



Bits and Pieces

- Look for Institute Updates 3 times throughout the year!
- Visit our new webpage at www.iivs.org for the latest information on happenings at the Institute. Many publications and documents are searchable through the "IIVS Publications" page.
- If you missed us at SOT, our posters are now available in pdf format on the website.



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IIVS Works With Industry And Government To Advance Non-Animal Testing Approaches

If that new cleaning product you're using on your kitchen counter says "antimicrobial" on the label, then under US law it had to have been registered as a pesticide with the EPA. As a result, it will have some type of cautionary labeling that was most likely determined by the results of a Draize eye and skin irritation test. Interestingly that same formulation – minus the "antimicrobial" claim – could be on the market today without any animal testing.

Recently, seven major cleaning products manufacturers have embarked on a novel program with the US EPA to obtain acceptance of non-animal methods specifically to determine the appropriate safety labeling of antimicrobial cleaning products. The **Colgate-Palmolive Co.**, The **Clorox Company**, The **Dial Corporation**, **Ecolab**, **JohnsonDiversey**, the **Procter & Gamble Company** and **S.C. Johnson** are cooperating to carefully define and substantiate existing non-animal approaches for eye and skin irritation. The intent is that these non-animal methods, many of which are used by the companies on a routine basis, should provide

sufficient data to meet regulatory hazard classification and labeling requirements.

Each of the companies has willingly provided animal and/or in vitro data on nearly 300 representative cleaning products.

IIVS - acting as a neutral third party - has been asked by the corporate participants to collate these data, fill possible data gaps with additional non-animal testing, and determine the predictive capacity of the proposed approach. Formulations are being subdivided into categories according to their expected mechanism of irritation. Although a chemical description of the product will be included in the submission, the product name and company



Household cleaning products with anti-microbial claims

ECVAM Holds Eye Irritation Meeting

An eye irritation expert meeting was held at the European Centre for the Validation of Alternative Methods (ECVAM) in Ispra, Italy on February 8-11, 2005. IIVS's **John Harbell** and **Kevin Trouba** joined other invited scientists from government, academia, and industry to 1) review current test methods, 2) identify data gaps in promising methods, and 3) propose testing strategies for labeling of chemicals under the European Union classifica-

tion system. Discussions on the strengths and limitation of each method were candid and productive. All highlighted the challenge of predicting "moderate" irritants (R36). Thus, the proposed strategies focused on identifying nonirritants (unclassified) with one set of methods and severe irritants (R41) with others. Materials falling in between would be labeled as R36. ECVAM staff will prepare and publish a report of the workshop.

Technical Notes

Thoughts on the Expert Panel Review Document for the Bovine Corneal Opacity and Permeability Assay

In 2003, the USEPA asked the ICCVAM to review four *in vitro* methods; (isolated rabbit eye, isolated chicken eye, HET-CAM and BCOP) for the prediction of severe eye irritation. These were selected because they have been accepted for this purpose in the European Union. In November of 2004, the Background Review Document (BRD) on each assay was released by the NICEATM. The Expert Review Panel met in January, 2005 to discuss the BRDs in detail. While the BRDs were universally negative, the Panel report was positive for all of the assays and, in particular, the BCOP. Their report emphasized several points:

- 1) The depth of initial injury is a predictor of the eventual degree and duration of injury (from the work of Drs. Jim Maurer and James Jester).
- 2) The predictive capacity of the reference test must be evaluated.
- 3) Relevance is not equivalent to accuracy.
- 4) The inter- and intra-laboratory reproducibility of the BCOP assay was acceptable.
- 5) The predictive capacity of the BCOP assay was demonstrated except for certain organic solvents (over) and solids (under). The concern with solids came from the EC/HO study published in 1996.
- 6) Histology should be included for the BCOP assay unless the action of the test substance is well characterized by opacity or permeability.
- 7) The document also contains several important "Minority Opinions" from individual panel members. In particular, concerns were raised that the panel was not allowed to determine the actual validity of the test methods.
- 8) The complete draft report and public comments may be obtained from:
<http://iccvam.niehs.nih.gov/updates/updates.htm>

Practical Methods in In Vitro Toxicology 2005 Training Course a Success!

*"Assistance from
technical staff was
beyond
expectations...
SUPERB!"*

The 2005 Practical Methods in In Vitro Toxicology Workshop, sponsored by IIVS, was held June 14th through the 16th in our Gaithersburg, MD laboratories. This training was a combination of lectures which provided an overview of the techniques and tips on data interpretation; and both hands-on and demonstration-based laboratory activities where participants had the opportunity to carry out the assay procedures themselves. The lecturers included course founder, **Dr. Joseph Sina** of Merck Research Labs, **Dr. Robert Bronaugh** of the FDA CFSAN division, and IIVS staff.

Techniques practiced in the lab included conducting the Neutral Red Release and Skin Irritation assays as well as what is always the highlight of the course, isolating corneas from abattoir-sourced bovine whole eyes.

Due to the number of course participants, the lecture series was presented at the local Hilton hotel. Participants were then transported to our facility to conduct the hands-on training.

The traditional happy hour reception was held Tuesday evening at the home of **Dr.**

and **Mrs. Harbell**. This activity allowed participants, presenters, and IIVS staff to interact in a relaxed social setting. Wednesday evening included a cocktail hour and dinner at a local restaurant. Ms. **Marcia Brose** of IIVS organized the delicious lunches, breaks and after-hours events — all of which ran smoothly thanks to her efforts.

Participants stated in post-workshop evaluation forms that their expectations to learn *in vitro* methods that might be applied to their product lines in the future were met and even exceeded in many areas. They also were appreciative of the take home materials provided to them, which they stated would be useful for years to come. One participant had praise for the laboratory staff in particular, saying that the "Assistance from technical staff was beyond expectations...SUPERB!"

