Basic information

2000/0077(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Cosmetic products: animal experiments (7th amend. to "Cosmetics Directive" 76/768/EEC) **Subject** 3.40.12 Luxury products industry, cosmetics 4.20.02.06 Clinical practice and experiments	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
DELE EP Delegation to Conciliation Committee	ROTH-BEHRENDT Dagmar (PSE)	26/06/2002

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy	ROTH-BEHRENDT Dagmar (PSE)	19/06/2000
ENVI Environment, Public Health, Consumer Policy	ROTH-BEHRENDT Dagmar (PSE)	19/06/2000

Former committee for opinion	Former rapporteur for opinion	Appointed
JURI Legal Affairs and Internal Market	The committee decided not to give an opinion.	
ITRE Industry, External Trade, Research, Energy	SEPPÄNEN Esko (GUE/NGL)	06/06/2000

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2351	2001-05-30
Competitiveness (Internal Market, Industry, Research and Space)	2389	2001-11-26
Agriculture and Fisheries	2481	2003-01-27
Education, Youth, Culture and Sport	2408	2002-02-14

European

Commission DG	Commissioner

Commission	Internal Market, Industry, Entrepreneurship and SMEs	

Key events

Date	Event	Reference	Summary
05/04/2000	Legislative proposal published	COM(2000)0189	Summary
13/06/2000	Committee referral announced in Parliament, 1st reading		
20/03/2001	Vote in committee, 1st reading		Summary
20/03/2001	Committee report tabled for plenary, 1st reading	A5-0095/2001	
02/04/2001	Debate in Parliament		
03/04/2001	Decision by Parliament, 1st reading	T5-0167/2001	Summary
30/05/2001	Debate in Council		Summary
22/11/2001	Modified legislative proposal published	COM(2001)0697	Summary
14/02/2002	Council position published	15073/1/2001	Summary
28/02/2002	Committee referral announced in Parliament, 2nd reading		
23/05/2002	Vote in committee, 2nd reading		Summary
23/05/2002	Committee recommendation tabled for plenary, 2nd reading	A5-0180/2002	
11/06/2002	Decision by Parliament, 2nd reading	T5-0292/2002	Summary
11/06/2002	Debate in Parliament		
26/08/2002	Parliament's amendments rejected by Council		
07/10/2002	Formal meeting of Conciliation Committee		
20/11/2002	Final decision by Conciliation Committee		Summary
20/11/2002	Report tabled for plenary, 3rd reading	A5-0001/2003	
08/01/2003	Joint text approved by Conciliation Committee co-chairs	3668/2002	
15/01/2003	Decision by Parliament, 3rd reading	T5-0011/2003	Summary
15/01/2003	Debate in Parliament		
27/01/2003	Decision by Council, 3rd reading		
27/02/2003	Final act signed		
27/02/2003	End of procedure in Parliament		
11/03/2003	Final act published in Official Journal		

Technical information

Procedure reference	2000/0077(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)

Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	CODE/5/16392

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0095/2001	20/03/2001	
Text adopted by Parliament, 1st reading/single reading		T5-0167/2001 OJ C 021 24.01.2002, p. 0024-0088 E	03/04/2001	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0180/2002	23/05/2002	
Text adopted by Parliament, 2nd reading		T5-0292/2002 OJ C 261 30.10.2003, p. 0030-0104 E	11/06/2002	Summary
Report tabled for plenary by Parliament delegation to Conciliation Committee, 3rd reading		A5-0001/2003	20/11/2002	
Text adopted by Parliament, 3rd reading		T5-0011/2003 OJ C 038 12.02.2004, p. 0174-0246 E	15/01/2003	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	15073/1/2001 OJ C 113 14.05.2002, p. 0109 E	14/02/2002	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2000)0189  OJ C 311 31.10.2000, p. 0134 E	05/04/2000	Summary
Modified legislative proposal	COM(2001)0697  OJ C 051 26.02.2002, p. 0385 E	22/11/2001	Summary
Commission communication on Council's position	SEC(2002)0225 	26/02/2002	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2002)0435 	26/07/2002	Summary
Follow-up document	SEC(2005)0525 	14/04/2005	Summary

