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COMMISSION OF THE EUROPEAN COMMUNITIES

COMMISSION STAFF WORKING PAPER

A. SUMMARY


The year 2003 represented a landmark in the field of alternative test methods in cosmetics. The adoption of the 7th amendment to the Cosmetics Directive, European Parliament and Council Directive 2003/15/EC, was a major political success. For the first time a clear and detailed framework was established with agreed provisions for a ban on animal testing and on the marketing of cosmetic products and ingredients which have been tested on animals. In 2004, according to the requirements of the 7th Amendment, the Commission established the timetables for the implementation of the testing and marketing bans within the time frames set up by the Council and the European Parliament.

According to reports from Member States, the number of animals used in tests for cosmetic products decreased significantly from 1998 – 2003 (about 4200 to 1600), although the total number of animal experiments increased in all other sectors outside cosmetics and the market for cosmetics world-wide has continued to grow. However, a cautious assessment of the figures seems to be appropriate. At the same time, good progress was made in the development and validation of alternative methods to animal tests. Some human health effects can already today be assessed using alternative methods, i.e. skin corrosion, skin absorption and acute phototoxicity. It was a major breakthrough for alternative methods, since for the first time validated alternative methods replacing animal experiments were internationally accepted at the level of OECD.

However, for the data requirements in the other toxicological test areas further efforts will be needed in order to achieve full replacement of animal tests. The Commission is currently working on a strategy for the monitoring of progress in the implementation of timetables for the phasing-out of animal testing which will take into account the various recommendations and prospects of experts for possible future activities. It will keep pressure on all relevant actors involved in this area and pursue a climate of confidence-building between different actors, in particular, animal welfare organisations, industry and the scientific community.

B. REPORT ON ALTERNATIVE METHODS

I. Introduction

The present 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.

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. The delay of the presentation of the 2004 Report was due to a number of different circumstances, in particular those related with the Commission proposal and the adoption under co-decision of the 7th amendment. However, it allowed the Commission to include also data and information from the ten new Member States.

II. Number and type of experiments relating to cosmetic products carried out on animals

The European Commission has adopted on January 2005 its “Fourth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union (2002)” according to Art. 26 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. The report shows that 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 (France reporting for 2001).

![Figure 1](http://europa.eu.int/comm/environment/chemicals/lab_animals/home_en.htm)

*Figure 1*  
4th Statistical Report: Purposes of experiments (in total: 10.7 million animals)

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4 COM (2005) 7 of 20.01.2005  
5 (http://europa.eu.int/comm/environment/chemicals/lab_animals/home_en.htm)  
OJ L 358, 18.12.1986, 1
According to the 4th Statistical Report, 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 (Figure 1). 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 (Figure 2).

For the present report on the number of animals used for the safety testing of cosmetic products, the 15 old Member States conveyed data for 1998 – 2003, the 10 new Member States for 2003. According to the information submitted, cosmetic products/ingredients have been tested on animals from 1998 – 2003 only in the territories of FR, IT and DK (See table below). The other 12 old Member States did not perform such animal tests in their territory during this time period (ES did not convey complete data for 1998 -2003). The new Member States reported that they did not perform any such animal tests in their territory in 2003.
Number of animals used in Member States from 1998 to 2003

<table>
<thead>
<tr>
<th></th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
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<tbody>
<tr>
<td>France</td>
<td>4150</td>
<td>3518</td>
<td>2925</td>
<td>2591</td>
<td>2053</td>
<td>1618</td>
</tr>
<tr>
<td>Animals used:</td>
<td>Mice, rabbits, fishes, hamsters, guinea pigs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>19</td>
<td>98</td>
<td>129</td>
<td>1</td>
<td>60</td>
<td>0</td>
</tr>
<tr>
<td>Animals used:</td>
<td>Rabbits, rats</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Denmark</td>
<td>23</td>
<td>14</td>
<td>84</td>
<td>0</td>
<td>40</td>
<td>0</td>
</tr>
<tr>
<td>Animals used:</td>
<td>Mice, Guinea pigs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>No data available</td>
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<td>No data available</td>
<td>No data available</td>
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<td>No data available</td>
</tr>
<tr>
<td>Other Member States*</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*New Member States submitted data only for 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; Figure 4), although the total number of animal 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.

