EXPLANATORY STATEMENT

Background

1. On 6 April 2000 the Commission presented a proposal for a directive approximating the Member States' legislation on cosmetic products. This had the effect of amending Directive 76/768/EC on cosmetic products for the seventh time. The main purpose of this seventh amendment is to introduce a lasting and definitive ban on testing cosmetic products on animals in the European Union.

2. On 3 April 2001 Parliament adopted its position at first reading. The Council adopted its common position on 14 May 2002. At the second reading, on 2 June 2002, Parliament adopted 31 amendments to the Council common position. The Council was unable to accept these amendments, which meant that the conciliation committee was convened.

Conciliation

3. Parliament's delegation to the conciliation committee held its constituent meeting on 9 July 2002 and its members instructed the chairman, Mr Dimitrakopoulos, the chairman of the committee responsible, Ms Jackson, and the rapporteur, Ms Roth-Behrendt, to enter into informal negotiations with the Council.

4. In the course of a total of three trilogue meetings (on 10 July, 3 September and 17 September) provisional agreement on seven of Parliament's 31 amendments was reached. However, these seven amendments did not concern the central issues, but, essentially, a few recitals and the Commission's duty to report. On the main issue – the ban on testing and marketing animal-tested products –, although a number of compromise texts by the Council Presidency were discussed, no significant agreement was reached.

5. The first meeting of the conciliation committee was held on the afternoon of 22 October 2002 under the joint chairmanship of Mr Giorgos Dimitrakopoulos, vice-chairman, and Mr Schmidt, Danish Minister for the Environment. The discussion in this meeting concentrated on the testing and marketing ban called for by the European Parliament. A compromise text presented by the Council was rejected by all the members of the Parliament delegation. In the ensuing discussion the minimum requirements for a possible compromise were confirmed. They covered the following points in particular:

   - setting a clear timetable for entry into force of the testing and marketing ban;
   - any exceptions to this timetable were to be determined through the legislative process, with the full involvement of the European Parliament (and not by comitology);
   - validation of alternative testing methods at Community level (and not in the framework of the OECD).

Following the meeting of the conciliation committee a press conference was held, in which Mr Dimitrakopoulos and Ms Dagmar Roth-Behrendt commented on Parliament's priorities and the differences between these and the Council and Commission positions.

6. A further trilogue meeting was held on 22 October 2002, at which Parliament's negotiators presented a comprehensive compromise text on the testing and marketing ban. The text was based on the principles set out above and covered all the important issues, such as the timetable, exceptions and revision.

7. At the second meeting of the conciliation committee on the evening of 6 November 2002, at four o'clock in the morning after more than twelve hours of negotiation a compromise was reached covering all the unresolved issues.

8. The following components of the agreements deserve particular mention:

- Testing and marketing ban

The European Parliament has called repeatedly for a ban on animal testing of cosmetic products. A marketing ban had already been introduced with the sixth amendment of the cosmetics directive. However, since there were no satisfactory alternatives available that did not involve experiments on animals, the marketing ban was postponed several times by the Commission, until it finally came into force in June 2002.

Against this background the European Parliament already took the view at the first reading that the combination of a testing ban and a marketing ban was the most suitable way of stimulating the development of alternative testing methods. In order for these bans to be effective, both needed to be worked out in detail, i.e. with a set cut-off date and no exceptions. This would stimulate companies in the European Union to develop alternatives within a short period. In addition, the marketing ban would prevent animal experimentation from being shifted to third countries.

The compromise on the testing and marketing ban arrived at in the conciliation committee included the following:

- the testing and marketing ban will enter into effect six years after the directive enters into force for the majority of testing methods. The Commission will draw up timetables for gradual ending of the various kinds of tests by 2009 at the latest.

- an implementation period of 10 years (i.e. by 2013) is provided for ending three categories of test for which alternatives have still not been tested. If the Commission ascertains at the latest two years before the implementation time has elapsed that there has been a delay in developing and validating these tests, a possible extension can only be decided using the codecision process, with full involvement of the European Parliament.

