COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL DIRECTIVE

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

(submitted to the Council by the Commission)

COM(80) 917 final

PROPOSAL FOR A COUNCIL DIRECTIVE AMENDING FOR THE THIRD TIME DIRECTIVE 76/768/EEC OF ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO COSMETIC PRODUCTS

EXPLANATORY MEMORANDUM

The aim of the proposal is:

1. to authorize the use of the barium, strontium and zirconium lakes or salts of a limited number of colouring agents;

2. to permit, under certain conditions, the use of two complexes of zirconium as anti-perspirants;

3. to make the use of silver nitrate in the manufacture of cosmetic products subject to certain restrictions and conditions;

4. to draw up a list of permitted substances (approved list) as sunscreen agents;

5. to replace the expiry date by the minimum shelf-life (date of minimum durability);

6. to adapt the form in which the manufacturing batch number and the product identification reference is indicated to the most recent developments in technology.

1. The colouring agents permitted in cosmetic products are listed in Directive 76/768/EEC according to the Colour index number which identifies the basic molecule. For technological reasons, i.e. insolubility of the colouring agent, stability to light and prevention of the coloration of the mucous membranes, the epidermis and the nails, the cosmetics industry uses the barium, strontium and zirconium salts of a limited number of these colouring agents. Annexes III (Part 2) and IV (Part 2) should therefore be amended to permit their use which, in the case of barium, could be prohibited under Annex II (No 46) and, in the case of strontium and zirconium under Annex V (Nos 5 and 6). The industry has provided scientific data proving the technological need for these substances and

establishing that the use of such colouring agents should not constitute a health risk.

2. Zirconium and its compounds are included in Annex V to Directive 76/768/EEC. The use of these substances in cosmetic products is now prohibited in three countries and this creates technical barriers to trade. It is true that zirconium lactate has given rise to the formation of granulomas and that harmful effects in the lungs were reported when it was used in aerosol applications. Zirconium aluminium chlorhydrate and the zirconium aluminium chlorhydrate/glycine complex are extensively used in the preparation of anti-perspirants marketed in a form other than that of aerosol dispensers. These two substances have been studied in detail and do not appear to jeopardize health. This was confirmed in the United States by a problem-free period of use of over twenty years. It is therefore proposed to permit the use of these two zirconium complexes as anti-perspirants under certain conditions. Moreover, the FDA[1] has approved this use.

3. Since repeated use of silver nitrate may prove dangerous, it is proposed to subject the use of this substance in the manufacture of cosmetics to certain restrictions and conditions as a temporary measure only, pending the results of further studies.

4. Article 11 and the penultimate recital of Directive 76/768/EEC specify that the Commission shall, on the basis of the findings of the latest scientific and technical research, submit to the Council appropriate proposals establishing lists of permitted substances which may consist of antioxidants, hair dyes, preservatives and ultraviolet filters. As a first step, a list has been compiled of substances permitted as preservatives. This list was sent to the Council in support of the proposal for a second amendment which is still being examined by its subordinate bodies. A list of substances permitted as sunscreen agents (ultraviolet filters) may now be put forward.

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1 Food and Drug Administration

As a precautionary measure, the great majority of these substances have been accepted only provisionally to enable the additional information necessary for a final assessment of health risks to be gathered even though the available data point to the improbability of any risk. In any case, this approach will lead to better consumer protection since, in future, the sunscreen agents used in the manufacture of cosmetics will be fully identified and their conditions of use specified.

A list of substances permitted as antioxidants will be drawn up at a later date, as the work of the Scientific Committee on Cosmetology is still in progress. A list of substances permitted as hair dyes will be drawn up at a later stage in view of the complexity of the problem and the large number of substances to be examined (approximately 300). In the interests of consumer protection, it is therefore preferable to put forward these lists in stages, since scientific research has not progressed uniformly in respect of each category of substances.

5. Indicating the expiry date is perfectly legitimate in the case of medicinal products since their efficacy can no longer be 100% guaranteed beyond this date. Cosmetic products, like foodstuffs, may still be consumed after that date, however, so there is less justification for indicating the expiry date; the criterion of efficacy is, moreover, not included in Directive 76/768/EEC.

