II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/35/EEC

of 14 June 1993

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

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 cooperation with the European Parliament (2),

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

Whereas the legal ambiguities in Directive 76/768/EEC (4) 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 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;

(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 OJ No C 150, 31. 5. 1993.
(3) OJ No C 269, 14. 10. 1991, p. 15.
(4) 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).

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;

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 14 December 1994 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.

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.

[1] OJ No L 358, 18. 12. 1986, p. 1.

2. The inventory shall contain informtion 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 Organization, 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 14 December 1994, 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.