Cosmetic products: animal experiments (7th amend. to "Cosmetics Directive" 76/768/EEC)

2000/0077(COD) - 13/09/2011 - Follow-up document

In accordance with the requirements of Council Directive 76/768/EEC (Cosmetics Directive), the Commission presents the ninth report on the development, validation and legal acceptance of alternative methods to animal tests in the field of cosmetics. The purpose of the report is to:

- presents the data on the number and type of experiments on animals relating to cosmetic products in 2009, as well as progress made in the development, validation and acceptance of alternative methods to animal testing in the Union and internationally;
- inform the European Parliament and the Council that for technical reasons **full replacement of the animal tests covered by the 2013 deadline will not be achieved** before 11 March 2013.

It is recalled that the Cosmetics Directive requires the Commission to put forward a legislative proposal in accordance with Article 251 of the Treaty if the Commission analysis concludes by 2011 that for technical reasons one or more tests referred to in the Directive will not be developed and validated by 2013. The report does not prejudice the decision on how to address the lack of non-animal tests.

Compliance with the testing and marketing ban: the report notes that the Cosmetics Directive provides for a phasing-out of animal testing for cosmetics. 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. This marketing ban applies to all but the most complex human health effects to be tested to demonstrate the safety of cosmetic products (repeated-dose toxicity including skin sensitisation and carcinogenicity, reproductive toxicity and toxicokinetics), for which the legislator extended the deadline to March 2013.

Animal testing data: given that the testing ban for ingredients applies as of 11 March 2009, testing in line with the Cosmetics Directive was only possible between 1 January 2009 and 10 March 2009. In total, 344 animals were used in 2009 for tests carried out in relation to the safety of cosmetic ingredients. In the previous years, when testing was allowed during the entire period, the figures were 1.818 for 2007 and 1.510 for 2008.

According to the information received, cosmetic ingredients have only been tested on animals in Spain and France. These Member States provided detailed information, including the testing period, the toxicological endpoint, species of animals used for experiments and number of animals used for testing. The other 25 Member States reported that no such animal tests were performed in their territory in 2009.

Progress on alternative methods in the EU: endpoints falling under the 2009 deadline of the marketing ban are: skin corrosivity; skin irritation; dermal absorption; mutagenicity/genotoxicity; phototoxicity; acute toxicity; and eye irritation. .

Full replacement alternative methods are currently available for skin corrosivity, skin irritation, dermal absorption, and phototoxicity, while eye irritation, acute toxicity and mutagenicity/genotoxicity are only covered by partial replacement methods. For these endpoints the marketing and the testing ban apply fully. For mutagenicity/genotoxicity existing methods are being improved. For the two remaining endpoints, “eye irritation” and “acute toxicity”, progress is being made.

Accordingly, the report states that the **overall conclusion and outlook is positive** when looking at the developments since 2003, when the current provisions were introduced. Animal testing for cosmetics purposes in the EU is once and for all a thing of the past. The testing ban is well implemented and controlled.

Regarding the 2013 deadline, validated alternative methods will not be available for any of the three toxicological endpoints before the marketing ban enters into force. Thanks to serious efforts, a number of partial replacement methods are available. However, full replacement does not seem possible yet.