COMMISSION OF THE EUROPEAN COMMUNITIES

COM(92) 364 final - SYN 307

Brussels, 02 September 1992

Amended proposal for a

COUNCIL DIRECTIVE

amending for the sixth time Council Directive 76/768/EEC

of 27 July 1976

on the approximation of the laws of the Member States

relating to cosmetic products

(presented by the Commission pursuant to Article 149(3)
of the EEC-Treaty)

Explanatory memorandum

1. This amended text of the proposal for a 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 is submitted following the opinion of the European Parliament.

The amended proposal retains the objective and the basic elements of the original proposal, which was in general supported not only by the European Parliament but also by the Economic and Social Committee.

As the initial objective was to improve and harmonise the information made available to users and monitoring authorities, the original proposal opted to:

- draw up an inventory of the ingredients used in cosmetics;

- indicate on the packaging of each cosmetic product the ingredients used in it;

- establish information relating to the identity, quality, safety and efficacy of the product, which the manufacturer should keep available for the monitoring authorities.

In addition, some editorial and technical amendments have been introduced.

2. Following the first discussion of the 43 amendments to the Commission text proposed during the plenary sitting of the European Parliament in February 1992, a large majority (more than two thirds) of MEPs voted in favour of a ban on the testing of cosmetics on animals.

Subsequent discussions between Mrs Roth-Behrendt, the rapporteur, and the Commission resulted in approval by the plenary sitting of the European Parliament in June 1992 of three compromise amendments providing for the following:

- a ban on experiments involving animals for ingredients used exclusively for cosmetic purposes, to take effect on 1 January 1998 (Article 1(2a), new text, paragraph 1);

- deferment of this date in accordance with progress relating to substitute methods not involving animals (Article 1(2a), new text, paragraph 2);

- establishment of an annual report by the Commission relating to progress in the development, validation and legal acceptance of substitute methods for the ingredients used for cosmetic purposes (Article 1(2a), new text, paragraph 3);

- establishment of specific criteria relating to claims for cosmetics not tested on animals (Article 1(6a), new text).

3. In addition to these amendments, which appear to be the only possible compromise between a total and immediate ban on any animal experiments involving cosmetics, as desired by the European Parliament, and the general policy of the Community legislator, as set out in Directive 86/609 on the protection of animals used for experimental and other scientific purposes, the Commission also approved those relating to:

3.1. restoring the words "exclusively or principally" in the definition of cosmetics (Article 1(1)), as a criterion for assessing whether the products in question come under the scope of this Directive;

3.2. the separation into two groups of the inventory of ingredients used in cosmetics: those relating to perfumes and those relating to other substances (Article 1(3), paragraph 2), the reason being that, very often, the manufacturer of the cosmetics is unaware of the complete formula used in an aromatic composition or perfume; the complete formula for the latter remains the property of the supplier of the raw materials for reasons of trade secrecy;

3.3. a longer explanation of the rules governing the display of cosmetics following the introduction of a complete list of ingredients on the packaging (Article 1(5 and 6)), to avoid discrepancies when transposing this measure into national law;

3.4. a provision that Member States may require that particulars be expressed in their official language (Article 1(7)) so that they may be easily understood by consumers;

3.5. restoration of the words "adequate and sufficient information" in the article relating to treatment in the event of difficulties (Article 1(8)), specifying that this information refers to the generic formulae and to the details of certain ingredients;

3.6. the exemption of perfumes from the need for the manufacturer of cosmetics to have the complete formula of the product available (Article 1(9)) for reasons of trade secrecy.

4. All the amendments referred to above, which have been approved by the Commission, have been incorporated in the amended proposal below, in the form of editorial and legal changes to the text adopted by the European Parliament.

5. Apart from these amendments, the Commission has been unable to accept the others adopted by the European Parliament, as they were likely to give rise to insurmountable practical consequences. In particular, to administer the transformation of the inventory into a list of authorised substances would require considerable new financial and human resources; the result of implementing full labelling <u>following</u> approval of the

common nomenclature would be continual deferment due to a lack of information from cosmetics manufacturers, on which the Commission is dependent.

