EUROPEAN COMMUNITIES
THE COUNCIL

Brussels, 17 -12- 1992

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COMMON POSITION

ADOPTED BY THE COUNCIL ON 17 -12- 1992

WITH A VIEW TO ADOPTING COUNCIL DIRECTIVE

AMENDING FOR THE SIXTH TIME DIRECTIVE 76/768/EEC

ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES

RELATING TO COSMETIC PRODUCTS

COUNCIL DIRECTIVE 92/ /EEC

of

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

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In co-operation with the European Parliament (2),

Having regard to the Opinion of the Economic and Social Committee (3),

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(1) OJ No C 52, 28. 2.1991, p. 6 and OJ No C 249, 26.9.1992, p. 5.
(2) OJ No C 176, 13. 7.1992, p. 92 and Decision of (not yet published in the Official Journal).
(3) OJ No C 269, 14.10.1991, p. 15.

Whereas the legal ambiguities in Directive 76/768/EEC [1] particularly in Articles 1 and 2, should be removed;

Whereas it has become apparent that it is desirable that data on the ingredients employed in cosmetic products be gathered so that all issues relating to their use and the resulting action at Community level may be assessed with a view, in particular, to the establishment of a common nomenclature of ingredients used in cosmetic products; whereas the gathering of that data can be facilitated if the Commission compiles an inventory of the ingredients concerned; whereas that inventory will be indicative and is not intended to constitute a limitative list of substances used in cosmetic products;

Whereas greater transparency is needed regarding the ingredients employed in cosmetics if the latter are to be placed on the market without any prior procedure, if the necessary information on the finished product is to be available solely at the place of manufacture or of initial importation into the Community and if better information is to be provided to the consumer; whereas such transparency should be achieved by indication of a product's function and of the ingredients used in a cosmetic product on its packaging; whereas where for practical reasons it is impossible to

(1) OJ No L 262, 27. 9.1976, p. 169. Directive as last amended by Commission Directive 92/86/EEC (OJ No L 325, 11.11.1992, p. 18).

indicate the ingredients and any warnings regarding use on the container or the packaging, such particulars should be enclosed so that the consumer may have access to all necessary information;

Whereas, with regard to the finished cosmetic product, it should be made clear which information is to be made available to the monitoring authorities of the place of manufacture or of initial importation into the Community market; whereas that information should include all the necessary particulars relating to identity, quality, safety for human health and the effects claimed for the cosmetic product;

Whereas, however, for reasons of monitoring, the competent authority should be apprised of the place of manufacture and of the information needed for rapid and appropriate medical treatment in the event of difficulties;

Whereas the Commission should be authorized to amend Annexes I and VIII to Directive 76/768/EEC in view of their illustrative and technical nature;

Whereas assessment of the safety of use of the ingredients employed in cosmetics and of the final product should take account of the requirements of Directive 86/609/EEC (1), which concerns the protection of animals used for experimental and other scientific purposes, and in particular Article 7(2) thereof,

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(1) OJ No L 358, 18.12.1986, p. 1.

Whereas testing on animals of ingredients or combinations of ingredients should be banned as from 1 January 1998; whereas, however, that date should be postponed where alternative methods of testing have not been scientifically validated; whereas the Commission should submit a report on progress made with regard to such methods,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1) Article 1(1) shall be replaced by the following:

"1. A "cosmetic product" shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.";

2) Article 2 shall be replaced by the following:

"Article 2

A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.

The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Directive.";

3) The following subparagraph shall be added to Article 4(1):

"(i) ingredients or combinations of ingredients tested on animals after 1 January 1998 in order to meet the requirements of this Directive.

If there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been

scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines, the Commission shall, by 1 January 1997, submit draft measures to postpone the date of implementation of this provision, for a sufficient period, and in any case for no less than two years, in accordance with the procedure laid down in Article 10. Before submitting such measures, the Commission will consult the Scientific Committee on Cosmetology.

The Commission shall present an annual report to the European Parliament and the Council on progress in the development, validation and legal acceptance of alternative methods to those involving experiments on animals. That 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 Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The Commission shall in particular ensure the development, validation and legal acceptance of experimental methods which do not use live animals.";

4) The following Article shall be inserted:

"Article 5a

1. No later than (*) the Commission shall, under the procedure laid down in Article 10, compile an inventory of ingredients employed in cosmetic products, on the basis in particular of information supplied by the industry concerned.