The above mentioned 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 figures.

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.

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A large majority of Member States does not test on animals for the safety evaluation of cosmetic products. Some Member States reported that they have taken national legislative or comparable measures regarding animal testing on cosmetics/ingredients already before the adoption of European Parliament and Council Directive 2003/15/EC.

In the Netherlands, the Experiments on Animals Act entered into force on 5th February 1997. This measure prohibits animal experimentation in the development of new cosmetics or the testing of existing cosmetics, as per the provisions of the Commodities Act.

Germany also took measures to prohibit animal testing of cosmetics. In November 1997 the German Parliament passed a bill that placed a ban on animal testing for the purposes of development of cosmetics. This bill entered into force on 1st January 1998 and it effectively prohibits the testing of finished products or ingredients. However, it is possible for derogations to be granted.

In Ireland, the use of live animals in scientific research and other experimental activity is strictly controlled in accordance with the Cruelty to Animals Act, 1876 as amended by the European Communities Acts (Amendment of Cruelty to Animals Act, 1876). Only in circumstances where no alternative is available may a licence to perform specified procedures on a specific number and species of animal be granted by the Minister for Health and Children. Licences are granted in accordance with the provisions of the act and are subject to stringent conditions.

The Belgian authorities reported that the scope of national legislation concerning the replacement of animal tests with alternative methods is much broader than the Cosmetics Directive.

In 1997, the UK announced an end to animal testing of both cosmetic products and cosmetic ingredients. This was achieved following discussions between the Home Office and the remaining three test houses that carried out such animal tests. The licences were returned to the Home Office on a voluntary basis, ensuring that no testing on animals for cosmetic purposes could continue to be carried out. This voluntary ban was never enshrined in UK law, however, the Home Office continue to inspect and check test houses that carry out animal testing for other purposes to ensure that the voluntary agreement is being adhered to.
Some Member States have notified their national legislation for the transposition of Directive 2003/15/EC. The Commission will thoroughly examine whether this legislation is in conformity with the provisions concerning the ban on animal testing as well as the ban on marketing of cosmetic products/ingredients which have been tested on animals.

III. Progress in the development, validation and legal acceptance of alternative methods

1. State of Play

a) In comparison with the last report from 1999, significant progress in the development, validation and legal acceptance of alternative methods was achieved. On 1 October 2004, the Commission established the timetables for the phasing-out of animal testing according to Art. 4 a §2 to Directive 76/768/EEC\(^7\). In order to establish these deadlines and to estimate the time necessary to achieve full replacement of animal testing in the field of cosmetics, the Commission set up an Ad Hoc Group of 75 scientific experts representing industries, academia, animal welfare groups and governmental bodies that agreed on a “Report for establishing the timetable for phasing-out animal testing for the purpose of the Cosmetics Directive (May 2004)\(^8\). After having provided an inventory of the most valuable and/or advanced alternative methods currently known to be available in the respective toxicological areas, it identified alternative methods for a number of toxicological endpoints which will most likely be validated and legally accepted before the cut-off-dates in 2009/2013. Some human health effects can already today be assessed using alternative methods, i.e. skin corrosion, skin absorption and acute phototoxicity. However, for the data requirements in the other toxicological areas further efforts will be needed in order to achieve full replacement of the animal tests. The Ad Hoc Group has identified eight toxicological endpoints for which no alternative methods are foreseen before the cut-off-dates in 2009/2013.

