
This document highlights the most important findings of a panel of scientific experts tasked with assessing the availability of alternative methods to animal testing in view of the full marketing ban foreseen in Europe in 2013 for cosmetic ingredients tested on animals. The experts concluded that considerable scientific challenges have to be overcome before a full replacement of animal tests will be possible. Whereas substantial progress has been made over the past years, they predict that, for five specific areas, alternative methods to fully replace animal tests will not be available by 2013. However, the experts noted that significant contributions to reduce, refine and partially replace animal testing have been made and are feasible before full substitution is possible.

Context

The Cosmetics Directive 76/768/EEC, which establishes the European regulatory framework for the placing on the market of cosmetic products, foresees a phasing-out of animal testing for these products. A ban on animal testing of finished cosmetic products has been in force since September 2004 and a testing ban on ingredients or combinations of ingredients since March 2009. As from March 2009, it is also prohibited in the EU to market cosmetic products and their ingredients which have been tested on animals, irrespective of the origin of these products. The latter applies to all but the most complex human health effects to be tested to demonstrate the safety of cosmetic products (these being repeated-dose toxicity, including skin sensitisation and carcinogenicity, reproductive toxicity and toxicokinetics), for which the deadline is extended to March 2013.

This year (2011), the European Commission will review the situation regarding the technical difficulties in complying with the 2013 ban and inform the European Parliament and the Council, proposing measures to be taken if necessary. In 2010, the Commission appointed a panel of experts to report on the current status and future prospects of alternative (non-animal) methods for cosmetics testing, and to provide realistic estimates of the time required for the development of alternative methods where not already existing. The resulting expert panel report underwent a period of public consultation prior to its finalisation. The European Centre for the Validation of Alternative Methods (ECVAM), hosted by the Institute for Health and Consumer Protection of the European Commission's Joint Research Centre, coordinated the whole review activity on behalf of the Commission's Directorate General for Health and Consumers.

Current status of alternative methods (2010)

Whereas the experts noted that significant advances have been made in reducing the number of animals used in tests via the use of in vitro tests and computer-based
modeling alongside animal tests, they concluded that considerable scientific challenges have still to be overcome before a full replacement of animal tests is possible. Notwithstanding the substantial progress made over the past years, the report predicts that, for the five specific areas identified, full replacement alternative testing methods will not be available by 2013.

More particularly:

- No specific timeline could be estimated in the areas of toxicokinetics, repeated dose toxicity, carcinogenicity and reproductive toxicity due to the underlying scientific challenges.

- The timelines estimated for full replacement of animal tests in the area of skin sensitisation point to a further 7-9 years (i.e. 2017-2019), including the possibility to differentiate weaker from stronger sensitisers. Alternative methods able to simply discriminate between skin sensitisers and non-sensitisers might become available earlier.

In this regard, the forecasts for the full availability of alternative test methods do not diverge much from estimates provided in a similar review already conducted by the Commission in 2005.

Future prospects

The present report underlines the continuous effort both in Europe and worldwide to find alternative approaches that avoid testing on animals wherever possible. As a result of this effort, 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. International cooperation and collaboration has never been as extensive in this field as now and shared access to an increasing amount of data and tools will allow a new generation of test methods and integrated test systems to emerge. The descriptions of both in vitro and computational models in the tables and accompanying texts of the full report illustrate the many alternative methods under current development. The central importance of toxicokinetics is underlined.

The report highlights that the current momentum for developing alternative methods and testing strategies should be maintained. Research and development activities in the field of non-animal testing, both in the public sector (European framework programmes and national research programmes) and industry, have already yielded many promising methods and approaches, and these activities should be further stimulated and encouraged. Moreover, there still remains the need for the validation of these future methods as well as the need for gaining regulatory acceptance at a global level.

Although the goal of complete replacement of animal tests remains elusive in the short- to mid-term, this should not eclipse the progress being made both in the refinement and the reduction of animal tests to reduce the suffering to and number of animals used. While full replacement is not yet accomplished or possible by 2013, the report argues that there is a potential for partial replacement strategies. In the short- to mid-term, providing a combined "toolbox" of well-defined test methods with established reliability and relevance for particular purposes, (for example, clearly addressing well-defined mechanisms of toxicity), could support the development of integrated testing strategies. While each of the methods alone may not be able to generate all required information, their combination might provide a sufficient basis for an integrated safety assessment with the ultimate aim of completely replacing animal testing.

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