- 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)."

6) 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***.

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 terms "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 regulatory 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.";

7) ***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 point (g) may, however, be indicated on the packaging alone or as otherwise prescribed in point (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."

8) the last sentence of Article 6(3) shall be replaced by the following subparagraph:

"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 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."

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

10) in Article 7a(1) the following point (h) shall be added:

"(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 third countries."

11) in Article 7a the following paragraph 1a shall be added:

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

12) 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";

13) 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 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.***

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."

14) 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*	

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

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before ..... *. 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.

---

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

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 3

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

By way of derogation from Article 2, Article 1, point (1) shall apply from the date referred to in the first paragraph of this Article.

Article 4

This Directive is addressed to the Member States.

Done at ,

For the European Parliament

The President

For the Council

The President

COUNCIL OF
THE EUROPEAN UNION

Brussels, 17 June 2002

9843/02

Interinstitutional File:
2000/0077 (COD)

CODEC 743
ECO 207

INFORMATION NOTE

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
– Outcome of the European Parliament's second reading
(Strasbourg, 10 to 13 June 2002)

I. INTRODUCTION

The Rapporteur, Mrs Dagmar ROTH-BEHRENDT (PSE – D) put forward a recommendation for 2nd reading including 29 amendments to the Council's common position, on behalf of the Committee on the Environment, Public Health and Consumer Policy [1]. The political groups tabled 4 additional amendments to the Plenary vote.

[1] With a view to avoiding conciliation, informal contacts between the representatives of the three Institutions took place before the EP Plenary vote and the Council WP considered the EP draft amendments. A compromise agreement on 2nd reading was not possible since the Council and the Commission were not in a position to accept at that stage the key elements of the Rapporteur's proposal for an overall compromise package.

At the Plenary debate, the Rapporteur declared that the proposed amendments aimed at reinstating European Parliament's 1st reading in a series of key areas:

- a marketing ban for cosmetics tested on animals with a cut-off date (5 years),
- a testing ban,
- labelling of products tested on animals,
- ban on dangerous substances in cosmetics,
- indication of the durability of the products once opened,
- information and reporting requirements.

The political groups supported the Rapporteur's proposals and the marketing ban of cosmetics tested on animals in particular. Only some MEPs from the PPE and the UEN expressed some doubts regarding the possible implications at WTO level and the impact on producers in some Member States. The PPE proposed an alternative amendment that foresees a longer derogation period (10 years) covering some tests for which there are no alternative methods at present.

On behalf of the Commission, Mr LIIKANEN declared that his Institution welcomed the amendments related to some categories of products, those related to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) and those related to the fragrance allergies issue. On the key issues (testing ban and marketing ban), while sharing EP's concern on the need to put an end to animal testing, Mr LIIKANEN confirmed that the Commission supports the Council common position. He underlined that there are still no alternative validated methods for a number of key toxicological parameters and that the marketing ban must be linked to its acceptance at OECD level and must exclude any cut-off date in order to reduce the risk of disputes within the WTO. Mr LIIKANEN gave finally the Commission's position on each amendment.

II. VOTE

The Plenary adopted 29 amendments [1] at a very large majority, except amd 13 (the 1st part received 318 votes in favour and the 2nd part was rejected). Amds 32 and 33 by the EDD group fell. All the amendments of the recommendation for 2nd reading (except amd 13, 2nd part) plus the 2 amendments by the PPE (amds 30 and 31) were therefore strongly supported by the EP Plenary. Around 530 MEPs took part in the vote.

[1] Amds 13 & 31 as well as amds 15 & 16 have been merged.

On the marketing ban issue, the EP adopted the approach originally suggested by Mr BOWIS (PPE/DE – UK) and endorsed by his group (amds 30 and 13&31), i.e. the introduction of a marketing ban for new cosmetic products tested on animals 5 years after the adoption of the present Directive, with a derogation up to 10 years for 3 tests (repeated dose toxicity, reproductive toxicity and toxicokinetics) for which there are no alternatives yet under consideration.