Follow-up document	COM(2005)0175	29/04/2005	Summary
Follow-up document	COM(2007)0232	03/05/2007	Summary
Follow-up document	COM(2008)0416	02/07/2008	Summary
Follow-up document	COM(2010)0480	16/09/2010	Summary
Follow-up document	COM(2011)0558	13/09/2011	Summary

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2010)0480	15/04/2011	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0998/2000 OJ C 367 20.12.2000, p. 0001	20/09/2000	
CSL/EP	Joint text approved by Conciliation Committee co-chairs	3668/2002	08/01/2003	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Directive 2003/0015
OJ L 066 11.03.2003, p. 0026-0036 Summary

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

2000/0077(COD) - 14/04/2005 - Follow-up document

This is the Commission's fifth report on the development, validation and legal acceptance of alternative methods to animal testing in cosmetics. It is, however, the first Report to assess the approximation of national laws relating to cosmetic products, as required by the seventh amendment to the Cosmetic Directive, (Council Directive 2003/15/EC). To recall, this amendment allowed, for the first time, the establishment of a clear and detailed framework for a ban on animal testing and on the marketing of cosmetic products and ingredients which have been tested on animals.

In preparing this study, the Commission refers to a 2005 Commission paper relating to the “Number of Animals used for Experimentation and their Scientific Purposes in the EU’s Member States”. The findings of that, earlier Report, indicate that in 2002 10.7 million animals were used for testing purposes. Only a fraction of that figure was used by the cosmetic industry. Based on information received from the Member States, the number of animals used in tests for cosmetic products decreased significantly between 1998-2003 down from 4200 to 1600. On the other hand, in all other areas of animal testing (research and human medicine, medicine and dentistry, fundamental biology etc.) the use of animal testing has increased. Moreover, according to information received by the Commission from the Member States, the only countries to have tested animals for the cosmetic purposes are France, Italy and Denmark.

As the Commission points out, however, the cosmetic industry is a “downstream” user of many ingredients. A large proportion of the ingredients used in cosmetic products are industrial in nature. In order to assess the safety of ingredients in cosmetic products, the cosmetic industry relies on data produced by their suppliers who, in turn have tested their ingredients, under chemicals legislation. It is, therefore, difficult for the Commission to assess the figures accurately, which makes it difficult to make a comprehensive assessment of the use of animals in cosmetic tests. The Commission promises to open a dialogue with the cosmetic industry on this matter in order to establish a more complete picture of animal tests carried out on ingredients used or intended to be used in cosmetic products.

As far as progress in the development, validation and legal acceptance of alternative methods is concerned the Commission notes significant progress, particularly when compared to 1999 findings. In 2005 the Commission established a timetable for the phasing-out of animal tests in accordance with the revised Article 4 of Directive 76/768/EEC. Together with the Ad Hoc Group of 75 scientific experts the most valuable and/or advanced alternative methods currently known vis-à-vis toxicological tests have been identified. It is expected that these will become law before the cut-off-dates in 2009 /2013. Indeed, some human health effects can already be assessed using alternative methods and relate mostly to conditions such as skin corrosion, skin absorption and acute phototoxicity.

Lastly, the manufacture, distribution and sale of cosmetics are a global industry. The EU’s cosmetics and perfumes industry market volume, based on retail prices at the point of sales, amounted in 2000, to some EUR 50 billion compared to the US EUR 30 billion and Japan’s EUR 14.3billlion. An estimated EUR 7 160 billion was exported to third countries in 2001. The acceptance of alternative methods at an international level is therefore of clear importance to the EU cosmetics industry. One of the major breakthroughs reported by the Commission is the OECD adoption of alternative methods aimed at replacing animal tests given that alternative methods have the broad support of both the scientific community and the regulatory authorities.

