

# IIVS UPDATE

A Quarterly Newsletter for Friends of the Institute for In Vitro Sciences



## Spotlight On Ingredients In Vitro Alternatives Forum

### BITS & PIECES

Rodger Curren to present Advantages and Difficulties in using 3-Dimensional Human Skin Models in Toxicology and Efficacy Studies at Linz 2008

Prof. Ian Kimber appointed as the chair of the Board of the UK's NC3R's [www.nc3rs.org.uk](http://www.nc3rs.org.uk)

### UPCOMING MEETINGS

Linz 2008  
15th Congress on Alternatives to Animal Testing  
19-21 Sept. 2008  
Linz, Austria  
[www.zet.or.at](http://www.zet.or.at)

15th International Congress on In Vitro Toxicology  
25 -28 September  
Stockholm, Sweden  
[www.estiv2008.org](http://www.estiv2008.org)

TestSmart DNT2 Developmental Neurotoxicity  
12 -14 November  
Reston, VA  
[www.caat.jhsph.edu](http://www.caat.jhsph.edu)

Learn more at [www.iivs.org](http://www.iivs.org)

## A Meeting to Address Issues of the 7th Amendment & REACH

In a changing international regulatory landscape the need for *in vitro* testing is on the rise. The requirements in the European Union's 7th Amendment to the Cosmetics Directive demand that selected safety data for cosmetic ingredients are generated using only non-animal methods. In addition, the European chemical regulation REACH will rely heavily on non-animal methods to determine the hazards associated with new and existing chemicals.

IIVS has partnered with the Alternatives Research & Development Foundation (ARDF) and Chemical Heritage Foundation (CHF) to organize **Spotlight on Ingredients**, a forum devoted to the application of *in vitro* methods to chemical ingredients. The meeting will give practical information on the requirements of the non-animal testing bans, activities by international organizations (e.g. ECVAM, COLIPA) to meet these requirements, testing strategies and how non-animal data can be used in risk assessment. The one-and-a-half day program will also offer a perspective from product formulators on what other useful data can be generated, and how suppliers and manufacturers can work together to build effective programs.

Speakers Include: Jon Anderson, Actives International; Daniel Bagley, Colgate-Palmolive; Frank Gerberick, The Procter & Gamble Company; Laura Gribaldo, ECVAM; Thomas Hartung, University of Konstanz and EU Joint Research Center; Jon Lalko, RIFM; Manfred Liebsch, ZEBET; Pauline McNamee, COLIPA and The Procter & Gamble Company; Vera Rogiers, EU Scientific Committee on Consumer Products; William Stokes, ICCVAM/ NIEHS

We invite you to join us in historic Philadelphia, PA on October 23 & 24, 2008 to learn more about the science of *in vitro* testing and how these methods can help you meet the challenges of new international requirements. To view the program, registration details and information on the extraordinary venues for the event, please visit [www.spotlightoningredients.com](http://www.spotlightoningredients.com).

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Institute for In Vitro Sciences, Inc.

## Workshop on the Use of Histopathology for In Vitro BCOP Eye Irritation Studies

June 19-20, 2008  
Sponsored by IIVS and ARDF

IIVS has been the leader in using histology to expand the usefulness of the Bovine Cornea Opacity and Permeability (BCOP) assay for more than ten years. We have found that some eye irritants are not easily detected with the traditional BCOP endpoints of opacity and permeability. However the damage they cause can often be visualized using histopathology. IIVS has shared our findings through posters and presentations at various scientific meetings, and the importance of this approach has recently been recognized during the ICCVAM review of *in vitro* eye irritation assays. Their recommendation for future BCOP assay optimization was to "conduct histopathological evaluation of the corneal tissue, using a standardized scoring scheme."

