

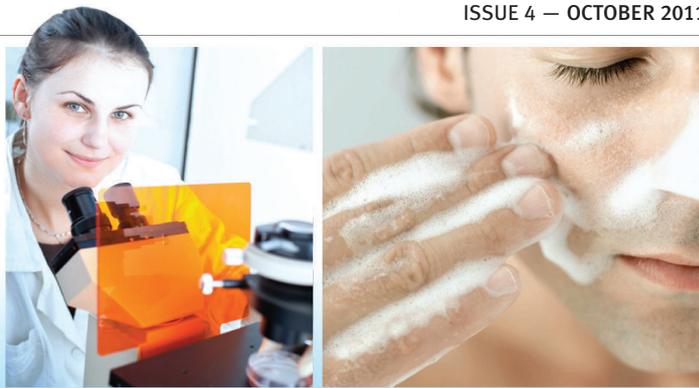


COSMETICS EUROPE: NEWS ON ALTERNATIVES

OCTOBER 2011

News on Alternatives

NEWS ON THE DEVELOPMENT OF ALTERNATIVE APPROACHES TO ANIMAL TESTING



Working towards alternatives to animal testing



Bertil Heerink
Director-General, Colipa

Welcome to the latest edition of the Colipa Alternatives newsletter.

This newsletter is a valuable way of informing decision-makers, civil society and the public about the latest developments led by the cosmetics and personal care products industry.

This latest issue focuses on international efforts to develop alternatives to animal testing, and in particular on the outcomes of the 8th World Congress on Alternatives and Animal Use in the Life Sciences. The Congress – also known as WC8 – was held in Montreal in August 2011. It highlighted the great progress that is being made in finding alternatives to animal testing.

As well as providing a general update on the WC8, this newsletter will look in particular at progress in the areas of eye irritation, skin sensitisation and genotoxicity testing. In these areas, as elsewhere, the cosmetics and personal care products industry continues to

support scientists and researchers and to facilitate collaboration in order to make as much progress on alternatives as possible, as fast as possible.

We are also working closely with regulatory authorities and other industry associations in order to advance research into alternatives. In this newsletter, we highlight our contribution to the SEURAT initiative, a €50m project that we are co-funding and working on with the European Commission.

We hope you enjoy reading the newsletter!

The 8th World Congress on Alternatives and Animal Use in the Life Sciences (WC8)

'The Three Rs – Together It's Possible'

Launched in 1993, the World Congress on Alternatives and Animal Use in the Life Sciences has become a key forum for leading scientists and members of the global animal welfare community to discuss how to advance the replacement, reduction and refinement of animal studies (known as the '3Rs').

This year, the World Congress was held in Montreal, Canada. It attracted 850 participants from more than 50 countries. The theme of the 8th World Congress (WC8) was 'The Three Rs – Together It's Possible', and its aim was to build on current achievements by bridging the gap between science and policy and identifying further opportunities for collaboration. The presentations and workshops addressed developments and challenges regarding scientific breakthroughs, regulatory risk assessment and animal welfare around the world.



Colipa representatives attended the WC8 and heard reports of significant progress in the development of alternatives to animal testing, as well as works of extensive collaboration. Here's what they found...

Eye irritation

Reconstructed human tissue (RHT) that replicates the cornea in the human eye is a key breakthrough in the development of alternatives to animal tests for eye irritation. Colipa's Eye Irritation Task Force is contributing to the development of these *in vitro* testing methods (laboratory-based, test-tube experiments) by leading integrated research projects. A prospective validation study of two *in vitro* test methods for the detection of eye irritation effects by chemicals (EpiOcular™ and SkinEthic™) is currently being conducted by ECVAM (European Centre for the Validation of Alternative Methods) and Colipa.

Pauline McNamee, who chairs Colipa's Eye Irritation Task Force, said that the development and optimisation process is, "providing promising results, in particular through application of better understanding of eye injury and recovery and what drives eye irritation". This work is contributing to the 'toolbox' of methods that will be able to be used in combination. As Pauline explains, "Such a combination of methods is necessary because all *in vitro* tests have strengths and limitations, and cannot be applied universally. We are working to develop an effective combination of different tests to predict reliably different levels of irritation for different types of chemical".

Pauline adds that, "we recognise the need for external acceptance of these methods and

their use in testing strategies, which is why we work so closely with external validation organisations, such as ECVAM".

Skin sensitisation

Skin sensitisation – an allergic reaction to a chemical, which worsens with subsequent exposure – is another complex area for the development of alternatives. This is one of the reasons why, at WC8, Colipa supported a session on the 'Three Rs approach to Skin Sensitisation'.

As Gavin Maxwell, Chair of Colipa's Task Force on Skin Sensitisation, points out, much progress has been made, but it is not as simple as replacing one animal test with one *in vitro* test, "A smart *in vitro* 'toolbox' is required that will allow us to have several tests to address individual elements of skin sensitisation".

