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

2000/0077(COD) - 03/05/2007 - Follow-up document

This is the 6th Report on the Development Validation and Legal Acceptance of Alternative Methods to Animal Experiments in the Field of Cosmetics. It analyses the number of tests on animals for cosmetic products in 2004. It also analyses alternative replacement methods and the acceptance and recognition of alternative methods at an international level.

Number and type of experiments relating to cosmetic products carried out on animals: The testing ban on finished cosmetic products has applied since 11 September 2004, whilst the testing ban on ingredients or combined ingredients will apply, step-by-step as soon as alternatives methods have been validated and adopted – but with a maximum cut-off date of 11 March 2009, irrespective of the availability of alternative non-animal tests. For this report, 23 Member States forwarded information to the Commission on animals tests carried out for safe cosmetic products in 2005. The UK and EL did not transmit any data given that they do not carry out animal tests dealing with cosmetic safety. According to the information submitted only three countries have conducted animal test for cosmetic purposes. They are France, Denmark and Spain.

In total about 9000 animal were used in tests – showing a significant increase: 9000 compared to 1618 in 2003. Part of this increase is attributed to growth in the cosmetic sector. In 2005, sales in the "old" 15 Member States, Switzerland and Norway reached EUR 60 billion in retail sales prices. A further reason for the large increase is that Spain did not transmit any data in 2003 but it did for the year 2004 and the increase in animal testing in France (from 1600 in 2003 to 5500 in 2004) is due to three additional test protocols being carried out by two laboratories.

The report does go on to point out that the reported number of animals tested for cosmetics or toiletries remains relative small compared to the total number of animals used for experimental and other scientific purpose. In 2002, for example, the then 15 EU Member States used a total number of 10.7 million animals for testing for scientific purposes.

The report considers, in some depth, the difficulty of obtaining accurate information from the Member States. The Commission notes that the information it received from the Member States for the present report demonstrates how difficult it is to generate accurate figures on animal testing in the field of cosmetics. Data on animal tests relating to cosmetic products are collated and generated differently through the EU. There is no uniform practice to collect animal testing data accurately.

Progress in the development, validation and legal acceptance of alternative methods: Currently, there are four alternative *in vitro* methods relating to two toxicological endpoints namely, skin corrosion and acute phototoxicity. These are the only legally accepted tests at Community level for the purpose of fully replacing animal tests for toxicological endpoints in the field of chemical and cosmetics.

A 2005 "Cosmetics Technical Report" indicated that efforts for the 2009 deadline look promising. For skin corrosion, acute phototoxicity and skin penetration, accepted replace assay already exist, whilst for mutagenicity accepted partial replacement assays exist. Significant progress is also being made in the field of eye irritation. For acute toxicity, the results of completed validation studies indicate the possibility of identifying non-toxic substances without the use of animals. Furthermore, as a result of work carried out under the 6th Framework Programme, the proportion of substances, for which acute toxicity can be established, might be expanded in the near future.

For the 2013 deadline, however, the situation appears to be more critical. The Commission reports that it is highly unlikely that the chronic toxicity with any test strategy or battery of non-animal tests will be predicted. For reproductive toxicity some opportunities might emerge. Cancer bioassays are very unlikely to be requested for cosmetic ingredients since chemical identified as positive in mutagenicity/genotoxicity assays are usually abandoned. However, in case the carcinogenic potential needs to be evaluated, cell transformation assays, which are currently under validation, might be used. Promising alternative methods exist for skin and respiratory sensitisation.

Acceptance and recognition of alternative methods at international level: The OECD plays a prominent role in promoting and accepting alternative methods at an international level. OECD test guidelines have the broad approval of the international scientific community. The EU works closely with the OECD in the validation, acceptance and promotion of alternative methods. In 2004, the OECD adopted, for the first time, alternative methods aimed at replacing animal tests. The EU also plays a leading role in international regulatory dialogues with authorities in the US and Japan in order to facilitate the compatibility of cosmetics regulations and in order to avoid trade conflicts. In 2005, the EU and the US signed a Roadmap on co-operation for the development of alternative methods. Co-operation also extends to the Japanese Centre for the Validation of Alternative Methods (JACVAM), which was founded in December 2005.

Conclusions: The Commission doubts, based on the data it received from the Member States, whether all of the Member States have established mechanisms that provide for accurate animal testing data. As a result, the Commission is working on new guidelines that facilitate a more accurate compilation of data.