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

2000/0077(COD) - 22/11/2001 - Modified legislative proposal

The Commission amended its original proposal following the first reading of the Directive in the European Parliament. A number of changes have been made to the initial recitals taking into account Parliamentary views. Other cherished Parliamentary amendments have been rejected outright. Many of the amendments accepted in part or in principle by the Commission included, inter alia, the following: - The Commission has accepted that a budget of EUR 17.5 million from the new framework programme for research and innovation in Europe over the period 2003-2006 should be allocated to the reduction, refinement and replacement of animal tests for cosmetic products. - The Commission has accepted in principle that the SCCNFP should offer guidance on the safety of products intended for children. Similarly, the Commission has agreed that there should be a specific assessment for cosmetic products intended exclusively for use on children under the age of three and for cosmetic products intended exclusively for use in intimate hygiene. - On the question of minimum durability of cosmetic products, the Commission has agreed to include a recital which obliges producers to improve information on a products durability. - In a similar vein the Commission accepts those amendments requiring more information on the presence in cosmetic products of fragrant ingredients with well-recognised potential to cause contact allergy. At the same time however, the Commission has rejected an amendment, which would have obliged a full listing of ingredients, including those for perfume composition. The Commission deems such measures disproportionate to the risks involved. - An amendment calling for regular reporting on the implementation of the Directive has been agreed to, with the Commission announcing that reports will be prepared every three years. A number of key amendments have been rejected outright by the Commission. They include, amongst others: - Amendments seeking the presentation of further Commission proposals. - On the matter of making claims that some cosmetic products are free from animal testing, the Commission notes that such claims could be misleading. Tests have necessarily been performed on almost every ingredient at least by someone. - Concerning the issue of an EU marketing ban as and when alternatives are available, the Commission is unable to accept this amendment since it is in breach of the EU's WTO obligations/commitments. To reassure the Parliament on this point the Commission has pledged to raise the matter of animal testing on cosmetic products at multi-lateral forums in the future. - Amendments making the labelling of "tested on animals" and the listing of data on animal tests on the final product obligatory have similarly been rejected by the Commission.

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

2000/0077(COD) - 14/02/2002 - Council position

The Council's Common Position corresponds with the Commission's amended proposal, especially concerning the provisions to improve health and consumer protection. However, concerning the issue of animal testing, the Council has made changes to the Commission proposal. The Common Position of the Council has been adopted with a qualified majority. The Common Position of the Council includes most amendments of the European Parliament aiming at improving health and consumer protection, already included in the Commission amended proposal. Furthermore, as requested by the European Parliament, it includes specific provisions on substances classified as carcinogenic, mutagenic or toxic for reproduction. Concerning the

issue of animal testing, the Council shares the aim of abolishing animal testing as soon and whenever possible. However, the Common Position incorporates a new approach. Concerning the EU testing ban on ingredients, the Council has rejected the idea of any fixed cut-off date for its total implementation, as it would compromise the health and safety of consumers. The Common Position provides for a stepwise approach, based on the 3 Rs principle (replacement, refinement and reduction) and links the progressive implementation of such a testing ban to the availability of alternative methods, including those which reduce the number of animals used or diminish their suffering. In addition, it reinforces the regulatory framework to ensure that scientifically validated alternative methods are effectively used when they exist. Concerning the marketing ban, the Common Position provides a marketing ban on cosmetic products when the final product or its ingredients have been subject to animal testing, but links the progressive implementation of such a ban to the existence of alternative testing methods accepted at international level within the framework of the OECD, to reinforce the multilateral character of the measure.

