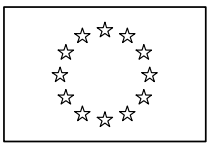


COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.4.2005
COM(2005) 175 final

Report from the Commission to the Council and the European Parliament

on the Development, Validation and Legal Acceptance of Alternative Methods to Animal Tests in the Field of Cosmetics (2004)

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 as of December 2004. The report is produced in order to comply with Art. 9 of the Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (Cosmetics Directive), as amended by the European Parliament and Council Directive 2003/15/EC of 27 February 2003. 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[1]. The present report covers the situation from 1998 to 2003, including data and information from the ten new Member States.

II. NUMBER AND TYPE OF EXPERIMENTS RELATING TO COSMETIC PRODUCTS CARRIED OUT ON ANIMALS

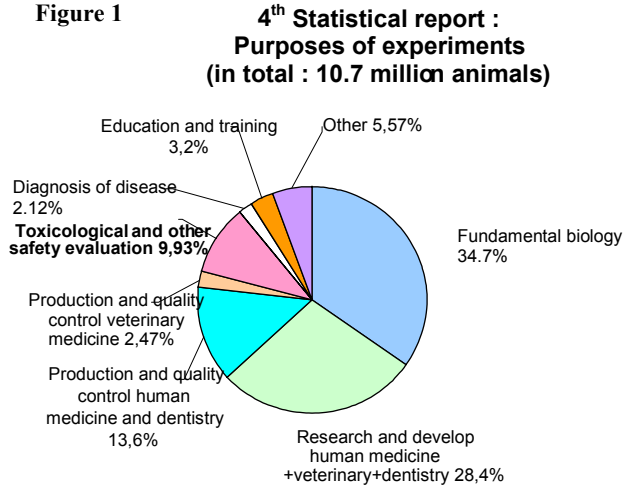
The European Commission has adopted on 20 January 2005 its "Fourth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union (2002)[2]" according to Art. 26 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[3]. 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).

1 COM (1999) 5 final of 6.1.1999

2 COM (2005) 7 of 20.01.2005 (http://europa.eu.int/comm/environment/chemicals/lab_animals/home_en.htm)

3 OJ L 358, 18.12.1986, 1

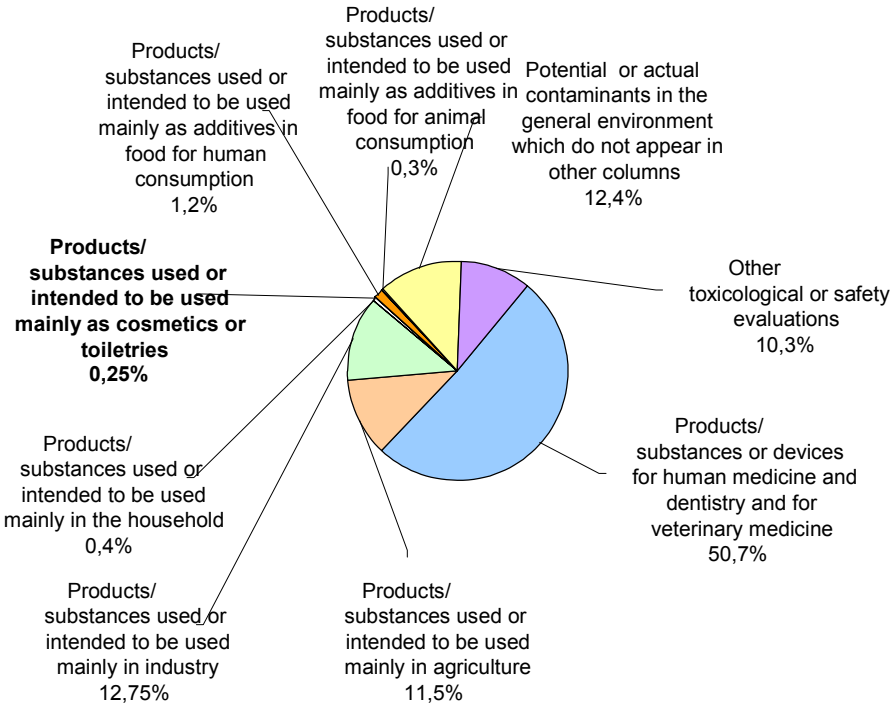
Figure 1



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).

Figure 2

4th Statistical Report : Animals used in toxicological or other safety evaluations of products (in total 1.07 million animals)



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 the 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 test in their territory in 2003.

Number of Animals used in the Member States from 1998 to 2003

	1998	1999	2000	2001	2002	2003
France	4150	3518	2925	2591	2053	1618
	Animals used : Mice, rabbits, fishes, hamsters, guinea pigs					
Italy	19	98	129	1	60	0
	Animals used : Rabbits, rats					
Denmark	23	14	84	0	40	0

	Animals used : Mice, Guinea pigs					
Spain	No data available	No data available	No data available	No data available	0	No data available
Other Member States*	0	0	0	0	0	0

*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), 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[4].

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.

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[5]. 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,

[4] COLIPA, The European Cosmetic, Toiletry and Perfumery Market 2003, Brussels June 2004, page 5; COLIPA, The European Cosmetic, Toiletry and Perfumery Market 2001, Brussels June 2002, page 20

[5] Commission Staff Working Document of 1.10.2004, SEC (2004) 1210

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)"[6].

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"[7].

b) The 6th Framework Programme on Research and Development[8] 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)[9] 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)[10]. The Action Plan Science and society also foresees activities in the area of ethics and animal welfare[11]. As an outcome of the first calls to proposals, 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.

c) Private initiatives play a crucial role in promoting alternative test methods, as e.g. ECOPA and SCAAT. The European Consensus-Platform for Alternatives (ECOPA)[12] 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.

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 1992 focuses on mechanisms of eye irritation, skin irritation and skin allergy.

d) 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.

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6 Available on the website of the European Commission, http://pharmacos.eudra.org/F3/home.html

7 SCCNFP/0834/04; available on the website of the European Commission, http://europa.eu.int/comm/health/ph_risk/committees/sccp/sccp_en.htm

8 Decision n°1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth Framework Programme of the European Community for research , technological development and demonstration activities, contributing to the creation of the European research Area and to innovation, 2002-2006, OJ L232, 29.08.2002, page 1

9 More information is available from the following web-site: http://www.cordis.lu/fp6/lifescihealth.htm

10 More information is available from the following web-site: http://www.cordis.lu/fp6/support.htm

11 More information available from the following: http://www.cordis.lu/science-society

12 http://ecopa.vub.ac.be/

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[13]. 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.

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.

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)[14]. 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[15].

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)"[16] commissioned by DG Enterprise.

1. 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. 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.

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13 See footnote 7

14 http://europa.eu.int/comm/trade/issues/sectoral/industry/chem/cosmetics

15 Eurostat (2003)

16 Available on the website of the European Commission, http://pharmacos.eudra.org/F3/home.html

2,12%

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.