The Commission's preliminary position on these amendments, as stated by Mr LIIKANEN during the Plenary debate and as confirmed by Mr BYRNE before the vote is as follows:

1) Amendments acceptable in principle

These are amds 1(1st part), 5(1st part), 27(2nd part) and 28(2nd part).

2) Amendments which are not acceptable

All other amendments, in particular those reinstated from the 1st reading and related to the major issues such as the marketing ban, the testing ban, the labelling and the ban on dangerous substances.

On the marketing ban, Mr LIIKANEN declared that the EU is seeking to promote considerations relating to animal welfare within the WTO, so far with very little success. Challenging the WTO with a ban would be counterproductive and would increase the polarisation between developed and developing countries.

On the testing ban on 31 December 2004 at the latest, Mr LIIKANEN underlined the need of linking it to the existence of internationally recognised alternative methods, which is impossible to predict. A total ban on all animal testing would endanger the safety of cosmetics and therefore human health.

On amds 21 and 28, Mr LIIKANEN pointed out that the Commission could accept in principle the listing of these recognised fragrance allergens in Annex III, but it should be in the form of a Commission Directive adapting technical progress to be adopted by comitology. Given their large number, including all the ingredients of fragrances in the label would not be feasible.

The text of the amendments adopted and the European Parliament's legislative Resolution are set out in Annex hereto.

ANNEX
(11.6.2002)

Cosmetic products ***II

European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council directive amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (15073/1/2001 – C5-0072/2002 – 2000/0077(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (15073/1/01 – C5-0072/2002 [1]),

– having regard to its position at first reading [2] on the Commission proposal to Parliament and the Council (COM(2000) 189 [3]),

– having regard to the Commission's amended proposal (COM(2001) 697 [4]),

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 80 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0180/2002),

1. Amends the common position as follows;

2. Instructs its President to forward its position to the Council and Commission.

---

1 OJ C 113E, 14.5.2002, p. 109.
2 OJ C 21E, 24.1.2002, p. 88.
3 OJ C 311E, 31.10.2000, p. 134.
4 OJ C 51E, 26.2.2002, p. 385.

Council common position	Amendments by Parliament

Amendment 1
RECITAL 2 a (new)

	(2a) In accordance with 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([1]) and with Council Directive 93/35/EEC of 14 June 1993([2]) amending for the sixth time Directive 76/768/EEC, it is essential that the aim of abolishing animal experiments for cosmetics be pursued and that the prohibition of such experiments becomes effective on 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.
	([1]) *OJ L 358, 18.12.1986, p. 1.* ([2]) *OJ L 151, 23.6.1993, p. 32.*

Amendment 2
RECITAL 3

(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* 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 ***implementation of this provision*** in the cosmetic sector, specific provisions have been introduced by	(3) Directive 86/609/EEC 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 which do not use live animals*** in the cosmetic sector, specific provisions have been introduced by Directive 93/35/EEC. However, these provisions concern only alternative methods which do not use animals and do not take account of alternative methods developed in order to

Directive 93/35/EEC *amending for the sixth time Directive 76/768/EEC.* However, these provisions concern only alternative methods which do not ***entail the*** use ***of*** animals and 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 ***experimental purposes, the provisions of Directive 76/768/EEC*** should be amended in order to provide for the systematic use of ***all alternative methods***, as foreseen 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.	reduce the number of animals used for experiments or to reduce their suffering. Therefore, in order to afford optimal protection to animals used for ***cosmetics testing pending implementation of the prohibition of animal tests for cosmetics and the marketing of animal-tested cosmetics 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 foreseen 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.

