering its goal to technically assist in the adoption of non-animal methods in countries

where animal testing has historically been required, the IIVS hosted a four-day workshop for 11 attendees from Russia. Through a combination of lectures and hands-on laboratory training, the delegates gained first-hand knowledge of how non-animal test methods can be used to assess the safety of cosmetic and personal care products.

"Scientists in Russia are interested in learning more about non-animal test methods. This course gave an extremely useful technical overview and also highlighted how the data from these methods can be incorporated into a product safety testing programme", said Tatiana Puchkova, Chairman of the Board of the Perfumery and Cosmetic Association of Russia, which organised this training for Russian regulators and leading toxicologists. "This is the beginning of an extensive collaboration with IIVS to establish non-animal safety testing in Russia. This effort is extremely important for further harmonisation and plans to enter the OECD."

Although several non-animal tests have been formally validated and accepted by the OECD, the corresponding Test Guidelines often lack sufficient detail for users to execute the new methods or interpret the resulting data. This workshop is one example of many educational and training activities in the International Outreach Program of IIVS, which is focused on bridging information gaps to make non-animal test methods more readily adoptable by scientists around the world. Generous support from The Alternatives Research & Development Foundation, the Colgate Palmolive Company, and the Humane Society International, enabled IIVS to provide the workshop for the Russian attendees. Additional IIVS training programmes are being planned for Russia, as well as for the USA, China and Brazil.

IIVS Webinar on 'An *In Vitro* Ocular Hazard Testing Strategy for EPA Registered Antimicrobial Cleaning Products: A Collaborative Success Story'

This webinar will take place on 12 November 2012, and will be presented by Dr Rodger Curren, President of IIVS.

The majority of cleaning products in the USA do not undergo a pre-market registration

process. However, once an ‘anti-microbial’ claim is made for the product, it is regulated by the US Environmental Protection Agency’s Office of Pesticide Programs (US EPA OPP), and animal testing for hazard identification is required before the product can be sold. An investigation of whether an *in vitro* approach for evaluating the safety of anti-microbial cleaning products (AMCP) could replace some of the required animal tests, was suggested by OPP’s Pesticide Program Dialog Committee. Both the EPA and the industry recognised that many essentially identical products had been marketed safely for years — without anti-microbial claims and without animal testing. All the interested parties believed that eye irritation should be the first animal test to be replaced. They agreed that a predictive, conservative *in vitro* testing strategy to label for eye irritation hazard had the potential to satisfy the industry’s need for non-animal testing, while providing the data necessary for regulatory approval. Key approaches which ultimately led to the success of the programme, were:

- agreement by all parties on the purpose and goal of the study;
- addressing known toxicity mechanisms whenever possible; and
- providing transparency in data collection and analysis.

The webinar is complimentary, but registration is required. Please visit www.iivs.org to register.

Registration for IIVS Training Workshop Now Open

The IIVS workshop on Practical Methods for *In Vitro* Toxicology will be held 14–17 January 2013, at the IIVS laboratory facility in Gaithersburg, MD, USA. The 3.5-day course will include lectures given by experts in the field of *in vitro* toxicology, as well as hands-on laboratory experience. For registration details, or to view a sample agenda, please visit www.iivs.org.