- validation and confirmation of alternative testing methods will be undertaken

at Community level, with developments in the OECD being taken into consideration. In its common position the Council named the OECD as the place of validation. However, since the OECD process is based on the principle of unanimity, delays could be caused if a single OECD member blocked this acceptance.

- Storage life of product

Parliament considered clear indication of the storage life of cosmetic products to be of central importance. For this reason it was decided in the conciliation committee that, firstly, the best-before date should be indicated on the package. Secondly, in the case of cosmetic products with long lives consumers must also be told how long they could go on using the opened product without endangering their health. For this purpose a suitable symbol showing an open jar of cream will be used on labelling. This symbol will be incorporated in the annex to the directive using comitology.

- Indication of allergenic ingredients

The annex to Directive 67/548/EC[1] defines a list of carcinogenic, mutagenic or reproductively toxic substances and classifies them, depending on their risk potential, in categories 1, 2 and 3. In the view of Parliament, all of these substances should also be banned from use in cosmetics, in accordance with the precautionary principle. The compromise reached in the conciliation committee provides that category-1 and -2 substances which are carcinogenic, mutagenic or toxic for reproduction should be entirely banned from use in cosmetic products. Substances in category 3, and hence posing a lower risk potential, can only be used in cosmetic products if they have been evaluated by the relevant scientific committee and found to present no risk.

9. A further trilogue meeting was held on 13 November 2002 for the purpose of making technical adjustments to the recitals to bring them into line with the agreement reached, and on 20 November the Parliament delegation adopted the compromise agreement unanimously.

Conclusions

The European Parliament delegation is satisfied with the agreement reached, as it goes far beyond what was possible before the second reading. The establishment of the testing and marketing principle represents a substantial improvement on the common position. The delegation wishes to thank the Danish Council Presidency and the Commission for the constructive cooperation. It recommends to Parliament that it adopt the attached common position.

[1] Directive of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

EUROPARL

Find...

Daily Notebook : 15-01-2003

Editors: Roy Worsley
Richard Freedman
Tel. 74751/73785

Secretariat: Sarah Donohoe
Annette Kronlins

Close: 5 pm

Codes for parliamentary procedures

A series	Reports and recommendations
B series	Resolutions and oral questions
C series	Documents of other institutions
*	Consultation procedure
**I	Cooperation procedure (1st reading)
**II	Cooperation procedure (2nd reading)
***	Assent procedure
***I	Codecision procedure (1st reading)
***II	Codecision procedure (2nd reading)
***III	Codecision procedure (3rd reading)

Abbreviations

EPP/ED	European People's Party/European Democrats
PES	Party of European Socialists
ELDR	European Liberal, Democratic and Reformist Group
Greens/EFA	Green Group in the European Parliament
EUL/NGL	Confederal Group of the European United Left-Nordic Green Left
UEN	Union for Europe of the Nations
EDD	The Europe of Democracies and Diversities Group
IND	Independents

B	Belgium	**F**	France	**A**	Austria

Votes

At Long Last - Agreement on Cosmetic Products

Dagmar ROTH-BEHRENDT (PES, D)
Report on the joint text approved by the Conciliation Committee for a European Parliament and Council directive 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 cosmetic products
(PE-CONS 3668/2002 - C5-0557/2002 - 2000/0077(COD))
Doc.: A5-0001/2003
Procedure : Codecision procedure (3rd reading)
Debate : 15.01.2003
Vote: 15.01.2003

Vote

Parliament approved a conciliation agreement between Parliament and Council on cosmetics. The agreement means that the ban on animal testing and sales would start immediately where alternative non-animal tests are available. This will be followed by a complete ban six years after the directive enters into force, thereby ending the use of animals in the testing of cosmetic products but without jeopardising consumer safety since alternative ways of testing will have to be developed in the transition period to replace animal testing. The other main points of the agreement reached in conciliation can be summarised as follows:

A test and marketing ban will come into effect **six** years after the entry into force of the directive, i.e. 2009, for the large majority of tests;