Amendment 3
RECITAL 4

(4) 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 the Community level. However, the safety of cosmetic products ***can*** 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 ***can guarantee*** an equivalent level of protection to consumers. ***For this purpose, the Commission should ensure that conventional testing methods are replaced as a priority by validated alternative methods which do not entail the use of animals or, failing that, by methods limiting significantly the number of animals used or by methods reducing significantly animal suffering.***	(4) 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 the 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.

Amendment 4
RECITAL 5 a (new)

(5a) 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. 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 will 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 foreseen for the introduction of a definitive prohibition.

Amendment 30
RECITAL 5 b (new)

(5b) The Commission should agree a timetable of deadlines for each test currently carried out using animals up to a maximum of five years for all tests. An exception may however be made for tests concerning repeated dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, in which case the deadline should be a maximum of ten years from the date of the adoption of this Directive. Such exceptions should be authorised by the Commission.

Amendment 5
RECITAL 6

(6) 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 its efforts and take the measures necessary for the promotion of research and the development of new methods, in particular within *its* Sixth *Framework* Programme as set out in Decision No 2002/...../EC of the European Parliament and of the Council.	(6) 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 *the* Sixth *Community Action* Programme *on the Environment* as set out in Decision No 2002/...../EC of the European Parliament and of the Council.

Amendment 6
RECITAL 6 a (new)

	(6a) If necessary, in order not to prevent the introduction of new products which offer significant improvements in health protection in terms of preventing illness, disease or serious health disorders, the Commission should bring forward a proposal in accordance with the procedure laid down in Article 251 of the Treaty. Such a proposal should not compromise the objectives of this Directive.

Amendment 7
RECITAL 7 a (new)

	(7a) Public opinion demands that animal testing for cosmetics should be forbidden. In order to promote rapid development of alternatives and to ensure animal testing is not relocated to third countries, a Community prohibition on animal testing needs to be combined with mandatory labelling of products and ingredients tested on animals and measures which ensure that cosmetic products and ingredients tested on animals are not put on the Community market after a specified date. If satisfactory non-animal

	alternatives are not fully available by that date, it will be possible to apply such measures without compromising consumer safety while still allowing a considerable amount of product innovation.

Amendment 8
RECITAL 8

(8) It should be possible to ***provide consumers with information relating to tests performed on cosmetic products. However, in order to ensure the transparency of the information made available to consumers in this regard and to guarantee the free movement of cosmetic products within the Community, it is important to specify the conditions under which it is possible to make claims for such products, or in the context of their marketing, that no animal testing has been carried out for their development or manufacture. For this purpose, it is necessary that, after consultation of all interested parties, the Commission prepare guidelines in order to provide clear guidance for economic operators on the use of such claims within the Community.***	(8) 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.***

Amendment 9
RECITAL 8 a (new)

	(8a) Fragrances should not be used where they do not fulfil an essential purpose, in particular in products intended for children or products for external intimate hygiene.

Amendment 10
RECITAL 8 b (new)

(8b) 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.

(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).

Amendment 11
RECITAL 9

(9) Given the special risks that substances classified as carcinogenic, mutagenic or toxic for reproduction, category 1 and 2, 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, may entail for human health, their use in cosmetic products should be ***avoided***, unless the *Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers* considers such use as safe. The evaluation of these substances for use in cosmetic products should not involve, ***as far as possible,*** the use of

(9) Given the special risks that substances classified as carcinogenic, mutagenic or toxic for reproduction, category 1 and 2, 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, may entail for human health, their use in cosmetic products should be ***prohibited. Given the special risks that substances classified, pursuant to Directive 67/548/EEC, as carcinogenic, mutagenic or toxic for reproduction, category 3, may entail for human health, their use in cosmetic products should be prohibited,***

animals.	unless the *SCCNFP* considers such use as safe. The evaluation of these substances for use in cosmetic products should not involve the use of animals.

Amendment 12
RECITAL 11 a (new)

	(11a) A number of substances have been identified by the SCCNFP as likely to cause allergenic reactions and it will be necessary to restrict the use and/or impose certain conditions concerning these substances.

