12. By incorporating provisions on specific safety assessments for cosmetic products intended exclusively for use on children or in external intimate hygiene, the Council considers that it has taken due account of the particular risks potentially associated with such products and therefore rejected amendments 9 and 43.

13. The Council rejected amendments 13, 21 and 28 on information to be included in the inventory drawn up and published by the Commission due to concerns that such a provision could be in conflict with provisions on protection of data.

14. The Council considers that amendments 16 and 20 concerning, respectively, a reference to a prototype in relation to finished cosmetic products and the definition of cosmetic ingredients do not add to the clarity of the terms and therefore rejected the two amendments.

15. The Council rejected amendment 27 concerning detailed information on any animal test performed in connection with development of the product and its ingredients as such a requirement would be impossible to enforce and would be in conflict with the Community's obligations in relation to the WTO.

16. Concerning labelling, the Council has for the sake of clarity for consumers opted for a single date on the durability of cosmetic products by extending the current requirement of a minimum durability date to all products and therefore rejected the part of amendment 32 that refers specifically to a maximum product life and period after opening. The Council rejected part of amendment 23, as the Council considers it necessary to exempt perfume and aromatic compositions from systematic inclusion in the list of ingredients when these substances have no allergenic potential. The Council rejected amendment 39 and part of amendment 37 which relate to an obligatory labelling of products where the final product or ingredients therein have been subject to animal testing, partly due to the rejection of the specific criteria on size of the labelling, and partly due to concerns as to whether an obligatory labelling would be in compliance with WTO rules. The Council agrees with the need to consult all interested parties in relation to the development of guidelines for the use of claims of non-animal tested products but

does not consider it appropriate in this context to specify the modalities of such consultations and therefore rejected the part of amendments 7 and 47 relating to consultation of specific parties.

17. While the Council in principle can support an adaptation of Annex III, as proposed in amendment 49, it considers that this should be done in accordance with the procedure relating to adaptation to technical progress and therefore rejected amendment 49.

18. The Council in addition has made a number of linguistic changes to the Commission proposal.

IV. Conclusion

As recommended by the European Parliament, the Council has incorporated provisions in order to improve the level of information to be made available to consumers in relation to the use of cosmetic products and to better guarantee that all risks associated with these products are properly assessed. Regarding the use of animal testing for cosmetic products, the Council has sought to strike a balance between the imperative requirement to ensure the protection of consumers, the need to offer optimal protection to animals used for experimental purposes and the necessity for the Community to respect its international obligations.

Whilst recognising animal welfare as a legitimate objective to be pursued under Community legislation, the Council could not endorse a solution which would have totally prohibited the performance of animal tests for cosmetic products after a fixed date, irrespective of the availability of adequate alternative methods. In its view, such an approach would have jeopardised consumer safety in disregard of the fundamental objectives to be pursued under the Cosmetics Directive and of the duty of the Community to secure a high level of protection to human health.

Given the need for additional scientific knowledge for the development of alternative methods, the Council considers that the most effective way to improve the protection of animals used for experimental purposes is to promote the development of alternative methods through co-ordination of all scientific resources available and to ensure that alternative methods are effectively used when they exist and are scientifically validated. The Council

therefore welcomes the commitment of the Commission to review the current framework of Directive 86/609/EEC and to consider the availability of appropriate funding under the EC Research and Development Framework Programme for the research of alternative methods.

With regard to provisions for a ban on imported cosmetic products tested on animals, the Council considers it to be indispensable to implement such a ban gradually along with the availability of alternative testing methods agreed at international level in order to ensure compliance with WTO commitments.

添付資料－5

COUNCIL OF
THE EUROPEAN UNION

Brussels, 15 February 2002
(OR. en)

15073/1/01
REV 1

Interinstitutional File:
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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject :	Common position adopted by the Council on 14 February 2002 with a view to the adoption of a 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

DIRECTIVE 2002/ /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 [3],

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1 OJ C 311, 31.10.2000, p. 134.
2 OJ C 367, 20.12.2000, p. 1.
3 Opinion of the European Parliament of 3 April 2001 (not yet published in the Official Journal), Council Common Position of (not yet published in the Official Journal) and Decision of the European Parliament of (not yet published in the Official Journal).

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 stipulates 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.

[1] OJ L 262, 27.7.1976, p. 169. Directive as last amended by Commission Directive 2000/41/EC (OJ L 145, 20.6.2000, p. 25).

(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 [1] 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 Council Directive 93/35/EEC [2] 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.

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1 OJ L 358, 18.12.1986, p. 1.
2 OJ L 151, 23.6.1993, p. 32.

(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.

(5) 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.

(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 [1].

(7) The recognition by third 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 third countries requiring the repetition of such tests using animals.

(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.

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[1] OJ L

(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 [1], 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 animals.

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

(11) 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.

(12) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EEC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [2],

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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).

2 OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

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

2) the following Articles shall be inserted:

"Article 4a

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

(a) the marketing of cosmetic products where the final formulation, in order to meet the requirements of this Directive, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated, accepted and published by the Organisation for Economic Cooperation and Development (OECD) and adopted at Community level;

(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 OECD and adopted at Community level;

(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.

2. No later than ..... [1], 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-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.

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1 18 months after the entry into force of this Directive.

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.

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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).;

Article 4b

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.

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

"(c) the date of minimum durability. The date of minimum durability of a cosmetic product shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with Article 2.

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.

If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.";

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 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.

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* OJ L 140, 23.6.1995, p. 26.";

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

"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.";

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/authorities concerned.";

7) 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";

8) Articles 9 and 10 shall be replaced by the following:

"Article 9

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. 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 *;

(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;

(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.

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.".

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.

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.

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