



Introduction by Bertil Heerink, Director-General, Colipa



On behalf of all the member companies and associations of Colipa, I would like to invite you to read the first issue of our twice-yearly update on alternatives to animal testing.

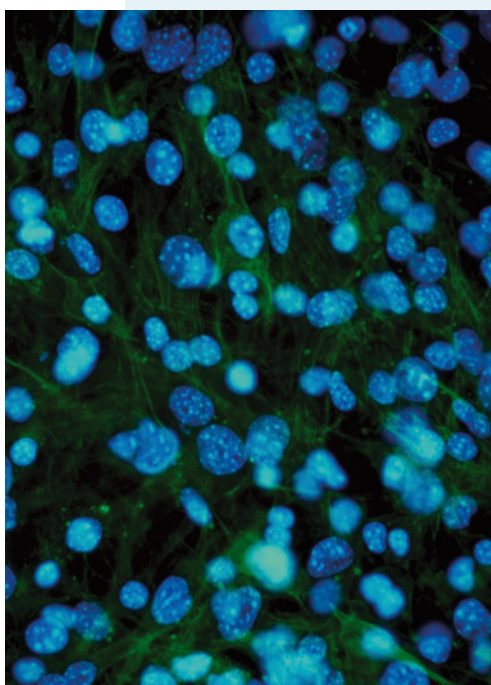
The cosmetics industry has been working hard for many years to replace animal testing for cosmetic ingredients. Alternative methods need to be found which ensure the same rigorous safety standards that our industry has always applied. The industry plays a leading role in research into alternative methods and indeed we have been pioneers in research into replacement methods globally.

The full replacement of animal testing can only be achieved by working together in cooperation with all stakeholders, other sectors and partners. Colipa cooperates with partners, academia and regulatory bodies on both a European and an international scale. In Europe, the industry cooperates with the European Commission through DG Enterprise and DG Research, the Joint Research Centre, the SCCS (European Commission's Scientific Committee on Consumer Safety) and ECVAM (European Centre for the Validation of Alternative Methods). Colipa has been working within the EPAA (The European Partnership for Alternative Approaches to Animal Testing) since it was launched in 2005.

It is clear that developing alternative methods for safety testing is a tremendous scientific challenge. Colipa is committed to achieving the best possible results. Working together will help us to achieve our aim.

The latest information on developments in particular areas will be communicated to you via this newsletter twice a year. Given that the testing and partial marketing ban for cosmetic ingredients enters into force this month, this edition focuses on alternatives that are most relevant to this deadline, namely the areas of eye irritation, skin irritation and genotoxicity. I hope that you find this regular update useful and would invite you to contact us for any further information. ■

Skin Irritation – Validation of HRT



The cosmetics industry is in a position to be able to confidently evaluate new and existing ingredients for their potential skin irritancy using only alternative methods. Indeed, for several years, the cosmetics industry has been using *in vitro* models to detect skin irritants as an alternative to the rabbit skin irritation test.

The cosmetics industry developed a method using a skin model for skin irritation as a stand alone method. This was subsequently validated by ECVAM in April 2007. Two other models have now also been demonstrated as equivalents.

There are now three validated methods for testing skin irritation. These are Episkin™, Epiderm™ and SkinEthic™. ■

Eye Irritation

For many years, the cosmetics industry has been working hard to replace the Draize test for evaluation of eye irritation potential of ingredients. Extensive research has been undertaken in this area.

Although several assays have been developed, some of which have undergone formal validation, today no single method has been formally validated as a stand-alone replacement for the Draize test. However, it is clear that the progress made so far is a significant step forward in the search for alternative methods and strategies.

Several other *in vitro* models have been used by the cosmetics industry for over a decade as screening and safety assessment tools. >>>

>>> Organotypic assays are now accepted, for specific and limited regulatory purposes. The use of combinations of assays has a good potential to provide information about the whole range of irritancy (from non-irritant to severe) for different chemical classes.

Industry is therefore using a combination of regulatory-accepted and non-validated assays, together with other available information, in order to come closer to reaching full replacement approaches. Several extensive validation activities are on-going, in order to provide the necessary data and review to regulatory bodies for future acceptance. ■

“Working together to replace animal testing”



Working together to replace animal testing - the latest brochure published by Colipa which presents the Association's work on the development of alternative approaches to animal testing in the cosmetics industry.



Genotoxicity

Nowadays, genotoxicity assessment is often conducted or completed using read-across data, *in silico* and/or *in vitro* data as well as a Threshold-of-Toxicological-Concern approach when appropriate.

There are many validated and routinely used *in vitro* mutagenicity and genotoxicity assays. However, these assays can generate false positive results, which could put an unnecessary end to the use of existing ingredients. More predictive *in vitro* methods are therefore needed as full replacements for the traditional confirmatory *in vivo* tests in the light of the 7th Amendment to the EU Cosmetics Directive.

Colipa is working with external partners, including academics and ECVAM, to increase the specificity of current standard *in vitro* genetic toxicology models, and to develop new *in vitro* assays with higher relevance to human exposure. One is also to develop genotoxicity assays based on 3D skin models. The knowledge generated by this task force will be applied to support the use of *in vitro* assays as replacements for animal experiments and to generate test data with higher relevance for dermal exposure. ■



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In the next edition:

- Systemic toxicity – working in partnership with the European Commission
- Skin allergy – three methods submitted by Colipa
- Eye irritation - outcome of the Eye Irritation Workshop for validation studies

“News on alternatives” is issued twice a year by Colipa in order to deliver recent news on the development of Alternative Approaches to Animal Testing.