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On 1 July 2004, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) adopted its opinion on the “Report for establishing the timetable for phasing-out animal testing for the purpose of the Cosmetics Directive”9.

b) The European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre has validated a number of alternative methods to animal tests during 1998-200310. In 2004, ECVAM has carried out and/or initiated six (pre)validation studies (acute systemic toxicity, skin irritation, carcinogenicity, 3 studies in reproductive toxicology) and planned three up-coming (pre)validation studies (carcinogenicity, 2 studies on eye irritation) with the scope to partially or fully replace the animal tests in the toxicological areas of concern to the safety evaluation of cosmetics.

c) Validated alternative methods are listed in Annex V to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances11. At present, there are no alternative methods listed in Annex IX to the Cosmetics Directive. Annex IX was introduced by Commission Directive 2004/94/EC of 21 September 200412 only for the purpose of listing those alternative methods to animal testing that have been validated by ECVAM and that are not listed in Annex V to Council Directive 67/548/EEC. The Commission is currently examining the question whether four alternative methods for different toxicological endpoints (skin corrosion as well as reproductive and developmental toxicity) which have been validated by ECVAM should rather be included in Annex V to Directive 67/548/EEC than in Annex IX to the Cosmetics Directive. It would be inappropriate to include them in the Cosmetics Directive if these methods are not limited to the testing of substances in cosmetic products.

d) The 6th Framework Programme on Research and Development13 supports the development of alternative methods in the areas of development of new in vitro tests to replace animal experimentation (Thematic Priority 1 - Life Sciences, Genomics and Biotechnology for Health)14 and of alternative in vitro testing methods and strategies for chemical substances (Specific activities covering a wider field of research - Policy support and anticipating scientific and technological needs)15. The Action Plan Science and society also foresees activities in the area of ethics and animal welfare16.

As an outcome of the first calls for proposals, the following specific projects have been selected for funding under areas of Thematic Priority 1 and support to the Chemical Policy, amounting to 22,6 Mio Euros:

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10 See “Report for establishing the timetable...”, Appendix III, footnote 8
11 OJ 196, 16.8.1967, 1
12 OJ L 294, 17.9.2004, 28
14 More information is available from the following web-site: http://www.cordis.lu/fp6/lifescihealth.htm
15 More information is available from the following web-site: http://www.cordis.lu/fp6/support.htm
16 More information available from the following: http://www.cordis.lu/science-society
– Optimization and pre-validation of an *in vitro* test strategy for predicting human acute toxicity.

– Biosensors Based on Membrane Organisation to Replace Animal Testing.

– Consensus Networking on Alternative Methods within Europe.

– A Prospective Analysis of the Mechanisms of Nuclear Hormone Receptors and their Potential as Tools for the Assessment of Developmental Toxicity.

– Short-term in vitro assays for long-term toxicity.

– Development of a novel approach in hazard and risk assessment for reproductive toxicity by a combination and application of *in vitro*, tissue and sensor technologies.

– Highly parallel cell culture in nanodrops, a new format for high content cell-based toxicity screening on cell on chips.

The Communication of the European Commission on “Life Sciences and Biotechnology – A Strategy for Europe” highlights the Commission’s willingness to work with public and private partners in order to establish a consensus on ethical guidelines, standards or best practise, such as those applicable to the use of animals in research.

e) Currently available alternative methods, even if not formally validated through the formal procedures of the European Commission, are already used by industry in order to compare the results of new formulations with those previously obtained on formulations of the same type and which have not been associated with problems. This information could be introduced into the official validation process if the experience gained in practice is considered to be useful in this respect.

f) The Commission is currently preparing a Recommendation on establishing guidelines on the use of claims referring to the absence of tests on animals pursuant to Art. 6 §3 to Directive 76/768/EEC. It aims at ensuring that common criteria are applied with regard to claims on a cosmetic product that no animal testing was carried out in relation to its development.