For those three tests for which there are no alternatives yet under consideration a marketing ban shall come into effect within **ten** years after entry into force, i.e. 2013;

Any prolongation of the 2013 deadline will be decided by **codecision** between Council and Parliament;
Alternative methods of testing shall be validated and adopted at the Community level "with due regard to the development of validation within the OECD";

A ban on certain substances classified as carcinogenic, mutagenic or toxic for reproduction;

The qualitative and quantitative composition of the cosmetic product as well as information on undesirable effects on human health should be easily accessible to the public; and

Enhanced labelling requirements for substances which may cause allergic reactions.

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5433/03 (Presse 13)

2481st Council meeting

- AGRICULTURE AND FISHERIES -

Brussels, 27 and 28 January 2003

President : **Mr Georgios DRYS**

Minister for Agriculture of the Hellenic Republic

Internet: http://ue.eu.int/
E-mail: press.office@consilium.eu.int

INTERNAL MARKET

Cosmetics – Ban on the use of animal experiments* - public deliberation
(Doc. 5295/03 Add1 Cor1 - doc. 3668/02)

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.

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 of its international obligations. It aims at promoting the development of alternative testing methods, and ensuring that these methods are effectively used when they exist and that they are scientifically validated.

The Directive has four main objectives:

- to prohibit in the Community the testing of cosmetic products on animals;
- to prohibit in the Community 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 if necessary 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 an existing cosmetic ingredient.

DIRECTIVE 2003/15/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 February 2003

amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty in the light of the joint text approved by the Conciliation Committee on 3 December 2002 [3],

Whereas:

(1) Council Directive 76/768/EEC [4] has comprehensively harmonised the national laws relating to cosmetic products and has as its main objective the protection of public health. To this end, it continues to be indispensable to carry out certain toxicological tests to evaluate the safety of cosmetic products.

(2) The Protocol on protection and welfare of animals annexed by the Treaty of Amsterdam to the Treaty establishing the European Community provides that the Community and the Member States are to pay full regard to the welfare requirements of animals in the implementation of Community policies, in particular with regard to the internal market.

(3) 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 [5] has established common rules for the use of animals for experimental purposes within the Community and laid down the conditions under which such experiments must be carried out in the territory of the Member States. In particular, Article 7 of that Directive requires that animal experiments be replaced by alternative methods, when such methods exist and are scientifically satisfactory. In order to facilitate the development and use of alternative methods in the cosmetic sector which do not use live animals, specific provisions have been introduced by Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products [6].

However, these provisions concern only alternative methods which do not use animals and they do not take account of alternative methods developed in order to reduce the number of animals used for experiments or to reduce their suffering. Therefore, in order to afford optimal protection to animals used for testing cosmetic products pending implementation of the prohibition of animal tests for cosmetic products and the marketing of animal-tested cosmetic products in the Community, these provisions should be amended in order to provide for the systematic use of alternative methods, which reduce the number of animals used or reduce the suffering caused, in those cases where full replacement alternatives are not yet available, as provided by Article 7(2) and (3) of Directive 86/609/EEC, when these methods offer consumers a level of protection equivalent to that of the conventional methods which they are intended to replace.

(4) In accordance with Directive 86/609/EEC and with Directive 93/35/EEC, it is essential that the aim of abolishing animal experiments for testing cosmetic products be pursued and that the prohibition of such experiments becomes effective in the territory of the Member States. In order to ensure that this prohibition is fully implemented, it may be necessary for the Commission to bring forward further proposals to amend Directive 86/609/EEC.

(5) Currently, only alternative methods which are scientifically validated by the European Centre for the Validation of Alternative Methods (ECVAM) or the Organisation for Economic Cooperation and Development (OECD) and applicable to the whole chemical sector are systematically adopted at Community level. However, the safety of cosmetic products and their ingredients may be ensured through the use of alternative methods which are not necessarily applicable to all uses of chemical ingredients. Therefore, the use of such methods by the whole cosmetic industry should be promoted and their adoption at Community level ensured, when such methods offer an equivalent level of protection to consumers.