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II

(Preparatory Acts)

COMMISSION

Amended proposal for a 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 (1)

(92/C 249/04)

COM(92) 364 final — SYN 307

(Submitted by the Commission pursuant to Article 149 (3) of the EEC Treaty on 3 September 1992)

(1) OJ No C 52, 28. 2. 1991, p. 6

ORIGINAL PROPOSAL	AMENDED PROPOSAL
Proposal for a Council Directive amending for the sixth time Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products	**Amended proposal for a Council Directive amending for the sixth time Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products**
THE COUNCIL OF THE EUROPEAN COMMUNITIES,	Unchanged
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,	
Having regard to the proposal from the Commission,	
In cooperation with the European Parliament,	
Having regard to the opinion of the Economic and Social Committee,	
Whereas legal ambiguities in Council Directive 76/768/EEC (1), as last amended by Directive 89/679/EEC (2), particularly in Articles 1 and 2, should be removed;	

(1) OJ No L 262, 27. 9. 1976, p. 169.
(2) OJ No L 398, 30. 12. 1989, p. 25.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
Whereas it has become apparent that it is desirable that data on the ingredients employed in cosmetic products be gathered with a view to the assessment, on the one hand, of all issues relating to their use and, on the other, of the resulting action at Community level, with a view particularly to the establishment of a common nomenclature of ingredients used in cosmetic products; whereas the gathering of this data can be facilitated if the Commission compiles an inventory of the ingredients concerned; whereas this inventory is indicative and is not intended to constitute a definitive 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 and in order to obtain the necessary information on the finished products solely at the place of manufacture or of initial importation into the Community and provide better information to the consumer; whereas such transparency should be attained by indicating the product's function and by indicating 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 indications should be given on an enclosed leaflet with a suitable symbol;	
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 this information should include all the necessary elements relating to identity, quality, safety for human health and the claimed effects of the cosmetic product;	
Whereas the competent authority should be apprised of the place of manufacture, for reasons of monitoring, and of the information needed for rapid and appropriate medical treatment in case 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 natures;	

ORIGINAL PROPOSAL

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. Article 1 (1) is replaced by the following:

'1. A "cosmetic product" means any substance or preparation intended for placing 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 to cleaning them, perfuming them, protecting them, keeping them in good condition, changing their appearance and/or correcting body odours.'

2. Article 2 is replaced by the following:

'*Article 2*

Cosmetic products put on the market within the Community must not cause damage to human health when they are applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of every communication made in this regard by the manufacturer or his authorized agent or by all others responsible for placing these products on the Community market.'

(1) OJ No L 358, 18. 12. 1986, p. 1.

AMENDED PROPOSAL

Whereas assessment of the safety of use of the ingredients employed in cosmetics and of the final product must take account of the requirements of Council Directive 86/609/EEC (1) regarding the protection of animals used for experimental and other scientific purposes, and in particular Article 7 (2) thereof; whereas experiments involving the use of ingredients on animals in order to satisfy the requirements of Directive 76/768/EEC as referred to above must cease after 1 January 1998; whereas, however, deferment of this date would have to be considered if satisfactory methods have not been legally accepted prior to that date; whereas the Commission must report on progress achieved in this regard;

Whereas specific criteria for cosmetics not tested on animals must be drawn up,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

1. Article 1 (1) is replaced by the following:

'1. A "cosmetic product" means any substance or preparation intended for placing 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 exclusively or principally with a view to cleaning them, perfuming them, protecting them, keeping them in good condition, changing their appearance and/or correcting body odours.'

