Alternatives to Animal Testing: A Regulatory Update of the State of the Art in the EU

Dr Raniero De Stasio

Former Chairman of the Colipa Project Team Communications on Alternatives

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The EU 7th Amendment prohibits:
- the performance of animal tests in the EU to meet the requirements of the Cosmetics Directive...
- the sale of cosmetics products, when the final formulation or ingredients have been tested on animals to meet the requirements of the Cosmetics Directive...

A Marketing ban for products or ingredients tested on animals for local and/or acute effects evaluation.

A New EU Regulatory Context...
Science and Cosmetics Business

- **Products and safety assessment**: responsibility with the manufacturer, open choice of data/methods consistent with the 7th Amendment

- **Ingredients regulated** by the Cosmetics Directive: *need* for EU scientifically validated and accepted replacement methods by regulatory authorities or the Scientific Committee for Consumer Safety (SCCS, previously SCCP)

- **Other ingredients**: data/methods consistent with REACh & the 7th Amendment
SAFETY ASSESSMENT

- Evaluation – Human exposure
- Presentation
- Mode of Use
- Post Marketing Safety Experience (Actual / Similar Formulation)
- Confirmatory safety Information
- General Toxicological Profile (all available sources of information)
- Analytical Profile
- Chemical Structure

- Safety Assessment: Ingredients or Combination of Ingredients

- QSAR / In silico
- In vitro studies
- Animal studies (file data)
- Clinical studies
- Human epidemiology
Safety assessment

Many in vitro methods are available and COLIPA has prepared a scientific review … however …

Eye irritation is complex and there will be a need for several methods to achieve full replacement expected by 2010

EU Validation under way (ECVAM)
- 2008/2009 : 2 Human corneal models submitted by COLIPA in December will soon start validation after optimisation and development of an extensive data base
- 2009/2010 : evaluation of 8 existing methods with industry data

Research
- COLIPA is sponsoring research to include mechanistic endpoints which could improve predictivity of existing methods
Safety assessment: methods are available and COLIPA has prepared a scientific review

EU Validation (ECVAM):
For skin irritation industry validated replacement methods developed in part by COLIPA companies. The Episkin method was validated as a stand alone in 2007 and the SkinEthic one in 2008.

Further regulatory acceptance:
The validated methods are now under discussion at SCCS and OECD levels.
Acute toxicity is a very complex test to replace, and when it is needed, information is obtained from animal studies. More research is needed.

EU Validation (ECVAM) :
Methods aiming at reduction are under pre-validation, results will become available from 2010 onwards.
Safety assessment: Methods are available and COLIPA has prepared a scientific review.

For genotoxicity, non animal tests exist and industry teams are working to improve their predictive capacity.

The COLIPA research programme is already making significant improvements to existing assays, that will result in fewer chemicals being rejected. These improvements are anticipated to continue up to the deadline and beyond.

New COLIPA tests, using reconstructed 3D human skin models, are shaping up to be effective tools.

COLIPA efforts are shared with scientists and regulators (SCCS).
The Commission will

– assess the progress made and the difficulties to meet the bans.

– make a legislative proposal to the Council and the Parliament
COLIPA aims to provide:

- a first generation integrated testing strategy capable of providing skin allergy information, based on validated in vitro tests developed by COLIPA companies. 3 methods been submitted by Colipa this year.

- Cutting-edge research aimed at delivering second generation methods more predictive and more applicable by 2013

- The COLIPA Programme goal is to progress the most scientifically advanced and comprehensive research in the field of replacement
With the support of the International Cosmetics Companies CEOs, COLIPA has proposed a joint collaboration with the European Commission for the co-funding of systemic toxicity research for a total of 50Mios€.

This new initiative has been officially announced by Commissioner Potocnik at the opening of the Annual Conference of the European Partnership for Alternative Approaches (EPAA).

Contracts are currently being finalized, the Joint Expert Group set up by the Commission with the help of Colipa has started its work ie preparing the specific call for tender which will be launched in 2009.

This will contribute to move forward effectively in this area of science.
Conclusions

1. The Cosmetics & Personal Care Industry is involved in the development of alternatives to animal testing since the early 80s. We have boosted our efforts in alternative strategies to achieve the best possible results vs. the specific goals set by the March 2009 deadline.

Innovation for cosmetics & personal care products will continue and, at the same time, their safety will be ensured and the 2009 European deadline will be adhered to by our industry.
2. Science is a continuous process. We will face very significant challenges to meet the 2013 goals. At this stage it is recognized by the scientific community and the regulatory authorities as well that some important toxicological end points will not be met.

Some research projects are already well under way whilst others are about to start. A progress review is set by the 7th amendment in 2011.
3. The cosmetics and personal care products industry will not lower their efforts in researching alternatives in spite of deadlines and difficulties encountered. We are fully committed to answer in the best possible way the societal and ethical demands.

4. We are and we will continue to be proactive ambassadors of these moral values at the international level.