[1] OJ C 311 E, 31.10.2000, p. 134 and OJ C 51 E, 26.2.2002, p. 385.
[2] OJ C 367, 20.12.2000, p. 1.
[3] Opinion of the European Parliament of 3 April 2001 (OJ C 21 E, 24.1.2002, p. 24), Council Common Position of 14 February 2002 (OJ C 113 E, 14.5.2002, p. 109) and Decision of the European Parliament of 11 June 2002 (not yet published in the Official Journal). Decision of the European Parliament of 15 January 2003 and Decision of the Council of 27 February 2003.
[4] OJ L 262, 27.7.1976, p. 169. Directive as last amended by Commission Directive 2002/34/EC (OJ L 102, 18.4.2002, p. 19).
[5] OJ L 358, 18.12.1986, p. 1.
[6] OJ L 151, 23.6.1993, p. 32.

(6) The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. Provisions prohibiting animal testing of finished cosmetic products can therefore be incorporated into Directive 76/768/EEC. The Commission should establish guidelines in order to facilitate the application, in particular by small and medium-sized enterprises, of methods which do not involve the use of animals for assessing the safety of finished cosmetic products.

(7) It will gradually become possible to ensure the safety of ingredients used in cosmetic products by using non-animal alternative methods validated at Community level, or approved as being scientifically validated, by ECVAM and with due regard to the development of validation within the OECD. After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) as regards the applicability of the validated alternative methods to the field of cosmetic products, the Commission should immediately publish the validated or approved methods recognised as being applicable to such ingredients. In order to achieve the highest possible degree of animal protection, a deadline must be set for the introduction of a definitive prohibition.

(8) The Commission should establish timetables of deadlines for the prohibition of the marketing of cosmetic products, the final formulation, ingredients or combinations of ingredients which have been tested on animals, and for the prohibition of each test currently carried out using animals, up to a maximum of six years from the date of entry into force of this Directive. In view, however, of the fact that there are no alternatives yet under consideration for tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, it is appropriate for the maximum deadline for the prohibition of the marketing of cosmetic products for which those tests are used to be 10 years from the date of entry into force of this Directive. On the basis of annual reports, the Commission should be authorised to adapt the timetables within the respective abovementioned maximum time limits.

(9) Better coordination of resources at Community level will contribute to increasing the scientific knowledge indispensable for the development of alternative methods. It is essential, for this purpose, that the Community continue and increase its efforts and take the measures necessary for the promotion of research and the development of new non-animal alternative methods, in particular within its Sixth Framework Programme as set out in Decision No 1513/EC/2002 of the European Parliament and of the Council [1].

[1] OJ L 232, 29.8.2002, p. 1.

(10) The recognition by non-member countries of alternative methods developed in the Community should be encouraged. In order to achieve this objective, the Commission and the Member States should take all appropriate steps to facilitate acceptance of such methods by the OECD. The Commission should also endeavour, within the framework of European Community cooperation agreements, to obtain recognition of the results of safety tests carried out in the Community using alternative methods so as to ensure that the export of cosmetic products for which such methods have been used is not hindered and to prevent or avoid non-member countries requiring the repetition of such tests using animals.

(11) It should be possible to claim on a cosmetic product that no animal testing was carried out in relation to its development. The Commission, in consultation with the Member States, should develop guidelines to ensure that common criteria are applied in the use of claims and that an aligned understanding of the claims is reached, and in particular that such claims do not mislead the consumer. In developing such guidelines, the Commission must also take into account the views of the many small and medium-sized enterprises which make up the majority of the 'non-animal testing' producers, relevant non-governmental organisations, and the need of consumers to be able to make practical distinctions between products on the basis of animal testing criteria.

