Food Products intended for Consumers, establish the contents of Annex IX referred to in paragraph (1)(d). The alternative methods included in Annex IX shall offer consumers a level of protection equivalent to the animal tests they are intended to replace. ***When proceeding with the technical adaptation of the said Annex IX, in accordance with Article 8(2), the Commission shall ensure that only alternative methods which do not involve the use of animals are employed, when such methods exist and offer an equivalent level of protection to consumers, and, failing that, the use of reduction methods limiting significantly the number of animals used or the use of refinement methods reducing significantly animal suffering.***	***Ingredients found to be unsafe or only safe to be used under specific conditions shall be listed in a separate annex to the Directive, which shall include a reference to the location of the test data and any specific conditions of use which shall apply.***

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

** ***18 months after the entry into force of this Directive.***

Amendment 17
ARTICLE 1, POINT 2
Article 4a, paragraph 3 (Directive 76/768/EEC)

3. For the purpose 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. ***(b) "alternative method" means a method which does not entail the use of animals or, failing that, a method which reduces significantly the number of animals used, or a method which reduces significantly animal suffering;*** ***(c) "animal" means any live non-human vertebrate, including free-living larval forms and/or reproducing larval forms, but excluding foetal or embryonic forms.***	3. For the purpose of this Article, "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.***

Amendment 18
ARTICLE 1, POINT 2
Article 4b (Directive 76/768/EEC)

Article 4b	***Deleted***
The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 1 or 2, under Annex I to Directive 67/548/EEC shall, without delay, be subject to a risk evaluation by the Commission. Measures which are deemed necessary, following this evaluation, shall be adopted in accordance with the regulatory procedure referred to in Article 10(2), after consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers	

Amendment 19
ARTICLE 1, POINT 2 a (new)
Article 5a, paragraph 2, indent 1 a (new) (Directive 76/768/EEC)

	2a) In Article 5a(2) the following indent shall be added after the first indent:
	"- the information required under Article 7a(1) (a), (b), (d), (f), (g) and (ga). The quantitative information pursuant to Article 7a(1)(a) that is to be included in the public inventory shall be limited to dangerous substances pursuant to Directive 67/548/EEC,"

Amendment 20
ARTICLE 1, POINT 3
Article 6, paragraph 1, point c, subparagraphs 2 and 3 (Directive 76/768/EEC)

The date of minimum durability shall be indicated by the ***date itself followed by a symbol to be decided upon in accordance with the regulatory procedure referred to in Article 10(2).*** The date shall be clearly expressed and shall consist of either the month and year or the day, month and year in that order.	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. ***Indication of the date of durability shall not be mandatory for cosmetic products with a***

	minimum durability of more than 30 months.
If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.	If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability. ***For cosmetic products with a minimum durability of more than 30 months, 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 month, year).***

Amendment 21
ARTICLE 1, POINT 4
Article 6, paragraph 1, point (g), subparagraph 3 (Directive 76/768/EEC)

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.	***Deleted***

Amendment 22
ARTICLE 1, POINT 4 a (new)
Article 6, paragraph 1, subparagraph 1 a (new) (Directive 76/768/EEC)

	4a) In Article 6(1) the following subparagraph shall be added: "Where a manufacturer has carried out or commissioned animal tests, after the date of implementation of the animal test ban established in Article 4a(1), on the finished product, its prototype or any of its ingredients, or has purchased the finished product or its ingredients from a third party who has carried out such tests, the product may only be marketed if the packaging and container bear the indication "Tested on animals" in indelible, easily legible lettering. The information contained in (g) may, however, be indicated on the packaging

	alone or as otherwise prescribed in (g). The information must be displayed on the most prominent and visible surface of the container and packaging and shall not be less than 20 percent of the total surface area."

Amendment 23
ARTICLE 1, POINT 5
Article 6, paragraph 3, last sentence (Directive 76/768/EEC)

Guidelines shall be adopted in accordance with the regulatory procedure referred to in Article 10(2) regarding the information which a manufacturer or person responsible for placing the product on the market may specify on the products or in any document, leaflet, label, tape or card accompanying or referring to them, indicating that no animal tests have been carried out for their development or manufacture.	***Furthermore, the manufacturer or the person responsible for placing the product on the Community market may only 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 provided 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, nor knowingly used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products. The Commission, in consultation with the Member States and the European Parliament, shall for this purpose publish guidelines on the implementation of this principle.***

Amendment 24
ARTICLE 1, POINT 6
Article 7a, paragraph 1, point (d), subparagraph 2 (Directive 76/768/EEC)

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/authorities concerned;	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/authorities concerned. ***In this case the information shall be easily accessible within the European Union***;

Amendment 25
ARTICLE 1, POINT 6 a (new)
Article 7a, paragraph 1, point (g a) (new) (Directive 76/768/EEC)

6a) In Article 7a(1) the following point (ga) shall be added:
"(ga) data on any animal testing performed by the manufacturer, its 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 third countries."