Course participants, presenters, and IIVS staff all had a good time meeting one another and discussing the intricacies of conducting the various *in vitro* assays presented in the program. The only negative comment was that there was too much food!



2005 Practical Methods Course Participants and Dr. John Harbell of IIVS

Catch us in Berlin at the 5th World Congress on Alternatives & Animal Use in the Life Sciences

Five members of the IIVS staff will be traveling to Berlin, Germany to take part in the 5th World Congress on Alternatives & Animal Use in the Life Sciences, August 21st through the 26th. IIVS will be giving both oral and poster presentations throughout the conference. Look for us in the sessions listed below. We hope to see many of you at the conference yourselves! For more information, please visit the 5th World Congress website at <http://www.ctw-congress.de/act2005/>.



Sponsored by:



IIVS will co-sponsor the Practical Training Workshop on In Vitro Eye Irritation Methods along with BfR-ZEBET and Beiersdorf AG. This training session will take place on August 26th at the Federal Institute for Risk Assessment (BfR), immediately following the World Congress. No fees will be charged for the training session, but registration will be limited to a maximum of 45 participants. Visit the World Congress Website to view the program and register.

Day and Time	Session Name
Monday (am)	<i>Mechanisms of Chemically-Induced Ocular Injury and Recovery: Current Understanding and Research Needs</i>
Monday (pm)	<i>Strategies for Using Non-animal Methods in Relation to HPV, Endocrine Disruptor, and REACH legislation</i>
Tuesday (am)	<i>Progress and Needs for Developing and Validating Alternatives for Dermal Toxicity Testing and In Vitro Approaches for Determining Acute Systemic Toxicity</i>
Tuesday (pm)	<i>Progress in Quality Assurance for In Vitro Alternatives Studies</i>
Wednesday (am)	<i>Policy Implementation</i>
Wednesday (pm)	<i>Advancements and Needs for Developing and Validating Alternatives for Ocular Irritancy and Corrosivity Testing</i>

Continuation of EPA Initiative

ownership will remain confidential.

A document describing the approach will be submitted to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). ICCVAM will then coordinate a review of the method, and provide the results to the EPA.

A favorable outcome would lead the Agency to consider an interim policy for acceptance of non-animal testing to determine hazard classification and labeling requirements for antimicrobial cleaning products. This interim policy could then lead to new EPA guidelines, which would more permanently cover this type of non-animal approach.

“A favorable outcome would lead the Agency to consider an interim policy for acceptance of non-animal testing...”

SAP Member Highlight

June Bradlaw, Ph.D., a career FDAer and a member of IIVS’s Scientific Advisory Panel for over seven years, recently spent a week in Phoenix, Arizona at the 2005 Intel International Science and Engineering Fair (ISEF). The ISEF, with over 1,400 students from 40+ countries, is the largest international science and engineering competition for pre-college students. The students displayed projects to compete for \$3 million in scholarships and prizes in 14 different categories. June had the honor of interviewing doz-

ens of exciting students to choose the recipients of \$8,000 in scholarship awards from the National Anti-Vivisection Society. June is very enthusiastic when she speaks of the zeal with which these young students approach the demanding world of science. Our thanks to June for lending her experience and knowledge to help guide and encourage tomorrow’s scientific leaders. Check out the winners at <http://www.sciserv.org/isef/results/>. To find out more about June, click on our website <http://www.iivs.org/pages/panel.php>.



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Together

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**Advancing Science & Animal Welfare
Together**

**New and Improved
Website!**
www.iivs.org

Founded in 1997, IIVS is a non-profit science-based organization dedicated to the advancement of alternative, non-animal testing methods. IIVS seeks to refine the science, broaden the use, and increase the acceptance of in vitro testing worldwide.

To learn more about IIVS or how you can support our programs, please visit us at www.iivs.org.

It is only with the generous support of industry, the animal protection community, and the general public that we can continue to make a difference in acceptance of in vitro methods.

What's New at Our House

Amanda Ulrey certified as a registered quality assurance professional in Good Laboratory Practices (RQAP-GLP)! IIVS continued its commitment to remaining current in the latest regulatory requirements and industry interpretations of these requirements by encouraging Amanda to participate in the Quality Assurance Professional Registry program. This program was established by the Society of Quality Assurance (SQA) to test and identify QA professionals knowledgeable in the regulations and application of GLP principles. Amanda passed the exam which focused on FDA, EPA, and OECD GLPs and is now credentialed as RQAP-GLP. Every three years, Amanda will have to prove continued involvement and competency in the profession to retain her certification. Amanda's registration ensures that IIVS will have a knowledgeable and up-to-date quality assurance and GLP philosophy.

Hans Raabe celebrates 15/16

years of service with the group. Hans, originally hired by **Rodger Curren** at Microbiological Associates in 1987, worked there for over 10 years in the Genetic Toxicology and In Vitro Toxicology Divisions. In 1997, along with other MA group members, he made the transition to IIVS as Laboratory Supervisor. Although Hans left IIVS for a brief time, he rejoined the Institute as a Study Director in 2001 and has made many significant contributions since. Although it took some of us a bit of time to calculate his actual seniority, IIVS finally honored Hans with a 15/16 year anniversary party (complete with gifts of a tie decorated with eye balls and a wooden boxed desk clock) in March.



Hans, now and then

New biologist at IIVS! **Valerie Deoudes**, joined IIVS as a Biologist I in July. Valerie graduated from University of Maryland with a B.S. degree in Biology - emphasis on cell biology and genetics. Val had previously worked for IIVS as an intern during her college breaks over the last three years. Obviously she enjoyed the work situation enough to sign on permanently.