(12) The SCCNFP stated in its opinion of 25 September 2001 that substances classified pursuant 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 substances [2] as carcinogenic (except substances only carcinogenic by inhalation), mutagenic or toxic for reproduction, of category 1 or 2, and substances with similar potential, must not be intentionally added to cosmetic products, and that substances classified pursuant to Directive 67/548/EEC as carcinogenic, mutagenic or toxic for reproduction, of category 3, and substances with similar potential, must not be intentionally added to cosmetic products unless it can be demonstrated that their levels do not pose a threat to the health of the consumer.

(13) Given the special risks that substances classified as carcinogenic, mutagenic or toxic for reproduction, category 1, 2 and 3, pursuant to Directive 67/548/EEC may entail for human health, their use in cosmetic products should be prohibited. A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.

[2] OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).

(14) In order to improve the information provided to consumers, cosmetic products should bear more precise indications concerning their durability for use.

(15) Certain substances have been identified as an important cause of contact-allergy reactions in fragrance-sensitive consumers. In order to ensure that such consumers are adequately informed, it is therefore necessary to amend the provisions of Directive 76/768/EEC to require that the presence of these substances be mentioned in the list of ingredients. This information will improve the diagnosis of contact allergies among such consumers and will enable them to avoid the use of cosmetic products which they do not tolerate.

(16) A number of substances have been identified by the SCCNFP as likely to cause allergenic reactions and it will be necessary to restrict their use and/or impose certain conditions concerning them.

(17) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(18) The provisions of Directive 93/35/EEC banning the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals should be superseded by the provisions of this Directive. In the interests of legal certainty therefore it is appropriate to apply Article 1(1) of this Directive with effect from 1 July 2002, whilst fully respecting the principle of legitimate expectations,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC is hereby amended as follows:

1. Article 4(1)(i) shall be deleted;

2. the following Articles shall be inserted:

'*Article 4a*

1. Without prejudice to the general obligations deriving from Article 2, Member States shall prohibit:

(a) the marketing of cosmetic products where the final formulation, in order to meet the requirements of this Directive, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

(b) the marketing of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Directive, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

(c) the performance on their territory of animal testing of finished cosmetic products in order to meet the requirements of this Directive;

(d) the performance on their territory of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Directive, no later than the date on which such tests are required to be replaced by one or more validated alternative methods 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 substances (*)or in Annex IX to this Directive.

No later than 11 September 2004 the Commission shall, in accordance with the procedure referred to in Article 10(2) and after consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers (SCCNFP) establish the contents of Annex IX.

2. The Commission, after consultation of the SCCNFP and of the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, shall establish timetables for the implementation of the provisions under paragraph 1(a), (b) and (d), including deadlines for the phasing-out of the various tests. The timetables shall be made available to the public not later than 11 September 2004 and be sent to the European Parliament and the Council. The period for implementation shall be limited to a maximum of six years after the entry into force of Directive 2003/15/EC in relation to paragraph 1(a), (b) and (d).

(2.1) In relation to the tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of paragraph 1(a) and (b) shall be limited to a maximum of 10 years after the entry into force of Directive 2003/15/EC.

(2.2) The Commission shall study possible technical difficulties in complying with the ban in relation to tests, in particular those concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration. Information about the provisional and final results of these studies should form part of the yearly reports presented pursuant to Article 9.

[1] OJ L 184, 17.7.1999, p. 23.

On the basis of these annual reports, the timetables established in accordance with paragraph 2 may be adapted within a maximum time limit of six years as referred to in paragraph 2 or 10 years as referred to in paragraph 2.1 and after consultation of the entities referred to in paragraph 2.

(2.3) The Commission shall study progress and compliance with the deadlines as well as possible technical difficulties in complying with the ban. Information about the provisional and final results of the Commission studies should form part of the yearly reports presented pursuant to Article 9. If these studies conclude, at the latest two years prior to the end of the maximum period referred to in paragraph 2.1, that for technical reasons one or more tests referred to in paragraph 2.1 will not be developed and validated before the expiry of the period referred to in paragraph 2.1 it shall inform the European Parliament and the Council and shall put forward a legislative proposal in accordance with Article 251 of the Treaty.

