The timetables shall be made available to the public not later than ..... [+] and be sent to the European Parliament and the Council.

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.

On the basis of these annual reports, the timetables established in accordance with paragraph 2 may be adapted within amaximum time limit of 6 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 2 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.

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

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.

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* 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).";

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.

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* 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 Communities. 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.

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* 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 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*
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*	

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*	

79	*Hydroxy-methylpentylcyclohexene carboxaldehyde (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*	

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-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*	
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 ..... 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 [ ] [**] 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 ..... [***]. They shall forthwith inform the Commission thereof.

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

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 Communities.

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,

For the European Parliament
The President

For the Council
The President

添付資料-6

EUROPEAN PARLIAMENT

1999 [redacted] *2004*

Session document

FINAL
A5-0001/2003

6 January 2003

***III

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))

European Parliament delegation to the Conciliation Committee

Rapporteur: Dagmar Roth-Behrendt

CODE3APP

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

CONTENTS

PROCEDURAL PAGE

At the sitting of 3 April 2001 Parliament adopted its position at first reading on the proposal for 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 (COM(2000) 189 – 2000/0077 (COD)).

At the sitting of 28 February 2002 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (15073/1/2001 – C5-0072/2002).

At the sitting of 11 June 2002 Parliament adopted amendments to the common position.

By letter of 26 August 2002 the Council stated that it was unable to approve all Parliament's amendments.

The President of the Council, in agreement with the President of Parliament, convened a meeting of the Conciliation Committee on 7 October 2002.

At its meetings of 7 October and 6 November 2002 the Conciliation Committee considered the common position on the basis of the amendments proposed by Parliament.

By letter of 13 November 2002 the President of Parliament informed the Council that it was necessary to extend the deadline for the work in committee and the deadline for adopting the act, as laid down in Article 251(7) of the EC Treaty.

Following the subsequent trilogues and delegation meetings an agreement was reached in the exchange of letters of 20 November 2002.

At its meeting of 20 November 2002 the Parliament delegation approved the results of the conciliation unanimously.

The following took part in the vote: Giorgos Dimitrakopoulos, vice-chairman and chairman of the delegation; Caroline F. Jackson, chairman of the Committee on the Environment, Public Health and Consumer Policy; Dagmar Roth-Behrendt, rapporteur; John Bowis (for Charlotte Cederschiöld), Alexander de Roo (for Patricia McKenna, pursuant to Rule 153(2)), Marialiese Flemming (for Karl-Heinz Florenz), Torben Lund, Guido Sacconi, Karin Scheele (for Renzo Imbeni) and Jonas Sjöstedt.

On 3 December 2002 the co-chairmen of the Conciliation Committee established that the joint text had been approved, pursuant to paragraph III.8 of the Joint declaration on practical arrangements for the new co-decision procedure,[1] and forwarded it to Parliament and the Council in all the official languages.

The report was tabled on 6 January 2003.

[1] OJ C 148, 28.5.1999, p. 1.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the joint text approved by the Conciliation Committee for 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 (PE-CONS 3688 – C5-0557/2002 – 2000/0077(COD))

(Codecision procedure: third reading)

The European Parliament,

– having regard to the joint text approved by the Conciliation Committee (PE-CONS 3688/2002 – C5-0557/2002),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2000) 189[2]),

– having regard to the amended proposal (COM(2001) 697[3]),

– having regard to its position at second reading[4] on the Council common position[5],

– having regard to the Commission's opinion on Parliament's amendments to the common position (COM(2002) 435 - C5-0369/2002)[6],

– having regard to Article 251(5) of the EC Treaty,

– having regard to Rule 83 of its Rules of Procedure,

– having regard to the report of its delegation to the Conciliation Committee (A5-0001/2003),

1. Approves the joint text;

2. Instructs its President to sign the act with the President of the Council pursuant to Article 254(1) of the EC Treaty;

3. Instructs its Secretary-General duly to sign the act and, in agreement with the Secretary-General of the Council to have it published in the Official Journal of the European Communities;

4. Instructs its President to forward this legislative resolution to the Council and Commission.

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[1] OJ C 21 E, 24.1.2002, p. 88.
[2] OJ C 311 E, 31.10.2000, p. 134.
[3] OJ C 51 E, 26.2.2002, p. 385.
[4] P5 TA-PROV(2002)0292.
[5] OJ C 113 E, 14.5.2002, p. 109.
[6] OJ C not yet published.