Unchanged

(1) OJ No L 358, 18. 12. 1986, p. 1.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
	2a. The following point (g) is added to Article 4 (1): '(g) Ingredients or combinations of ingredients tested on animals after 1 January 1998 in order to meet the requirements of this Directive. In accordance with progress achieved in developing satisfactory methods to replace experiments on animals, the Commission may, in accordance with Article 100a of the EEC Treaty, present a proposal to the Council to defer the entry into force of this provision. 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. 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 this information in addition to collecting statistics, as laid down by Council Directive 86/609/EEC 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 experimental methods which do not use live animals.'
	2b. The following paragraph 1 (a) is added to Article 4: 'Ingredients tested on animals exclusively for purposes other than their use in cosmetic products shall be authorized, on condition that no additional testing on animals is carried out in order to meet the requirements of this Directive.'
3. The following Article 5a is inserted: '*Article 5a* 1. Not later than 31 December 1993, the Commission shall, on the basis in particular of information supplied by the Member States, compile an inventory of ingredients employed in cosmetic products.	3. The following Article 5a is inserted: '*Article 5a* 1. Not later than two years following the adoption of this Directive, the Commission shall, on the basis in particular of information supplied by the Member States, compile an inventory of ingredients employed in cosmetic products.
For the purposes of this Article "cosmetic ingredient" means any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.	For the purposes of this Article "cosmetic ingredient" means any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.

ORIGINAL PROPOSAL	AMENDED PROPOSAL
	The inventory shall be divided into two parts: one relating to aromatic and perfume ingredients, and one relating to other ingredients used in cosmetics.'
2. The inventory shall contain information on:	Unchanged
— the identity of the ingredient, in particular its chemical name and, where appropriate, the EINECS, CAS and Color index numbers,	
— the 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.	
3. The Commission shall publish the inventory and shall update it periodically. The inventory is indicative and does not constitute a list of the substances authorized for use in cosmetic products or an exhaustive list of substances used in these products.'	
4. In Article 6 (1), the introductory phrase is 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, except for the information mentioned in (g) hereafter which may be indicated on the packaging alone:'.	
5. Article 6 (1) (d) is replaced by the following:	
'(d) particular precautions to be observed in use, and 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, this information must appear on an enclosed leaflet, with either abbreviated information on the container and the packaging or the symbol given in Annex VIII referring the consumer to the information specified.'	'(d) particular precautions to be observed in use, and 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, this information must appear on an enclosed leaflet, label or card, with either abbreviated information on the container and the packaging or the symbol given in Annex VIII referring the consumer to the information specified.'

ORIGINAL PROPOSAL	AMENDED PROPOSAL
6. The following points (f) and (g) are added to Article 6 (1):	6. The following points (f) and (g) are added to Article 6 (1):
'(f) the function of the product, unless it is clear from the description of the product;	'(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. This list shall be preceded by an appropriate indication including the word "ingredients". Where this is impossible for practical reasons, the ingredients must appear on an enclosed leaflet, with either abbreviated information on the container and the packaging or the symbol given in Annex VII referring the consumer to the ingredients specified. Perfume and aromatic compositions and their raw materials shall be referred to by the word "perfume". Ingredients of a concentration of less than 1 % may be listed in any order after those of a concentration of more than 1 %. Colouring agents may be listed in any order after the other ingredients.	(g) a list of ingredients in descending order of weight at the time they are added. This list shall be preceded by the word "ingredients". Where this is impossible for practical reasons, the ingredients must appear on a leaflet, label or card, with either abbreviated information on the packaging or the symbol given in Annex VIII referring the consumer to the ingredients specified. The leaflet may be supplied with the product if the customer is to be advised at the point of sale. For products sold without external packaging on trays or display stands, the ingredients may appear on a separate leaflet which must be presented or supplied in a pocket attached to the display unit. Perfume and aromatic compositions and their raw materials shall be referred to by the words "perfume" or "aroma". Ingredients of a concentration of less than 1 % may be listed in any order after those of a concentration of more than 1 %. Colouring agents may be listed in any order after the other ingredients. For products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the words "may contain" are added.
	Instead of information on the ingredients of colouring agents added to each product, the colouring agents in an assortment of cosmetic products sold together in the same packaging may be listed in any order in a single list, provided that this is not misleading and that it is pointed out that the list applies to all the products.
	Where there is an existing or foreseeable shortage of ingredients, the declaration may name a substitute ingredient, which must be listed directly after the ingredient normally used and preceded by the word "or".