(2.4) In exceptional circumstances where serious concerns arise as regards the safety of an existing cosmetic ingredient a Member State may request the Commission to grant a derogation from paragraph 1. The request shall contain an evaluation of the situation and indicate the measures necessary. On this basis, the Commission may, after consultation of the SCCNFP and by means of a reasoned decision, authorise the derogation in accordance with the procedure referred to in Article 10(2). This authorisation shall lay down the conditions associated with this derogation in terms of specific objectives, duration and reporting of the results.

A derogation shall only be granted if:

(a) the ingredient is in wide use and cannot be replaced by another ingredient able to perform a similar function;

(b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research Protocol proposed as the basis for the evaluation.

The decision on the authorisation, the conditions associated with it and the final result achieved shall be part of the annual report to be presented by the Commission in accordance with Article 9.

3. For the purposes of this Article:

(a) "finished cosmetic product" means the cosmetic product in its final formulation, as placed on the market and made available to the final consumer, or its prototype.

(b) "prototype" means a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed.

Article 4b

The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC shall be prohibited. To that end the Commission shall adopt the necessary measures in accordance with the procedure referred to in Article 10(2). A substance classified in category 3 may be used in cosmetics if the substance has been evaluated by the SCCNFP and found acceptable for use in cosmetic products.

(*) OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2001/59/EC (OJ L 225, 21.8.2001, p. 1).'

3. Article 6(1)(c) shall be replaced by the following:

'(c) The date of minimum durability shall be indicated by the words: "best used before the end of" followed by either:

— the date itself, or

— details of where it appears on the packaging.

The date shall be clearly expressed and shall consist of either the month and year or the day, month and year in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the date of durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product can be used without any harm to the consumer. This information shall be indicated by the symbol given in Annex VIIIa followed by the period (in months and/or years).';

4. Article 6(1)(g) shall be replaced by the following:

'(g) a list of ingredients in descending order of weight at the time they are added. That list shall be preceded by the word "ingredients". Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the packaging.

The following shall not, however, be regarded as ingredients:

— impurities in the raw materials used,

— subsidiary technical materials used in the preparation but not present in the final product,

— materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions.

Perfume and aromatic compositions and their raw materials shall be referred to by the word "perfume" or "aroma". However, the presence of substances, the mention of which is required under the column "other limitations and requirements" in Annex III, shall be indicated in the list irrespective of their function in the product.

Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.

Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV. For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the words "may contain" or the symbol "+/-" are added.

An ingredient must be identified by the common name referred to in Article 7(2) or, failing that, by one of the names referred to in Article 5a(2), first indent.

In accordance with the procedure referred to in Article 10(2), the Commission may adapt the criteria and conditions set out in Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products (*) under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.

(*) OJ L 140, 23.6.1995, p. 26.'

5. the last sentence of Article 6(3) shall be deleted and the following subparagraph shall be added:

'Furthermore, the manufacturer or the person responsible for placing the product on the Community market may take advantage, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the product, of the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products. Guidelines shall be adopted in accordance with the procedure referred to in Article 10(2) and published in the *Official Journal of the European Union*. The European Parliament shall receive copies of the draft measures submitted to the Committee.'

6. Article 7a(1)(d) shall be replaced by the following:

'(d) assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure. It shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. There shall be *inter alia* a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be available. In this connection, and when so requested for monitoring purposes, it shall be obliged to indicate the place so chosen to the monitoring authority or authorities concerned. In this case this information shall be easily accessible;'

7. the following point shall be added to Article 7a(1):

'(h) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of non-member countries.

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, Member States shall ensure that the information required under (a) and (f) shall be made easily accessible to the public by any appropriate means, including electronic means. The quantitative information required under (a) to be made publicly accessible shall be limited to dangerous substances covered by Directive 67/548/EEC.'