Colipa participates in international research efforts to explore the processes that cause skin sensitisation and the development of new *in vitro* tests and computer modelling ('*in silico*' tests). Gavin notes that, "Success will come eventually in this regard, and hazard identification may even be possible within years. But, unfortunately, it will still take many more years until a safety assessment of a chemical ingredient will be achievable with the new toolbox".

Colipa also supported a session on Toxicity Testing Strategies, at which five companies

presented their current approaches to non-animal skin sensitisation safety assessment. Gavin added that, "The cosmetics industry currently applies a range of approaches to reduce the need for animal test data to support skin sensitisation safety assessments. Such approaches are enriched by the integration of data obtained through *in vitro* test methods".

Genotoxicity testing

In vitro testing is a long-established and well-accepted practice in genotoxicity

testing. However, as Stefan Pfuhrer, Chair of Colipa's Genotoxicity Testing Task Force points out, "Very often these tests 'over-predict' - classing substances as potential carcinogens, producing 'false positive' results". Stefan went on to explain that in the past this would have triggered follow-up animal tests, but this is no longer a possibility for cosmetic ingredients.

Colipa is making substantial efforts on several projects to improve the current *in vitro* testing and avoid such 'false positive' findings, or to find new and more reliable

in vitro test methods to follow-up. "So far some promising results have come out of this", he states, "but we cannot say that a true alternative to animal tests exists just yet".

One promising development is the pre-validation by ECVAM of the 'Cell Transformation assay', which was presented at the WC8 and which could lead to better results and fewer 'false positive' findings for genotoxicity testing.

Three questions for Dr Horst Wenck



Dr Horst Wenck
Chair of Colipa's Strategic
Project Team on Alternatives

The 8th World Congress showed good progress in the development of alternatives. What obstacles remain?

"WC8 provides an important meeting place for a range of stakeholders to discuss progress on testing without animals. It is clear that Colipa has made significant progress in developing and evaluating new alternative models, and we are proud that our industry has led the way in developing alternatives to regulatory toxicology. We remain, of course, committed to phasing out animal testing as soon as it is scientifically possible – however, there are some significant hurdles remaining. Basic

knowledge – such as the causes of how cancer develops – is still lacking, and so it is extremely difficult to develop alternatives without this understanding."

What kind of timeframe are we looking at for the elimination of animal testing for cosmetic ingredients?

"Scientifically speaking, it is clear that it's unclear! For some health effects, we could be looking at around five years; for some, twenty years or more. The European Commission's recent technical report does, in the collective view of the scientific community, constitute an authoritative report that accurately represents the current status of non-animal safety testing, having been written by top scientists in the field of toxicology."

What is the industry doing to speed up this process?

Colipa's efforts include collaboration with the European Commission on the €50m

Framework project on systemic toxicity "SEURAT-1", and substantial other funding for research projects. The cosmetics industry, through Colipa, is spending €37m between 2007 and 2014 on research into alternatives. This is more spending on regulatory toxicology than any other sector, producing notable success. Scientifically that's all that can be done, with science having received all conceivable funding required to achieve our goals as fast as possible. The development of alternative methods requires new scientific knowledge, which often involves time-consuming scientific research as well as cooperation among many groups. The industry continues to work towards its goal of replacing animal testing by investing not only money, but also a lot of expertise and manpower in partnership with other sectors, governments and organisations."

SEURAT – Colipa and the European Commission working together



Michael Schwarz
University of Tuebingen,
co-author of first Annual
Report on Seurat-1

SEURAT-1 is a joint research initiative launched by the European Commission's FP7 HEALTH theme and Colipa as the first phase of a long term research initiative aimed at "Safety Evaluation Ultimately Replacing Animal Testing" ("SEURAT"). It brings together almost 100 scientists from over 70 European organisations in a €50 million research and innovation project cluster on novel human safety testing solutions on repeated dose toxicity testing. SEURAT-1 is co-funded by the European Commission's FP7 HEALTH theme and Colipa.

Michael Schwarz from the University of Tuebingen and co-author of the first Annual Report on SEURAT-1 highlighted the launch of the research initiative's first execution phase, which began on 1 January 2011, and which is destined to run for five years. He said that, "SEURAT-1 will develop knowledge and technology that will ultimately allow us to create solutions for the replacement of current repeated-dose systemic toxicity testing on animals".

Michael added, "SEURAT-1 comprises a cluster of five complementary research projects, a data handling and servicing project, and a coordination action. The aim of the cluster is to show how the latest scientific tools and know-how can be combined to deliver better safety assessment".

"The overall aim of SEURAT is to fundamentally change the way we assess the safety of chemicals, going beyond traditional animal experiments to create a predictive toxicology based on a comprehensive understanding of how chemicals can cause adverse effects in humans. We are hopeful that there will be positive results!"

The book, 'Towards the Replacement of *in vivo* repeated Dose Systemic Toxicity Testing', has been made available for downloading on www.seurat-1.eu as the Seurat-1 Annual Report.



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More information about alternatives can be found on our website: www.colipa.eu

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