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

2000/0077(COD) - 27/02/2003 - Final act

PURPOSE : to prohibit the marketing of cosmetics where the final formulation has been tested on animals using a method other than the alternative method. COMMUNITY MEASURE : Directive 2003/15/EC of the European Parliament and of the council amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetics products. CONTENT : the Council adopted, with the French delegation voting against, the Directive aimed at banning the use of animal testing for the development of cosmetic products within a period of six years, in accordance with the joint text agreed on in conciliation with the European Parliament on 3 December 2002. (Please refer to that document). The agreed text, which modifies Directive 76/768/EEC, is intended as a means of improving animal welfare without jeopardising consumer safety and the protection of human health, and without undermining the Community's respect for its international obligations. It aims to promote the development of alternative testing methods, and ensure that these methods are effectively used when they exist and that they are scientifically validated. The Directive has four main objectives: - to prohibit the testing of cosmetic products on animals; - to prohibit the testing of cosmetic ingredients on animals and the marketing of cosmetics tested on animals or containing ingredients tested on animals as soon as alternative testing methods have been validated by the Commission, with due regard to validation within the Organisation for Economic Co-operation and Development (OECD); - to align the provisions of Directive 76/768/EEC with the rules of the World Trade Organisation (WTO); - to improve consumer information in relation to the use of cosmetic products. The text includes deadlines for the introduction of the marketing ban and the testing ban, up to a maximum of 6 years from entry into force. The Commission is however empowered to allow Member States to derogate from the bans, by means of a committee procedure, if exceptional circumstances arise involving serious concerns for the safety of consumers. ENTRY INTO FORCE : 11/03/03. DATE FOR TRANSPOSITION : 11/09 /04.

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

2000/0077(COD) - 26/07/2002 - Commission opinion on Parliament's position at 2nd reading

The amendments accepted by the Commission concern: - the inclusion of a reference to Directive 86/609/EEC relating to the protection of animals used for experimental and other scientific purposes; - increasing the efforts in the development and validation of alternative methods, as it is already foreseen for the implementation of the Chemical policy; - the addition of the following paragraph: "The Commission shall in particular ensure the development, validation and legal acceptance of alternative test methods which do not use live animals"; - the principle of the listing of the recognised fragrance allergens in Annex III of Directive 76/768/EEC according to the suggested modalities (setting of threshold levels suggested by the SCCNFP). However, according to Directive 76/768/EEC, the proposed modification of Annex III has to be implemented via a Commission Directive adapting to technical progress, adopted under the comitology procedure. On the other hand, the Commission rejected the amendments concerning : - the requests for the Commission to present another proposal for amending Directive 86/609/EEC; - the EU testing ban for ingredients; - the deletion of the prioritisation of alternative methods (according to the 3Rs principle: replacement, reduction, refinement) introduced in the Common Position supported by the Commission; - the setting up of a fixed timetable for the tests within 5 years; - restricting the scope of research to non-animal alternative methods without taking into account the 3Rs principle; - reintroducing the marketing ban as and when alternatives are available, with a definitive date after which no products can be marketed if tested on animals, whether or not there are validated alternatives. Having noted the concerns of public opinion, it will stimulate discussions on trade and animal welfare in a multilateral forum; - the additional requirement of compulsory labelling "tested on animals"; - to avoid use of fragrances in some categories except when they fulfil specific purposes; - a general ban which is contrary to the principle of risk assessment set up in Directive 76/768/EEC; - ingredients potentially allergenic; - the definition of finished products. This definition has already been reconsidered in the Common Position with the aim of achieving a consistent and coherent legislation; - publishing all data concerning each cosmetic product in the Inventory; - the durability of cosmetic products; - achieving a full ingredient listing, including perfume composition; - product information, the current legislation already specifies that the information is accessible for control authorities for control purposes; - suggesting additional data on animal tests performed should be included in the product information required for each cosmeticproduct put on the market; - the request for an annual report.

