



## EUROPEAN COMMISSION - PRESS RELEASE

# Commission reports on Progress in the Development of Alternative Methods to Animal Testing for Cosmetics

Brussels, 13 September 2011 - The European Commission presented today its yearly report on Alternative Methods to Animal Tests in the Field of Cosmetics to the European Parliament and Council. The Cosmetics Directive<sup>1</sup> prohibits animal testing in the EU of finished cosmetic products since 2004, animal testing of ingredients of cosmetic products is prohibited since 2009. A marketing ban is also in place which prohibits selling in the EU cosmetic products containing ingredients which have been tested on animals irrespective of the place of the testing after March 2009. For many of the tests needed to ensure the safety of cosmetic products alternative methods are developed and validated by now. However, work continues to close the remaining gap for the small number of the most complex effects<sup>2</sup> on health for which the marketing ban deadline comes into force in March 2013.

The report published today stresses the **continued commitment in Europe and worldwide to find alternative approaches**. Despite this commitment and progress in research finding alternative methods for testing these **remaining complex endpoints will not be possible by the 2013 deadline** according to the Commission's report. The report is based on the findings of scientific experts who have been assessing the availability of alternative methods and prospects for the future. While full replacement is not possible, there is potential for partial replacement strategies and developing a 'toolbox' of test methods to be improved until the goal can be reached. The lack of full alternatives does not mean that the Commission will propose postponing the deadline. Instead, the Commission is currently assessing the impact of the entry into force of the ban in 2013 without alternatives and will decide on next steps on the basis of the full impact assessment.

Health and Consumer Commissioner, John Dalli said *"Over the last 20 years more than 200 million euros has been dedicated to research in this area in the EU and the commitment to finding alternatives to animal testing continues both in Europe and worldwide. This research and development has not only reduced the number of animals used in testing, it is at the same time yielding important results in terms of better science to the benefit of consumer safety."*

<sup>1</sup> The Cosmetics Directive 76/768/EEC establishes the European regulatory framework for the placing on the market of cosmetic products and foresees a phasing out of animal testing for these products.

<sup>2</sup> repeated-dose toxicity (including skin sensitisation and carcinogenicity), reproductive toxicity and toxicokinetics

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## **What efforts have been made to find alternatives?**

Considerable amounts of funding have been spent to find and validate new alternative tests. Over the **last 20 years the EU contribution to research on alternatives amounts to some 200 million Euro**; under the 7<sup>th</sup> Framework Programme more than 65 million Euro have been so far committed to the funding of alternative methods.

The Commission's Joint Research Centre is putting a lot of efforts into the validation of alternative methods, through its Centre for the Validation of Alternative Methods (ECVAM), hosted by the JRC's Institute for Health and Consumer Protection. Moreover, in order to promote synergies between different sectors concerning the development of alternative methods, the European Partnership for Alternative Approaches to Animal Testing (EPAA) was created in 2005. It is a joint initiative of the European Commission, industry and trade federations. The Partnership's work focuses on mapping existing research, developing new alternative approaches and strategies, and promoting communication, education, validation and acceptance of alternative approaches.

At international level, the Commission promotes intensified cooperation to facilitate the development and the validation of alternative methods and their recognition by our main partners. A framework of cooperation has been established between the US, Japan and Canada, in a regulatory dialogue called "International Cooperation on Cosmetic Regulation" (ICCR), which led to the International Cooperation on Alternative Test Methods (ICATM).

## **What progress has been made?**

Validated alternative methods are available for the identification of corrosive substances, skin irritants and severe eye irritants, skin phototoxicity and skin penetration as well as to assess genotoxicity. Significant advances have been made in reducing the number of animals used in tests, for example in relation to acute toxicity.

In relation to the complex endpoints of repeated-dose toxicity (including skin sensitisation and carcinogenicity), reproductive toxicity and toxicokinetics, the understanding of toxicological processes in the human body has improved significantly over the last decade and continues to do so at an accelerating rate. Advanced methods and approaches hold a lot of promise for the future development of more predictive risk assessment, based on improved understanding of how toxic substances reach the target cells/organs (toxicokinetics) and perturb critical biological pathways. Many alternative methods are under development and there is potential for partial replacement strategies.

## **What next ?**

The European Commission is currently **assessing the impacts of the implementation of the full marketing ban by 2013** (environmental, animal welfare, economic and social) and on the basis of that assessment will decide whether or not to make a proposal in relation to the marketing ban. The Commission will announce its final decision by the end of 2011.