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

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This 2004 report on the development, validation and acceptance of alternative methods to animal experiments in the field of cosmetics is the fifth report presented by the Commission. It reflects the state of play on the number and type of experiments on animals relating to cosmetic products between 1998 and 2003, the current status of alternative methods, as well as the acceptance and recognition of alternative methods at the international level as of December 2004. The report is produced in order to comply with Art. 9 of Council Directive 76/768/EEC (Cosmetics Directive), as amended by Directive 2003/15/EC. It is the first report on the basis of the 7th amendment to the Cosmetics Directive and after the inclusion of the Protocol on the Welfare of Animals in the Treaty of Amsterdam in 1999.

The last Commission report was presented in 1999 and covered the situation on the development, validation and acceptance of alternative methods to animal experiments in the field of cosmetics until 1997. This report includes data and information from the ten new Member States.

Firstly, the report details the number and type of experiments relating to cosmetic products carried out on animals. The 4th Statistical report showed the following:

- the total number of animals used was in the same order of magnitude as in previous reports. The total number of animals used in the EU Member States in 2002 was 10.7 Million -more than 60% of the 10.7 million animals were used in research and development for human medicine, dentistry and in fundamental biology studies, about 16 % in production and quality control of products and devices in human medicine, veterinary medicine and dentistry, and about 10 % for toxicological and other safety evaluation. From these 10 %, only 0.25 % (about 2600 animals) were used for toxicological or other safety evaluations of products/substances used or intended to be used mainly as cosmetics or toiletries.

For this report, information submitted showed that cosmetic products/ingredients have been tested on animals from 1998 – 2003 only in the territories of France, Italy and Denmark.. The other 12 old Member States did not perform such animal tests in their territory during this time period. The new Member States reported that they did not perform any such animal test in their territory in 2003;

- in total, the number of animals used for testing cosmetics in the old Member States of the EU decreased significantly from about 4200 to 1600 (1998 – 2003), although the total number of animals used in experiments increased in all sectors outside cosmetics and the market for cosmetics has continued to grow. Over the period 1999 – 2003, the Western European market (the EU-15 plus Norway and Switzerland) has grown by an average of around 4 % per year to increase to Euro 58,10 billion (retail sales prices) in 2003.

These figures on use of animals are unlikely to represent the full number of tests on substances used as cosmetic ingredients. There might be a number of reasons for this, e.g. the non-availability of comprehensive records on animal tests on substances used as cosmetic ingredients. Animal tests to assess the safety of ingredients are usually carried out on the basis of chemicals legislation, because they are normally used as industrial chemicals. Only in a few cases additional tests are necessary on the basis of the Cosmetics Directive. The cosmetic industry, as a downstream user of a number of such substances, mainly uses test data produced by the supplier under chemicals legislation in order to assess the safety of ingredients in cosmetic products. Therefore, it is difficult to get hold of accurate figure. The lack of accurate figures makes a comprehensive assessment of the use of animals in cosmetic tests difficult. The Commission will contact industry, Member States and other potential sources to clarify the matter and to

establish a framework which would provide a more complete picture of animal tests carried out on ingredients used or intended to be used in cosmetic products.

Secondly, the report discusses progress in the development, validation and legal acceptance of alternative methods. In comparison with the last report from 1999, significant progress in this area was achieved. On 1 October 2004, the Commission established the timetables for the phasing-out of animal testing and set up an Ad Hoc Group of 75 scientific experts representing industries, academia, animal welfare groups and governmental bodies. The Commission goes on to discuss action under the 6$^{th}$ framework programme on research and development, and private initiatives. It also discusses future activities.

Thirdly, the report looks at recognition of alternative methods on an international level. The manufacture, distribution and sale of cosmetics are a global industry within which the EU is a major player. The EU cosmetics and perfumes industry market volume, based on retail prices at the point of sales, amounted to nearly 50 billion Euro in 2000, compared to the US (EUR 30.7 billion) and Japan (EUR 14.3 billion Euro). Third countries represent significant and growing markets. In 2001, the export of cosmetics from the EU to third countries had a value of about EUR 7, 160 billion.

On the multilateral level, it is a major success that OECD adopted, for the first time in 2004, alternative methods aiming at replacing animal tests. OECD Test Guidelines are broadly accepted by the international scientific community and by appropriate regulatory authorities of OECD Member countries and a number of Non-Member countries. The European Centre for the Validation of Alternative Methods (ECVAM) is closely working with the OECD in the validation, acceptance and promotion of alternative methods. On a bilateral level, a key element of the EU-US cooperation is the implementation of the Guidelines for Regulatory Cooperation and Transparency agreed in June 2002. EU and U.S. agreed in June 2004 on a road map for further cooperation between the U.S. Food and Drug Administration (FDA) and DG Enterprise and Industry regarding alternative non-animal testing methods.