2) **Future Activities**

a) The Ad Hoc Group which agreed on the “Report for establishing timetables for phasing-out animal testing” gave important recommendations and prospects for future activities. It stated that in general, the longer deadlines for phasing-out the animal experimentation were identified in those areas where the alternative methods are still under research and development (R&D), or where specific methods under R&D are required to complete the test strategies necessary to achieve full replacement of the animal tests. According to the report, the necessity to have funds and human resources at R&D level is one of the major bottlenecks for obtaining alternative methods. However, good coordination and prioritisation to focus R&D and test optimisation efforts on alternative methods that are able to predict risks to human health are also crucial. Concerning those areas where the methods are already well

17 http://europa.eu.int/comm/biotechnology

18 See footnote 8
advanced and ready for entering the (pre)validation process, the following needs were identified: the assessment of the existing data using weight of evidence approaches, the use of high quality in vivo data and the definition of criteria for validating test strategies as well as in silico models.

b) The Commission is currently working on a strategy for the monitoring of progress in the implementation of timetables for the phasing-out of animal testing which will take into account the recommendations and prospects of the Ad Hoc Group for possible future activities. It will keep pressure on all relevant actors involved in this area and pursue a climate of confidence-building between different actors, in particular, animal welfare organisations, industry and the scientific community. The experience of the Ad Hoc Working Group should be used in this respect.

c) In order to reduce, refine or replace the use of animals for testing, a number of initiatives have already been launched on the national and community level to develop and promote alternative methods to animal tests. These activities are to a large extend uncoordinated due to the various actors involved and because some initiatives cover all, others only different industrial sectors. Given the multiple actors involved and the various actions taken, it will be important to follow the developments for alternative methods to animal testing in the different fora and coordinate the activities. The Commission will take into account particularly the views of the Scientific Committee on Cosmetics Products in this respect and in the area of innovative technologies.

d) The Commission will consider in how far alternative methods to animal tests can be included into the 7th Framework Programme on Research and Development. There is a need for initiatives to mobilise efforts to address a wide range of strategically important issues for Europe’s future growth, competitiveness and sustainable development by bringing together the key stakeholders and stimulating private-public interaction. Technology platforms, as being set up by Commission and industry, could play an important role in this respect.

e) Private initiatives can also play a crucial role in promoting alternative test methods, as e.g. ECOPA and SCAAT. The European Consensus-Platform for Alternatives (ECOPA) was founded November 10, 2002, in Brussels by national platforms from ten European states (i.e. Austria, Belgium, Czech Rep., Finland, Germany, Italy, Netherlands, Spain, Switzerland, UK). The purposes of ECOPA are to facilitate the exchange of scientific information, expertise and experience between national consensus platforms, industry, science, animal welfare and EU and government institutions to enhance the further development and implementation of refinement, reduction and replacement (3R-concept) in animal experimentation in Europe and worldwide. Adhering to the 3-R-concept, ECOPA strives to raise public, governmental and scientific awareness for a better acceptance of alternatives in experimental practice. ECOPA organises conferences, seminars, publish documents, collect

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19 Recent example: The final conference of the EU research funded project «Alternative methods in animal experimentation: evaluating scientific, ethical and social issues in the 3Rs concept», was held in Brussels on 27-28 October 2004 (see http://www.inemm.cnr.it/aniamlsee/presentation.html)

20 See footnote 10

21 “Technology platforms from definition to implementation of a common research agenda”, Report compiled by a Commission Inter-Service group on technology platforms, European Commission, Directorate-General for Research; http://www.cefic.org

22 http://ecopa.vub.ac.be/
and circulate information, support scientific and educational initiatives, and promote the implementation of co-operative action in the fulfilment of its purposes.

SCAAT is the Steering Committee on Alternatives to Animal Testing of COLIPA (European Cosmetic Toiletry and Perfumery Association). Since 1992, its main mission is to coordinate the Cosmetics Industry’s efforts in the development and acceptance of alternatives to animals in cosmetic safety evaluation. SCAAT is leading a Colipa-funded research program which since 2001 focuses on mechanisms of eye irritation, skin irritation and skin allergy. This aims at progressing the research and development of new mechanistic alternative tests with a view to developing/optimizing new tests ready for (pre)validation by ECVAM.

