



EUROPEAN COMMISSION

MEMO

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Questions and Answers: Animal testing and cosmetics

Cosmetic products range from everyday hygiene products, such as soap, shampoo, deodorant and toothpaste to luxury beauty items including perfumes and decorative cosmetics. These products are regulated at European level¹ in order to ensure consumer safety and to secure an internal market for cosmetic products.

The European Cosmetics and Toiletries industry is worth more than **EUR 70 billion**; this represents almost half of the global market for cosmetics. An estimated 184 000 people are directly employed by the cosmetics industry in the Union.

Animal testing for cosmetics is prohibited in the Union since March 2009. Before that 8988 animals were reported to be used for cosmetic purposes in the Union in 2004, a number that was reduced to 1510 animals in 2008 and to 344 animals in 2009. Animals used for testing for cosmetic purposes are rats, mice, guinea-pigs and rabbits. Any animal testing done for EU cosmetic purposes since 2009 is done outside the EU. Between 15000 and 27000 animals are estimated to be used outside the EU for this purpose yearly.

Is animal testing for cosmetics not already prohibited in Europe?

Yes, that is true : there can be **no animal testing for cosmetic purposes carried out in Europe**. Animal testing for finished cosmetic products is already banned since 2004, animal testing for cosmetic ingredients is banned since 11 March 2009 ('testing ban'). Since March 2009 it is also prohibited to market in the Union cosmetic products containing ingredients which have been tested on animals in order to meet the requirements of the Directive ('marketing ban').

But for the most complex tests the marketing ban deadline was extended to 11 March 2013. This means that for these tests companies could still carry out the tests outside the Union for cosmetic purposes and rely on the results for the safety assessment in the Union. This is not possible any more after 11 March 2013.

Why is animal testing carried out for cosmetics anyhow?

It is crucial to make sure that products that come into contact with our body day-by-day are safe for human health. Cosmetics are products that are used by consumers every day – there are estimates that **each consumer uses at least seven different cosmetics per day** and many of us will use more. Animal testing data is still needed to carry out this safety assessment – for example to establish whether or not a certain ingredient can cause skin allergy or contributes to the formation of cancer.

¹ Directive 76/768/EEC to be replaced as of July 2013 by Regulation 1223/2009/EU

So is it possible to fully replace animal testing by other methods?

No, this is not yet possible in all cases. A lot of progress has been made, but there remains a lot to be done. Several alternative test methods have been validated by the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) and have subsequently been included in OECD Testing Guidelines and in the respective Union legal texts. For example, reconstructed human skin models exist to test whether an ingredient can cause skin irritation.

However, for the complex health effects that concern the whole human organism the situation is much more complicated. Important progress has been made here as well and methods have been validated or are undergoing validation that can then be used as building blocks within an overall testing strategy. Replacement will however not be achieved by replacing one animal test with one *in vitro* test and it is difficult to predict when full replacement will be possible². More research is needed.

What is being done to find alternative methods?

The Commission has made about EUR 238 million available between the years 2007 and 2011 for research into alternative methods to animal testing alone. The largest part of this budget, around EUR 198 million, was spent on projects through the 6th and 7th Framework Programmes. The second largest part was spent on the European Reference Laboratory for Alternative Methods to Animal Testing for its work on alternatives. The Communication adopted by the Commission today recognises the importance of continuing this research.

In addition, the cosmetics industry plays an active role in the development of alternatives. A very concrete example is the **SEURAT-1³ initiative** ('Safety Evaluation Ultimately Replacing Animal Testing') in the field of repeated dose toxicity. This project is jointly funded by the European Commission and the cosmetics industry, each of which are contributing a EUR 25 million between 2011 and 2015.

Will cosmetic products remain safe for consumers after March 2013?

Yes, the same safety standards as now apply. The marketing ban does not change the stringent safety assessment required under the Cosmetics legislation, an assessment which was strengthened in the new Cosmetics Regulation.

In cases in which it will not be possible to carry out a conclusive safety assessment because data is missing and because new animal data cannot be created for the purposes of cosmetics use, the respective ingredient should not be used.

Will the cosmetics I am used to disappear from the shelves as a result of the ban?

No, cosmetics on the market and for which the safety is already established are not affected by the ban and can continue to be placed on the market, historic animal data can continue to be relied on.

² See 'Alternative (non-animal) methods for cosmetics testing: current status and future prospects—2010"

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/final_report_at_en.pdf

³ <http://www.seurat-1.eu>

Will there be impacts on the cosmetics and cosmetic ingredients industry?

The Commission carried out an impact assessment⁴ to determine the impacts. It is clear that there will be some impacts on industry, as in certain cases it will not be able to carry out the required safety assessment and thus to use certain ingredients. The impacts, however, were difficult to quantify.

Overall, the Commission considers that the **expected benefits for animal welfare and for innovative ways of carrying out human health assessment are likely to outweigh any negative impacts**. The Commission will however closely monitor the impacts on the industry in the coming years and will continue to fund research into alternative methods and to work internationally towards acceptance of alternative methods in order to mitigate impacts.

With the full ban in place – can consumers be sure that cosmetics and cosmetic ingredients purchased in Europe were not subject to animal testing?

With the testing and marketing ban in force **there can be no new animal testing for cosmetics purposes in the Union** – be it for cosmetics products or ingredients thereof - and **it is no longer possible to simply carry out testing for these purposes outside the Union and then use the data here to substantiate the safety of cosmetics**. Consumers can therefore be sure that the cosmetic use of an ingredient in Europe cannot be the reason for any new animal testing.

However, the majority of ingredients that go into cosmetics are ingredients that are also in use in many other consumer and industrial products, such as in pharmaceuticals, detergents, food, paints etc. They may therefore be subject to animal testing requirements under these respective legal frameworks.

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⁴ The Impact Assessment is available on the SANCO cosmetics website:
http://ec.europa.eu/consumers/sectors/cosmetics/animal-testing/index_en.htm