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

2000/0077(COD) - 05/04/2000 - Legislative proposal

PURPOSE: to adopt a Directive of the EP and of the Council amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. CONTENT: The proposed Directive has 4 main aims as follows: - to prohibit the performance of experiments on animals for finished cosmetic products in the territory of the EU; - to amend the prohibition on the marketing of cosmetic products containing ingredients tested on animals entering into force after 30/06/2000 by introducing a prohibition on the performance of experiments on animals for ingredients and combination of ingredients and to make mandatory use of validated alternative methods for the testing of chemicals used in cosmetic products, as soon as such methods become available. The Commission will endeavour to obtain the rapid acceptance by the OECD of alternative methods validated at Community level. This prohibition will enter into force 3 years after the implementation of the Directive by the Member States. However, the date of implementation of this prohibition should be postponed for no more than 2 years if there has been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated as offering an equivalent level of protection for the consumer; - to revise the current legislative provisions so as to make them WTO-compliant, legally and practically enforceable. For reasons of consistency and legal certainty, the Commission intends to adopt a Commission Directive postposing the date of entry into force of the marketing ban to avoid its enforcement while a substantial modification of the basic directive is pending before the EP and the Council. At international level, the Commission will endeavour to ensure the mutual recognition of test data from in vitro/in vivo studies through negotiations with third countries; -to improve the information provided to the consumer, to allow the use of claims indicating that animal testing has not been performed. However, to ensure that such claims do not mislead the consumer, the Commission, in consultation with the Member States, will publish guidelines so as to clarify their use. Commission Directive 97/18/EC postponed the ban on the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals until 30/06/2000. Article 2 of Directive 97/18/EC did, however, provide for a reassessment of the situation. The proposed EP and Council Directive amending Directive 76/768/EEC has to be adopted by co-decision procedure, and then will have to be transposed by the Member States into their national law. However, following the adoption of Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, it has become necessary to adjust the relevant decision-making procedures. In its declaration of 28/06/1999, the Commission agreed that the necessary adjustments to the decision-making process would be made in the course of the normal revision of the legislation. Thus, it is necessary to amend Article 10 to align the decision-making process. Finally, with regard to budgetary implications for the Commission, none are foreseenas a result of the provisions of the proposed Directive. It will take up to 2 years before the proposed Directive can be enforced. In the meantime, the ban as foreseen by the current Directive will enter into force. Therefore, in accordance with Article 4(1)(i) of Directive 76 /768/EEC and Article 2 of Directive 97/18/EC, the Commission should adopt a Directive postponing the date of the entry into force of the marketing ban. This postponement would just aim to cover the foreseeable period of time needed for this amendment to be adopted and transposed. When considering the issue of animal testing in the cosmetic sector, two chief objectives must be taken into consideration: consumer safety and the reduction, and wherever and as soon as possible, the elimination of animal suffering. These are the overriding factors that must be addressed in legislative measures. However, for any measures to be effective and enforceable, it is also necessary to take account of the constraints arising from compliance with international trade rules, in particular those of the WTO. The prohibition in its revised form cannot be challenged under WTO rules. Therefore, the prohibition will cover: -finished cosmetic products from the date of implementation of the Directive by the Member States, and - ingredients after publication in the Official Journal of the EC of an alternative method validated, or endorsed as being scientifically valid, by the European Centre for the Validation of Alternative Methods (ECVAM) and endorsed as being applicable to cosmetic products by the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP). International acceptance of such methods is no longer required though it is planned that the Commission will make efforts to secure such acceptance within the OECD and in bilateral negotiations. However, in order to achieve the highest possbile degree of animal protection, some specific action has to be taken in the sector of cosmetic products. Therefore, a deadline for the prohibition on the performance of experiments on animals for ingredients is foreseen 3 years after the implementation of the Directive by the Member States, regardless of whether an alternative method has been validated. A new approach is put forward in the proposed directive,in that regulatory acceptance at a European level will be sufficient to permit legislative proposals for cosmetic testing in the EU. Once a method has been validated or endorsed as being scientifically valid by ECVAM and the SCCNFP and endorsed by the Commission services, it will be published and accepted for use in the EU. Furthermore, use of an animal test that assesses the same toxic end-point will be prohibited in the EU.This will be the situation prior to OECD acceptance, and will be a major advancement in speeding up the regulatory acceptance of alternative methods. Finally, while continuing discussions with the OECD, the Commission will initiate bilateral talks on mutual recognition with third countries. Also, it will produce guidelines to include specific provisions which would require that the finished products and the ingredients have never been tested on animals, including for purposes outside the scope of this Directive.

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

2000/0077(COD) - 26/02/2002 - Commission communication on Council's position

The Commission supports the common position, which is in line with many items of its amended proposal and fulfils the public health and consumer protection, taking into account its international obligations. In a declaration, the Commission confirms its intention shortly to being work on the revision of Directive 86/609/EEC 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.