(*) Eighteen months after adoption of the Directive.

For the purposes of this Article, "cosmetic ingredient" shall mean any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.

The inventory shall be divided into two sections: one concerning perfume and aromatic raw materials and the second concerning other substances.

2. The inventory shall contain information on:

- the identity of each ingredient, in particular its chemical name, the CTFA name, the European Pharmacopoeia name, the international non-proprietary names recommended by the World Health Organisation, the EINECS, IUPAC, CAS and colour index numbers, and the common name referred to in Article 7(2);

- the usual function(s) of the ingredient in the final product;

- where appropriate, restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes.

3. The Commission shall publish the inventory and shall update it periodically under the procedure provided for in Article 10. The inventory shall be indicative and shall not constitute a list of the substances authorized for use in cosmetic products.";

5) In Article 6(1), the introductory sentence shall be replaced by the following:

"1. Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering; the information mentioned in point (g) may, however, be indicated on the packaging alone:";

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

"(d) particular precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label" in Annexes III, IV, VI and VII, which must appear on the container and packaging, as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the container and the packaging.";

7) The following subparagraphs (f) and (g) shall be added to Article 6(1):

"(f) the function of the product, unless it is clear from the presentation of the product;

(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 container and 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 "flavour". 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" 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 laid down in Article 10, the Commission shall, no later than (*), adopt the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.";

8) The following two paragraphs shall be added at the end of Article 6(1):

"Where it is impracticable, for reasons of size or shape, for the particulars referred to in points (d) and (g) to appear in an enclosed leaflet, those particulars shall appear on a label, tape or card which is enclosed or attached to the cosmetic product.

In the case of soap, bath balls and other small products where it is impracticable, for reasons of size or shape, for the particulars referred to in point (g) to appear on a label, tag, tape or card or in an enclosed leaflet, those particulars shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.";

(*) Eighteen months after the adoption of this Directive.

9) The following shall be added at the end of Article 6(3):

"Furthermore, any reference to testing on animals must state clearly whether the tests carried out involved the finished product and/or its ingredients.";

10) Article 7(2) shall be replaced by the following:

"2. They may, however, require that the particulars provided for in Article 6(1)(b), (c), (d) and (f) be expressed at least in their own national or official language or languages; they may also require that the particulars provided for in Article 6(1)(g) be expressed in a language easily understood by the consumer. To that end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.";

11) Article 7(3) shall be replaced by the following:

"3. Furthermore, a Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the competent authority, which shall ensure that that information is used only for the purposes of such treatment.

Each Member State shall designate a competent authority and send details thereof to the Commission, which shall publish that information in the Official Journal of the European Communities.";

12) The following Article shall be inserted:

"Article 7a

1. The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6(1)(a):

(a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;

(b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;

(c) the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation;

(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 ingredient, its chemical structure and its level of exposure.

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 kept available. In this connection, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned;

(e) the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;

(f) existing data on undesirable effects on human health resulting from use of the cosmetic product;

(g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.

2. The assessment of the safety for human health referred to in paragraph 1(d) shall be carried out in accordance with the principles of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances. (*)

3. The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.

4. The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market.

(*) OJ No L 15, 17.1.1987, p. 29.

5. Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish that information in the Official Journal of the European Communities.

The Member States shall ensure that the abovementioned authorities continue to co-operate in areas where such co-operation is necessary to the smooth application of this Directive.

13) Article 8(2) shall be replaced by the following:

"2. The common nomenclature of ingredients used in cosmetic products and, after consultation of the Scientific Committee on Cosmetology, the amendments necessary for the adaptation to technical progress of the Annexes shall be adopted in accordance with the same procedure, as appropriate.";

14) Annex VIII appearing in the Annex to this Directive shall be added.

Article 2

1. Member States shall take all necessary measures to ensure that from 1 January 1997 neither manufacturers nor importers established within the Community place on the market cosmetic products which fail to comply with this Directive.

2. Member States shall take all measures necessary to ensure that the products referred to in paragraph 1 cannot be sold or disposed of to the ultimate consumer after 31 December 1997.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary for them to comply with this Directive no later than (*). They shall forthwith inform the Commission thereof.

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

2. Member States shall communicate to the Commission the texts of the provisions of domestic law which they adopt in the field governed by this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

(*) Two years from the adoption of this Directive.

"Annex VIII