IIVS responded to this opportunity by organizing a Workshop on the Use of Histopathology in *In Vitro* BCOP Eye Irritation Studies. It brought together five veterinary pathologists knowledgeable in ocular lesions, along with experienced users of the BCOP assay, eye irritation researchers, and representatives from ICCVAM and NICEATM. The basis for much of the discussion was a BCOP histopathology operations manual originated by Dr. John Harbell (now of MaryKay Corporation) describing corneal preparation procedures, and documenting with photos many corneal histology changes induced by various classes of chemicals.

The workshop participants concluded that BCOP histopathology is an important addition for many product safety investigations, and can provide depth of injury information useful in determining regulatory hazard classifications. In addition, the participating pathologists volunteered to create a formal Pathology Working Group (PWG) which would agree on the appropriate nomenclature for BCOP corneal lesions, and suggest an acceptable reporting format for BCOP eye irritation histopathology.

A jointly-authored manuscript with the conclusions from the workshop will be submitted to a peer-reviewed journal and directly to ICCVAM as part of our mission to advance the use of alternative methods.



## BASF and Transinsight collaborate on Semantic Based Search Site: Go3R

BASF and Transinsight, a provider of semantic search technologies, have agreed to collaborate closely in the area of semantic analysis to search for alternatives to animal testing. Together with the German Federal Institute for Risk Assessment, the companies will expand the first specialized semantic search engine for alternatives into a research area to become a global internet platform. In the future, experts from all over the world will be able to use this platform to bring together their knowledge on alternative and supplementary methods to animal testing. Transinsight's semantic search engine finds related terms and web pages that are relevant for the respective search term and thus provides considerably more accurate and comprehensive search results than conventional full text search engines. The Go3R platform is available online at [www.Go3R.org](http://www.Go3R.org) and is free of charge.

## New Statistical Analysis of Animals Used in Testing is Published

A new analysis published in the August issue of ATLA estimates that 115 million animals are used in laboratory experiments around the world each year. Authors from the Dr Hadwen Trust for Humane Research and the British Union for the Abolition of Vivisection (BUAV) express grave concern over the way in which animal use figures are compiled in different countries. Despite widespread public and political interest in animal research worldwide, the authors state that only 21% of countries actually collect data on their national animal experiments. Furthermore, the authors cite that for those countries that do record statistics there are unacceptable omissions such as the number of animals used for tissue samples. To view the paper in its entirety please visit [www.iivs.org](http://www.iivs.org) and click on What's New.

SAVE THE DATE

## 2008 Alternatives Forum: Spotlight on Ingredients

Thursday and Friday October 23-24, 2008  
Chemical Heritage Foundation, Philadelphia, PA, USA  
[www.spotlightoningredients.org](http://www.spotlightoningredients.org)

# IIVS Annual Training Course Continues to Benefit Industry

Combination of lectures and hands-on training receives high praise

Representatives from 10 organizations from around the globe came together in June to attend IIVS' annual Practical Methods for *In Vitro* Toxicology Course held in June at IIVS. Our spacious new facility made the lecture and laboratory portions of the course more enjoyable for the attendees. This year presentations were given by Dr. Michael Orr (FDA), Dr. Sorin Damian (Lonza/BioWhittaker), Dr. Stewart Jacobson (Charles River Laboratories), Dr. Robert Bronaugh (FDA), and IIVS staff on a range of topics including *in vitro* ocular, dermal and cytotoxicity assays, pigmentation, new molecular tools, hepatocytes, and the political climate which affects the regulation of *in vitro* assays. IIVS would like to invite those individuals who have not had the opportunity to attend the course in the past to join us in June 2009 for the next Practical Methods Course. Please contact Amanda Ulrey at [aulrey@iivs.org](mailto:aulrey@iivs.org) for additional information, and visit our website this fall for the announcement of the 2009 course date and agenda.