8. in Article 8(2) and Article 8a(3), the title 'Scientific Committee on Cosmetology' shall be replaced by 'Scientific Committee for Cosmetic Products and Non-Food Products intended for Consumers';

9. Articles 9 and 10 shall be replaced by the following:

'Article 9

Every year the Commission shall present a report to the European Parliament and the Council on:

(a) progress made in the development, validation and legal acceptance of alternative methods. The report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by 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 Commission shall in particular ensure the development, validation and legal acceptance of alternative test methods which do not use live animals;

(b) progress made by the Commission in its efforts to obtain acceptance by the OECD of alternative methods validated at Community level and recognition by non-member countries of the results of the safety tests carried out in the Community using alternative methods, in particular within the framework of cooperation agreements between the Community and these countries;

(c) the manner in which the specific needs of small and medium-sized enterprises have been taken into account.

Article 10

1. The Commission shall be assisted by the Standing Committee on Cosmetic Products.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

(*) OJ L 358, 18.12.1986, p. 1.'

10. the following shall be added to Annex III, Part I:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
'67	Amyl cinnamal (CAS No 122-40-7)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
68	Benzyl alcohol (CAS No 100-51-6)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
69	Cinnamyl alcohol (CAS No 104-54-1)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
70	Citral (CAS No 5392-40-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
71	Eugenol (CAS No 97-53-0)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

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72	Hydroxy-citronellal (CAS No 107-75-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
73	Isoeugenol (CAS No 97-54-1)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
74	Amylcin namyl alcohol (CAS No 101-85-9)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
75	Benzyl salicylate (CAS No 118-58-1)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
76	Cinnamal (CAS No 104-55-2)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
77	Coumarin (CAS No 91-64-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
78	Geraniol (CAS No 106-24-1)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

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79	Hydroxy-methylpentyl-cyclohexenecarboxaldehyde (CAS No 31906-04-4)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
80	Anisyl alcohol (CAS No 105-13-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
81	Benzyl cinnamate (CAS No 103-41-3)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
82	Farnesol (CAS No 4602-84-0)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
83	2-(4-tert-Butylbenzyl) propionaldehyde (CAS No 80-54-6)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
84	Linalool (CAS No 78-70-6)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
85	Benzyl benzoate (CAS No 120-51-4)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

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86	Citronellol (CAS No 106-22-9)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
87	Hexyl cinnam-aldehyde (CAS No 101-86-0)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
88	d-Limonene (CAS No 5989-27-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
89	Methyl heptin carbonate (CAS No 111-12-6)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
90	3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one (CAS No 127-51-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
91	Oak moss extract (CAS No 90028-68-5)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	
92	Treemoss extract (CAS No 90028-67-4)			The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products	

11. an Annex VIIIa shall be added, consisting of a symbol representing an open cream jar. The Commission shall, in accordance with the procedure referred to in Article 10(2) establish this symbol by 11 September 2003 at the latest.

Article 2

For the application of Article 1, point 3 as regards Article 6(1)(c), third subparagraph of Directive 76/768/EEC as well as of Article 1, point 4 as regards Article 6(1)(g), third subparagraph of Directive 76/768/EEC:

Member States shall take all necessary measures to ensure that from 11 March 2005 neither manufacturers nor importers established within the Community place on the market cosmetic products which fail to comply with this Directive.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 11 September 2004. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 4

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

By way of derogation from Article 3, Article 1, point (1) shall apply from 1 July 2002.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 27 February 2003.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	M. CHRISOCHOÏDIS

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化粧品に関係する加盟各国の法律の統一化に関する理事会指令 76/768/EEC を修正する 2003 年 2 月 27 日付け欧州議会および理事会指令 2003/15/EC
（EEA に関連する条文）

欧州共同体設立条約、特にその第 95 条に鑑み、
欧州委員会の提案[1]を考慮し、
欧州経済社会委員会の見解[2]を考慮し、
欧州共同体設立条約第 251 条に定められた手順に従い調停委員会が 2002 年 12 月 3 日に承認した共同条文[3]に照らし、

欧州議会と欧州連合理事会は、以下の事項を考慮に入れて、本指令を採択した。

(1)理事会指令 76/768/EEC[4]は化粧品に関する国内法の包括的調整を定めており、公衆の健康の保護を主要目的とする。この目的を達するには、一定の毒性試験を行い化粧品の安全性を評価することが今後とも不可欠である。