ORIGINAL PROPOSAL	AMENDED PROPOSAL
	Where the product is sold by mail order, information on the ingredients may be given in a brochure or catelogue sent to each purchaser, provided that the purchaser is thereby able to identify the information relating to each product.
	Samples used for testing and free samples are not required to have a label listing the ingredients.
In accordance with the Article 10 procedure, the Commission shall, no later than 31 December 1993, 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.'	In accordance with the Article 10 procedure, the Commission shall, no later than two years following the adoption of this Directive, 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.'
	6.(a) Article 6 (3) is replaced by the following:
	'3. Member States shall take all measures necessary to ensure that in the labelling, presentation for sale and advertising of cosmetic products, the wording, use of names, trade marks, images or other signs, figurative or otherwise, suggesting a characteristic which the products in question do not possess, shall be prohibited. In particular, any reference to testing on animals must state clearly whether the tests carried out involved the finished product or its ingredients, specifying, in the latter case, whether they are used exclusively in cosmetics or whether they have previously been used for other categories of products.'
7. Article 7 (2) is replaced by the following:	7. Article 7 (2) is replaced by the following:
'2. They may, however, require that the particulars provided for in Article 6 (1) (b), (c) and (d) 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) (f) and (g) be expressed in a language easily understood by the consumer. To this end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.'	'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 this end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.'

ORIGINAL PROPOSAL	AMENDED PROPOSAL
8. Article 7 (3) is replaced by the following:	8. Article 7 (3) is replaced by the following:
'3. Furthermore, a Member State may require, for purposes of prompt and appropriate medical treatment in the event of difficulties, that the qualitative and quantitative formula of the product be made available to the competent authority, which shall ensure that this formula is used only for the purposes of such treatment.	'3. Furthermore, a Member State may require, for purposes of prompt and appropriate medical treatment in the event of difficulties, that adequate and sufficient information on the product be made available to the competent authority, which shall ensure that this information is used only for the purposes of such treatment. The generic formulae of the product and specific details relating to the various individual ingredients shall be provided.
Member States shall designate that competent authority and send details thereof to the Commission, which shall publish this information in the *Official Journal of the European Communities.*'	Unchanged
9. The following Article is inserted:	
'Article 7a	
1. The manufacturer or his agent provided he is established in the Community, or the person responsible for placing imported cosmetic products on the Community market, shall, for control purposes, keep the following information readily available to the competent authorities of the Member State concerned at the place of manufacture or, in the case of importation from a non-member country, at the place of initial importation into Community territory:	
(a) the qualitative and quantitative formula of the product;	(a) The qualitative and quantitative formula of the product; with regard to aromatic compositions and perfumes, this information shall be limited to the name and code number of the composition and the identity of the supplier, except for those substances listed in Annexes III, IV, VI and VII of Council Directive 76/768/EEC referred to above.
(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;	Unchanged
(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;	
(d) assessment of the safety for human health of the finished product. To this end, the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure.	

ORIGINAL PROPOSAL	AMENDED PROPOSAL

Should the same product be manufactured at several places on Community territory, the manufacturer may choose a single place of manufacture where this information will be kept available. With regard to this, 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 at (d). This person must have received university training in the field of natural sciences;

(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 this is justified by the nature of the product.

2. The assessment of the safety for human health referred to in paragraph 1 (d) of this Article 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 (1).

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, provided he is established in the Community, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent national authority of the address of the place of manufacture or of initial importation into the Community of cosmetic products before the latter are placed on the Community market.

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 this information in the *Official Journal of the European Communities.*

(1) OJ No L 15, 17. 1. 1987, p. 29.'

ORIGINAL PROPOSAL	AMENDED PROPOSAL
10. Article 8 (2) is replaced by the following:	
'2. The amendments necessary for adapting to technical progress the Annexes to this Directive and the common nomenclature of ingredients used in cosmetic products shall be adopted in accordance with the same procedure, after consultation of the Scientific Committee on Cosmetology'	
11. The Annex is added as Annex VIII.	
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 products which fail to comply with the provisions of the Directive.	
2. Member States shall take all necessary measures 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	*Article 3*
1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1993 and shall inform the Commission thereof forthwith.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than two years after the adoption of this Directive and shall inform the Commission thereof forthwith.
When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.	Unchanged
2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive.	
Article 4	
This Directive is addressed to the Member States.	