IIVS Scientists Demonstrate the Bovine Corneal Opacity and Permeability Assay at the 2008 Practical Methods Course

## June Bradlaw Memorial

June Bradlaw, Ph.D, longtime advocate for *in vitro* methods and a member of the IIVS Scientific Advisory Panel since its inception, passed away on 30 May 2008 while at her home in Connecticut, USA. Dr. Bradlaw spent the majority of her scientific career with the US Food and Drug Administration where she was active in several *in vitro* areas including *In Vitro* Toxicology, Genetic Toxicology, Cell and Tissue Culture practices, and standardization of cells used in Tissue Engineered Products. June was always a strong advocate for *in vitro* toxicology; not only during her long tenure at the FDA (much of which was during a period when *in vitro* methods were not commonly embraced), but also in her "retirement" as she continued to tirelessly support *in vitro* methods with scientists and the general public around the world.

One of her most important accomplishments was helping to organize and co-chair the 1993 IRAG workshop on alternatives to the Draize eye irritation test. For the first time, scientists from laboratories throughout the world came together to share data on the performance of over 30 *in vitro* methods to detect eye irritants. It was at this meeting that many researchers began to understand not only *in vitro* methods, but also the often lack-luster performance of the Draize test itself. It was a revelation to many that the "gold-standard" animal eye test might not be as shiny as once thought. June continued to put in long hours after the workshop to ensure that all the data were put into assay-specific manuscripts and then published in a single issue of Food and Chemical Toxicology - a reference that is still used today. We will all miss her dedication and perseverance.

## IIVS Update

### 2008 IIVS Science Advisory Panel

Marilyn Aardema  
Procter & Gamble

Daniel Bagley  
Colgate-Palmolive

Joel Burdick  
Beauty Avenues

Robert Priston  
Kimberly-Clark

Sheldon Sloan  
Johnson & Johnson

Usha Vedula  
S.C. Johnson & Son

#### Invited Members

Michael Balls  
FRAME

Manfred Liebsch  
ZEBET

Martin Stephens  
HSUS

Representative from ECVAM

Representative from ICCVAM

### Corporate Contributors

Alberto Culver

ARDF

Beauty Avenues

Clorox

Colgate-Palmolive

The Dial Corporation

Johnson & Johnson

Kimberly-Clark

Mary Kay

Peta

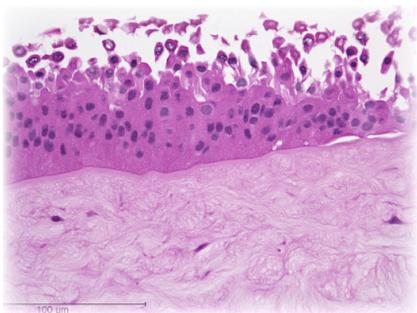
Procter & Gamble

POM Wonderful

Unilever

# BCOP Histopathology Workshop

This workshop, part of the IIVS Education and Outreach program, was co-sponsored by the Alternatives Research & Development Foundation (ARDF). We thank them for their understanding of the importance of this workshop for the advancement of alternative methods.



Bovine corneal epithelium damaged by exposure to SLS

We thank the following individuals for their valuable contributions towards the success of the Workshop.

Dan Cerven, M.S., MB Research Laboratories  
Mark Cesta, DVM, DACVP, NIEHS  
Rodger Curren, Ph.D., IIVS  
Henry Edelhauser, Ph.D., Emory University Eye Center  
Mark Evans, DVM, Ph.D., DACVP, Pfizer Inc.  
John Harbell, Ph.D., MaryKay Corporation  
Stewart Jacobson, DVM, DACVP, Charles River Laboratories  
James Jester, Ph.D., University of California-Irvine  
Elizabeth A. Lipscomb, Ph.D., ILS, Inc.  
Jill Merrill, Ph.D., FDA  
Jennifer R. Nash, M.S., IIVS  
Hans A. Raabe, M.S., IIVS  
Ken Schafer, DVM, Ph.D., DACVP, Vet Path Services, Inc.



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**Join us at the 2008 Alternatives Forum: Spotlight on Ingredients.  
Details inside!**