Amendment 26
ARTICLE 1, POINT 6 b (new)
Article 7a, paragraph 1a (new) (Directive 76/768/EEC)

6b) In Article 7a the following paragraph 1a shall be added:
"1a. The information required under paragraph 1(a), (b), (d), (f), (g) and (ga) shall be communicated both to the competent authorities of the Member State and to the Commission to allow its inclusion in the inventory to be drawn up by the Commission pursuant to Article 5a. The quantitative information pursuant to paragraph 1(a) that is to be communicated shall be limited to the dangerous substances pursuant to Directive 67/548/EEC."

Amendment 27
ARTICLE 1, POINT 8
Article 9 (Directive 76/768/EEC)

Every ***three years*** 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, ***as defined in Article 4a(3)(b)***. The report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals ***in order to comply with the requirements of this Directive.***	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

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;	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 ***to facilitate the*** recognition by third 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;	(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 third 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, ***in particular for the implementation of the provisions of Article 4a.***	(c) the manner in which the specific needs of small and medium-sized enterprises have been taken into account.

Amendment 28
ARTICLE 1, POINT 8 a (new)
Annex III, Part I (Directive 76/768/EEC)

8a) The following is added to Annex III, Part I:

Reference number	*Substance*	*RESTRICTIONS*			*Conditions of use and warnings which must be printed in 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*
	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*	
	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*	
	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*	
	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*	
	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*	
	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*	
	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*	
	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*	
	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*	

	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*	
	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*	
	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*	
	Hydroxy-methylpentylcyclohexene carboxaldehyd (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*	
	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*	
	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*	
	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*	
	2-(4-tert-Butylbenzyl) propionald-hyd (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*	
	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*	
	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*	
	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*	
	Hexyl cinnam-aldehyd (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*	

	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*	
	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*	
	3-Methyl-4-(2,6,6-tri-methyl-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*	
	Oak moss and treemoss extract (CAS No 90028-68-55)			*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*	
	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*	

Amendment 29
ARTICLE 1, POINT 8 b (new)
Annex VIIIa (new) (Directive 76/768/EEC)

8b) An Annex VIIIa is added, consisting of a symbol representing an open cream jar.

Brussels, 26 August 2002 (29.08)
11584/02 (Presse 255)
(OR.fr)

DECISIONS UNDER THE WRITTEN PROCEDURE

Conciliation on codecision items

The Council today decided under the written procedure that it would not accept all of the amendments adopted at second reading by the European Parliament and would therefore open the conciliation procedure for the following draft Directives:

- **Internal market**
  - proposal amending Directive 76/768/EEC on cosmetic products;
- **Health**
  - proposal for a Directive on the collection, testing, processing, storage and distribution of human blood and blood components.

The Conciliation Committee will be convened, in accordance with Article 251(3) of the Treaty, with a view to agreeing on joint texts for these items, which will then be submitted to the European Parliament and the Council for adoption.

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

EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

Brussels, 8 January 2003

2000/0077(COD)
C5-0557/2002

PE-CONS 3668/02

ECO 345
CODEC 1458

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject : 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

Joint text

approved by the Conciliation Committee

provided for in Article 251(4) of the EC Treaty

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

of

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 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],

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1 OJ C 311 E, 31.10.2000, p. 134 and OJ C 51 E, 26.02.2002, 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, 24.01.2002, 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 ..... and Decision of the Council of ..... .

Whereas:

(1) Council Directive 76/768/EEC [1] 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 [2] 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 [3].

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1 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).

2 OJ L 358, 18.12.1986, p. 1.

3 OJ L 151, 23.6.1993, p. 32.

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.

(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 of which have been tested on animals, and for the prohibition of each test currently carried out using animals, up to a maximum of 6 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 2002/1513/EC of the European Parliament and of the Council [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.

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

(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 [1] 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.

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

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

(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:

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1 OJ L 184, 17.7.1999, p. 23.

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 ..... + 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 period for implementation shall be limited to a maximum of 6 years after the entry into force of Directive 2003/...../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/..../EC.

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* OJ L 196, 16.8.1967, p. 1.

\+ 18 months after the entry into force of this Directive.