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

2000/0077(COD) - 11/06/2002 - Text adopted by Parliament, 2nd reading

The European Parliament adopted the report by Dagmar ROTH-BERENDT (PES, Germany) and inserted a large number of amendments in the directive on cosmetics products. (Please refer to the document dated 23/05/02.) Parliament stipulated that animal testing conducted after the complete ban will not preclude the marketing of cosmetic products or ingredients already in use within the Community if such testing was not conducted by or on behalf of the manufacturer, his agent or suppliers. There are provisions for a manufacturer or competent authority to apply for a derogation form the

ban in exceptional circumstances, where serious concerns arise with regard to the safety of an existing cosmetic ingredient, but which do not necessitate a precautionary immediate withdrawal from use. The derogation will only be granted if: -the ingredient is in wide use and cannot be substituted by another ingredient able to perform a similar function. -the specific human health problem is explained and the need to conduct animal tests is justified, supported by a detailed research protocol. -the results of the research are made publicly available.

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

2000/0077(COD) - 16/09/2010 - Follow-up document

The Commission has presented its eighth 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 2007 and 2008, the current status of alternative replacement methods, and the acceptance and recognition of alternative methods at international level.

The main points are as follows:

Animal testing data: according to the information supplied by the 27 Member States, cosmetic ingredients have only been tested on animals in the territories of France and Spain. These Member States provided detailed information, including the testing period, the toxicological endpoint, species of animals used for experiments and number of animals used for testing. In total, 1818 animals in 2007 and 1510 animals in 2008 were used in tests carried out in relation to the safety of cosmetic ingredients. The total number of animals used for testing the safety of cosmetics showed a slight increase compared to the last report's figures for 2006 (2005: 2 276, 2006: 1 329). Nevertheless, the reported number of animals used for the testing of cosmetics or toiletries remains small compared to the total number of animals used for experimental and other scientific purposes.

Evaluation of submitted data: the majority of Member States replied that no animal testing in relation to cosmetic products was performed in 2007 and 2008 in their territory. The main explanations they gave to substantiate their replies were the following: i) national legislation prohibits the carrying out of animal experiments in order to test and develop cosmetic products and their ingredients and ii) national legislation stipulates that animal testing must be authorised in order to be lawfully performed.

Some Member States elaborated on their replies by mentioning the difficulties they had in collecting the information. In fact, the majority of animal tests are conducted for multiple uses by manufacturers of chemical substances (industry assumes that approximately 80-90% of cosmetic ingredients are tested for multiple uses).

In view of the efforts requested of the Member States by the Commission to deliver the appropriate information, some Member States described the measures taken to improve data.

This present report is the last report covering the period before the coming into force of the full testing ban for ingredients and combinations of ingredients for cosmetics and the marketing ban for all human health effects with the exception of repeated-dose toxicity, reproductive toxicity and toxicokinetics on 11 March 2009.

In view of the forthcoming marketing ban, Member States have essentially informed the Commission that they will use the market surveillance instruments in place in order to enforce the marketing ban. A number of Member States also planned to particularly draw the attention of market surveillance authorities to the ban through guidance notes and similar tools.

In conclusion, the Commission acknowledges that **Member States have made efforts** to improve the availability of data and that the overall availability has improved. However, the Commission continues to be concerned about the **accuracy of the figures being reported**, and this concern is shared by certain Member States.

The main issue relates to **multiple use substances**. Some Member States, when mentioning that no animal testing has been performed for cosmetic ingredients, 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. Legislation stipulating that animal testing must be authorised in order to be lawfully performed appears a useful tool to determine the purpose of testing.

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

2000/0077(COD) - 15/01/2003 - Text adopted by Parliament, 3rd reading

The European Parliament approved the joint text of the Conciliation Committee. (Please refer to the document dated 03/12/02).

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

2000/0077(COD) - 29/04/2005 - Follow-up document

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.

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

2000/0077(COD) - 30/05/2001

The Council examined the proposal for the directive amending for the seventh time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. Having noted that there was no qualified majority in favour of this draft directive at this stage, the Council requested the Permanent Representatives Committee to pursue the examination of this file with a view to enabling the Council to reach agreement on it at a forthcoming session.

