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

2000/0077(COD) - 02/07/2008 - Follow-up document

The Commission presents its 7th report on the development, validation and legal acceptance of alternative methods to animal tests in the field of cosmetics. It reflects the state of play in terms of the number and type of experiments on animals relating to cosmetic products in 2005 and 2006, the current status of alternative replacement methods, and the acceptance and recognition of alternative methods at international level.

The salient points raised in this report are as follows :

Animal Testing Data: 26 Member States supplied information on animal tests carried out for the safety of cosmetic products in 2005 and 2006. Despite several requests, Portugal did not transmit any information. The Commission will consider opening infringement procedure.

According to the information submitted, cosmetic ingredients have only been tested on animals in the territories of France and Romania. These Member States provided detailed information, including the testing period, the toxicological test endpoint, species of animals used for experiments and number of animals used for testing. In total, about 2 276 animals in 2005 and about 1329 animals in 2006 were used in tests carried out in relation to the safety of cosmetic ingredients. The other 24 Member States reported that they did not perform such animal tests in their territory in 2005/2006 or that they cannot provide the information for the reasons explained in this report.

The total number of animals used for testing the safety of cosmetics showed a significant fall compared to the last report (2003: 1618, 2004: 8998). Indeed, the figures for 2006 are below those of 2003, even though twelve new Member States joined the EU in that period. The reported number of animals used for the testing of cosmetics or toiletries is still relatively small compared to the total number of animals used for experimental and other scientific purposes.

It can be noted that Member States have improved their internal structure in order to provide for accurate animal testing data and effective monitoring of the application of the testing and marketing bans, as it was encouraged in the guidelines annexed to the request to Member States for accurate data. However, the Commission continues to be concerned about the accuracy of the figures being reported, and this concern is shared by Member States.

The main issue relates to multi-use substances. Interestingly, some Member States, when mentioning that no animal testing has been performed for cosmetic products, reported that no toxicological tests were carried out for multiple or uncertain purposes where it could be considered that the substance might be used as an ingredient in cosmetic products.

The Commission will consider how further improve the availability of relevant information.

Development and Validation of Alternative Approaches: the report states that there currently four alternative in vitro methods in relation to three toxicological endpoints (skin corrosion, acute phototoxicity and skin penetration) listed in Annex V of Directive 67/548/EEC and one method for the mutagenicity testing listed under REACH. These alternative test methods are currently the only legally accepted tests at Community level aimed at fully replacing animal tests for toxicological endpoints in the area of chemicals and cosmetic products. A method concerning skin irritation is likely to be soon accepted for regulatory

purposes. For eye irritation and acute toxicity, the situation is uncertain and the Commission will focus its efforts on these human health effects in view of the 2009 deadline.

For the 2013 deadline, the situation is much more critical.

For the endpoints falling under the 2013 deadline, there is unfortunately no indication that the deadline can be met for the complex endpoints, such as chronic toxicity, reproductive toxicity and toxicokinetics, although several activities are ongoing.

Lastly, the report underlines that the questions of validation and regulatory acceptance of alternative methods are also at the core of the various bilateral regulatory dialogues with the main trading partners (the United States, Japan and China).