(2)アムステルダム条約により欧州共同体設立条約に付け加えられた動物の保護および福祉に関するプロトコールは、欧州共同体および加盟各国が欧州共同体政策、特に域内市場に関する政策を実施する際には動物の福祉に関する要求事項を十分に顧慮することを規定している。

(3)実験または他の科学的目的で使用する動物の保護に関する加盟各国の法律、規制および行政命令の統一化に関する 1986 年 11 月 24 日付け理事会指令 86/609/EEC[5]により欧州共同体域内における実験目的での動物使用に関する共通規則が確立され、加盟各国国内においてかかる実験を実施する際に従うべき条件が規定された。特に同指令の第 7 条は、動物実験の代替法が存在し、その方法が科学的に満足なものである場合には、動物実験に代えて代替法を使用することを求めている。化粧品部門において生きた動物を使用しない代替法の開発と使用を促進するために、化粧品に関する加盟各国の法律の統一化に関する指令 76/768/EEC の 6 回目の修正となる 1993 年 6 月 14 日付け理事会指令 93/35/EEC[6]により明確な規定が導入された。
ただし、上記の規定は動物を使用しない代替法のみに関するものであり、実験に使用する動物数を減らすか動物が受ける苦痛を低減させるために開発された代替法は考慮に入れられていない。従って、欧州共同体域内における動物を使用した化粧品試験の禁止および動物で試験した化粧品の販売の禁止が実施されるまでの期間に化粧品の試験に使用される動物の保護を最適に行えるように、指令 86/609/EEC の第

7 条(2)項および(3)項に規定する代替法への完全な移行が未だ可能でない場合には、代替法への移行が予定されている従来法と同等のレベルで消費者を保護できることを条件として、試験に使用する動物数を減らすか動物が受ける苦痛を低減させる方法を組織的に使用できるように上記の規定を修正する必要がある。

(4)指令 86/609/EEC および指令 93/35/EEC に基づき、化粧品試験のための動物実験を廃止するという目標を追及し、加盟各国国内においてかかる実験の禁止を実施することが肝要である。この禁止の完全実施を保証するためには、指令 86/609/EEC を修正する提案を欧州委員会がさらに提示することが必要となろう。

(5)現在のところ、欧州代替法バリデーションセンター（ECVAM）または経済協力開発機構（OECD）により科学的バリデーションが行われ、かつ化学部門全体に適用できる代替法のみが共同体レベルで組織的に採択されている。しかし、化粧品およびその成分の安全性は、化学成分のすべての用途には適用できない代替法でも保証できる。従って、このような代替法で同等レベルの消費者保護を行える場合には、化粧品業界全体における代替法の使用を促進し、共同体レベルでの採択を保証する必要がある。

(6)化粧品最終製品の安全性は、製品に含まれる成分の安全性に関する知見があれば、それに基づいて保証できる。従って、化粧品最終製品の動物試験を禁止する規定を指令 76/768/EEC に盛り込める。中小企業を主な標的として動物を使用しない方法による化粧品最終製品の安全性評価を促進するために、欧州委員会はガイドラインを設定する必要がある。

(7)共同体レベルのバリデーションが完了した動物を使用しない代替法、またはOECD 内でのバリデーションの進展を十分考慮した上で科学的バリデーションで妥当性が検証された方法として ECVAN が承認した動物を使用しない代替法により化粧品に使用される成分の安全性を保証することが次第に可能になると予測される。欧州委員会は、バリデーション済み代替法の化粧品分野における適用性に関して消費者向け化粧品および非食品製品に関する科学委員会（SCCNFP）と協議を行った後、化粧品成分への適用が可能とみなされたバリデーション済みの方法または承認された方法を直ちに発表する必要がある。できる限り高水準の動物保護を実現するために、完全禁止の導入期限を設定しなければならない。

(8)欧州委員会は、本指令の発効日から 6 年後を最終期限として、動物試験が行わ