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

2000/0077(COD) - 03/04/2001 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted the report of Dagmar ROTH-BEHRENDT (PES, D). The debate started with an amendment by the EPP-ED group calling for the rejection of the whole Commission proposal (the seventh amendment to the cosmetics directive). However, this proposed amendment was rejected by 132: 191 : 8 votes. The amendments adopted in plenary called for not only the proposed testing ban, but also to preserve the ban on marketing. The ban should come into force immediately for ingredients where other validated testing methods exist, and in any case five years after the adoption of the directive. Another amendment asked for manufacturers who have carried out animal tests after the date of implementation to label the packaging with "Tested on animals" in easily legible lettering covering at least 20 % of the total surface area (for other amendments, please refer to the previous text).

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

2000/0077(COD) - 13/09/2011 - Follow-up document

In accordance with the requirements of Council Directive 76/768/EEC (Cosmetics Directive), the Commission presents the ninth report on the development, validation and legal acceptance of alternative methods to animal tests in the field of cosmetics. The purpose of the report is to:

- presents the data on the number and type of experiments on animals relating to cosmetic products in 2009, as well as progress made in the development, validation and acceptance of alternative methods to animal testing in the Union and internationally;
- inform the European Parliament and the Council that for technical reasons **full replacement of the animal tests covered by the 2013 deadline will not be achieved** before 11 March 2013.

It is recalled that the Cosmetics Directive requires the Commission to put forward a legislative proposal in accordance with Article 251 of the Treaty if the Commission analysis concludes by 2011 that for technical reasons one or more tests referred to in the Directive will not be developed and validated by 2013. The report does not prejudice the decision on how to address the lack of non-animal tests.

Compliance with the testing and marketing ban: the report notes that the Cosmetics Directive provides for a phasing-out of animal testing for cosmetics. A ban on animal testing of finished cosmetic products has been in force since September 2004 and a testing ban on ingredients or combinations of ingredients since March 2009. As from March 2009, it is also prohibited in the EU to market cosmetic products and their ingredients which have been tested on animals, irrespective of the origin of these products. This marketing ban applies to all but the most complex human health effects to be tested to demonstrate the safety of cosmetic products (repeated-dose toxicity including skin sensitisation and carcinogenicity, reproductive toxicity and toxicokinetics), for which the legislator extended the deadline to March 2013.

Animal testing data: given that the testing ban for ingredients applies as of 11 March 2009, testing in line with the Cosmetics Directive was only possible between 1 January 2009 and 10 March 2009. In total, 344 animals were used in 2009 for tests carried out in relation to the safety of cosmetic ingredients. In the previous years, when testing was allowed during the entire period, the figures were 1.818 for 2007 and 1.510 for 2008.

According to the information received, cosmetic ingredients have only been tested on animals in Spain and France. These Member States provided detailed information, including the testing period, the toxicological endpoint, species of animals used for experiments and number of animals used for testing. The other 25 Member States reported that no such animal tests were performed in their territory in 2009.

Progress on alternative methods in the EU: endpoints falling under the 2009 deadline of the marketing ban are: skin corrosivity; skin irritation; dermal absorption; mutagenicity/genotoxicity; phototoxicity; acute toxicity; and eye irritation. .

Full replacement alternative methods are currently available for skin corrosivity, skin irritation, dermal absorption, and phototoxicity, while eye irritation, acute toxicity and mutagenicity/genotoxicity are only covered by partial replacement methods. For these endpoints the marketing and the testing ban apply fully. For mutagenicity/genotoxicity existing methods are being improved. For the two remaining endpoints, “eye irritation” and “acute toxicity”, progress is being made.

Accordingly, the report states that the **overall conclusion and outlook is positive** when looking at the developments since 2003, when the current provisions were introduced. Animal testing for cosmetics purposes in the EU is once and for all a thing of the past. The testing ban is well implemented and controlled.

Regarding the 2013 deadline, validated alternative methods will not be available for any of the three toxicological endpoints before the marketing ban enters into force. Thanks to serious efforts, a number of partial replacement methods are available. However, full replacement does not seem possible yet.

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.

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).