Amendments 13 and 31
ARTICLE 1, POINT 1
Article 4, paragraph 1, point (i) (Directive 76/768/EEC)

1) Article 4(1)(i) shall be ***deleted;***	1) Article 4(1)(i) shall be ***replaced by the following:*** ***"(i) ingredients or combinations of ingredients tested on animals in order to meet the requirements of this Directive, where satisfactory methods to replace animal testing exist or, where these are not yet available, methods which reduce the number of animals used, or reduce the suffering caused, in particular methods which are scientifically validated as offering an equivalent level of protection for the consumer, and in any case not later than five years after the adoption of Directive 2002/.../EC [amending Council Directive 76/768/EEC on the approximation of laws of the Member States relating to cosmetic products]. The Commission shall agree a timetable of deadlines for each test currently carried out using animals up to a maximum of five years for all tests. An exception may however be made for tests concerning repeated dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, in which case the deadline shall be a maximum of ten years from the date of adoption of Directive 2002/.../EC [amending Council Directive***

76/768/EEC on the approximation of laws of the Member States relating to cosmetic products]. Such exceptions must be authorised by the Commission.
Animal testing conducted after the date referred to in the first subparagraph shall 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 agents or suppliers.
When implementing this provision, the Commission and the Member States shall take account of the need to ensure that producers in third countries are afforded notice and treatment equivalent to those in the Community and in particular to avoid any discriminatory or unfair treatment.
Testing authorised in accordance with the procedure laid down in Article 4a (1a), second subparagraph, shall be exempted from this provision."

Amendment 14
ARTICLE 1, POINT 1 a (new)
Article 4, paragraph 1, points (i a) and (i b) (new) (Directive 76/768/EEC)

1a) In Article 4(1), the following points (ia) and (ib) shall be added:
"(ia) substances listed in Directive 67/548/EEC which are classified as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2,
(ib) substances listed in Directive 67/548/EEC which are classified as carcinogenic, mutagenic or toxic for reproduction, category 3, unless they have been evaluated by the SCCNFP and found acceptable for use in cosmetics."

Amendments 15 and 16
ARTICLE 1, POINT 2
Article 4a, paragraphs 1 and 2 (Directive 76/768/EEC)

1. Without prejudice to the general obligations deriving from Article 2, Member States shall prohibit:	*1. Member States shall take all necessary measures to prohibit the performance on their territory of animal tests:*
(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, accepted and published by the Organisation for Economic Cooperation and Development (OECD) and adopted at Community level;	*(a) for testing finished cosmetic products;*
(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, accepted and published by the Organisation for Economic Cooperation and Development (OECD) and adopted at Community level;	*(b) for testing ingredients or combinations of ingredients, as soon as an alternative method has been published by the Commission, after endorsement of its scientific validity by ECVAM and the ECVAM Scientific Advisory Committee, following consultation of the SCCNFP, and in any case from 31 December 2004.*
(c) the performance on their territory of animal testing of finished cosmetic products in order to meet the requirements of this Directive;	*1a. 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, a manufacturer or competent authority may apply for a derogation to paragraph 1(b). An application shall be made to the Commission, which shall consult the SCCNFP and the European Parliament. The decision shall be taken in accordance with the procedure referred to in Article 10(2). A derogation shall only be granted if:*
(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.*	*(a) the ingredient is in wide use and cannot be substituted by another ingredient able to perform a similar function;* *(b) the specific human health problem is explained and the need to conduct animal tests is justified, supported by a detailed research protocol proposed as the basis for the evaluation;* *(c) the results of the research are made publicly available and independently assessed.*
*2. No later than ...**, the Commission shall, in accordance with the regulatory procedure referred to in Article 10(2) and after consultation of the Scientific Committee on Cosmetic Products and Non-*	*Ingredients tested in accordance with this procedure and found to be safe shall be listed in a separate annex to the Directive, which shall include a reference to the location of the test data.*