IV. Acceptance and Recognition of Alternative Methods on 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 (30.7 billion Euro) and Japan (14.3 billion Euro)\(^2\). Although the major markets in the EU, USA, Japan and Canada account for a large proportion of total world cosmetics sale, third countries represent significant and growing markets. In 2001, the export of cosmetics from the EU to third countries had a value of about Euro 7,160 billion\(^2\).

The international character of the cosmetic market was highlighted in a “Comparative Study on Cosmetic Legislation in the EU and other Principle Markets with special attention to so-called Borderline Products (August 2004)\(^2\) commissioned by DG Enterprise.

I. Multilateral Level

In comparison with the last report, a number of additional initiatives to promote alternative methods to animal tests on the international level have been launched.

a) It is a major success that OECD adopted, for the first time in 2004, alternative methods aiming at replacing animal tests (Skin absorption: In vitro method, TG 428; In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test, TG 430; In Vitro Skin Corrosion: Human Skin Model Test, TG 431; In Vitro 3T3 NRU phototoxicity test, TG 432). OECD Test Guidelines (TG) are broadly accepted by the international scientific community and by appropriate regulatory authorities of OECD Member countries and a number of Non-Member countries.

ECVAM is closely working with the OECD in the validation, acceptance and promotion of alternative methods. During 2004, several collaborative activities took place. Two persons from ECVAM staff were seconded to the OECD; an OECD representative was invited to participate on a regular basis as observer at the ECVAM Scientific Advisory Committee (ESAC) meetings. Several collaborations in the peer review of validation studies (endocrine disrupters) and in the coordination of validation studies (Micronucleus test and Cell transformation assays) took place. ECVAM has a leading role in the development of the OECD programme on (Q)SAR (computer modelling) and was involved in the review of the OECD draft guidance document on the validation and international acceptance of new or

\(^{2}\) http://europa.eu.int/comm/trade/issues/sectoral/industry/chem/cosmetics

\(^{24}\) Eurostat (2003)

updated test methods for hazard assessment. Further to a recommendation of an ECVAM workshop on the standardisation of cell culture procedures held in 1999, ECVAM largely contributed to the elaboration of an OECD guidance document on Good Laboratory Practice for in vitro toxicology studies that was accepted in May 2004.

b) In addition to these initiatives, DG Enterprise and Industry is encouraging the technical harmonisation process in the field of cosmetics, as e.g. between EU – ASEAN and – MERCOSUR and intends to re-launch the discussions between the responsible authorities in USA, Canada and Japan under the Conference in International Harmonisation in the field of Cosmetics (CHIC). The next CHIC-conference is planned for March 2005 in Canada.

2. Bilateral Level

The EU takes also a leading role in the international regulatory dialogues with authorities in USA and Japan in order to facilitate the compatibility of cosmetics regulations and to avoid trade conflicts. A key element of the EU-US cooperation is the implementation of the Guidelines for Regulatory Cooperation and Transparency agreed in June 2002 under the Transatlantic Economic Partnership (1998) in the framework of the New Transatlantic Agenda (1995). 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.

ECVAM has a bilateral co-operation with the US Interagency Co-ordinating Committee on the Validation of Alternative Methods (ICCVAM) aiming at an early exchange of information on the validation of test methods so as to facilitate mutual recognition, acceptance, and implementation of scientifically validated testing methods; and at joint efforts to facilitate the OECD process in providing harmonised protocols to the scientific community and promoting international adoption of validated alternative methods.

Based on the existing collaboration in the field of alternative testing methods, the following activities have already been agreed by ICCVAM and ECVAM:

- Mutual observer status

- Setting up of a Consultancy Group to negotiate diverging judgements on alternatives

- Two joint workshops on validation principles

- A participation of ICCVAM in the ECVAM validation study on skin irritation (and future studies on invitation); two American laboratories were included in the collaborative study

- Joint activities in the field of ocular irritancy

- Joint promotion of a guidance document for Good Laboratory Practice (GLP) in in vitro toxicology studies

- A sabbatical programme to exchange personnel