   Indicating the date of minimum durability therefore appears to be more appropriate. It would not be mandatory for cosmetics the durability of which exceeds 24 months. It is therefore proposed that Article 6(1), subparagraph (c), of Directive 76/768/EEC be amended accordingly.

6. Subparagraph (e) of paragraph 1 of the same Article stipulates that the product labels must indicate the manufacturing batch number or an identification reference and also contains special provisions where this form of labelling is impossible in practice because the cosmetic products are too small.

   It is, not only the dimensions of the packaging which preclude identification of the goods but also the nature and shape of the packaging and the material of which it is made. It is therefore proposed to:

(a) align the wording of subparagraph (e) of Article 6(1) with that of subparagraph (d) of the same paragraph which, in general terms, provides for cases of practical impossibility;

(b) allow the use of modern technological processes, such as overprinting legible under ultraviolet light.

7. In formulating the proposal, the Commission has sought the opinion of national experts and consulted the trade and consumer representatives. As for sunscreen agents has to a considerable extent, been guided by the work of the Committee of Experts of the Council of Europe.

8. The proposal is based on Article 100. The opinion of the European Parliament and the Economic and Social Committee is required.

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive amending for the third time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(Submitted by the Commission to the Council on 23 January 1981)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas Article 11 of Council Directive 76/768/EEC (1), as last amended by Directive 79/661/EEC (2), provides that the Commission shall, on the basis of the results of the latest scientific and technical research, submit to the Council appropriate proposals establishing lists of permitted substances;

Whereas, on the basis of the studies carried out, the barium, strontium and zirconium lakes or salts of a limited number of colouring agents can be authorized;

Whereas, on the basis of information received, two complexes of zirconium can, under certain conditions, be permitted as anti-perspirants;

Whereas to safeguard public health, measures should be adopted in respect of silver nitrate;

Whereas, on the basis of the latest scientific and technical research, a list of substances authorized as sunscreen agents can be established;

Whereas the indication of the expiry date for cosmetic products whose period of stability is less than three years, provided for in Article 6 (1) (c) of Directive 76/768/EEC, is not justified in the case of cosmetic products which may still be used after that period; whereas indication of the date of minimum durability is therefore more appropriate;

Whereas it is not always the dimensions of the packaging which preclude indication of the manufacturing batch number or the product identification reference, but also the nature and shape of the packaging and likewise the material of which it was made; whereas account should therefore be taken of such cases and of the development of the technology,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC is amended in accordance with the following provisions.

Article 2

In Annex II, the wording relating to substance No 46 is replaced by:

'46. Barium salts, with the exception of barium sulphate, lakes prepared from barium sulphate and pigments prepared from the colouring agents listed under reference (5) in Annex III, Part 2 and Annex IV, Part. 2.'

(1) OJ No L 262, 27. 9. 1976, p. 169.
(2) OJ No L 192, 31. 7. 1979, p. 35.

Article 3

1. The following is added to Part 1 of Annex III:

Reference number	Substances	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
—	Zirconium aluminium chlorhydrate $Al_xZr(OH)_yCl_2$ and the zirconium aluminium chlorhydrate/glycine complex	Antiperspirants	20 % aluminium chlorhydrate and anhydrous zirconium 5·4 % zirconium	1. The ratio between the numbers of atoms of aluminium and zirconium must be between 2 and 10 2. The ratio between the numbers of atoms of (Al+Zr) and chlorine must be between 0·9 and 2·1 3. Prohibited in aerosol dispensers (sprays)	

2. Part 2 of Annex III is amended as follows:

— the following colour index numbers are deleted:

15.630: 1 (Ba)
15.630: 3 (Sr)
15.865: 3 (Sr)
45.170: 1 (Ba);

— reference (5) is inserted before the following colour index numbers:

12.085	10.316	42.051
15.585	12.075	
15.630	15.510	
15.850	15.985	
15.865	19.140	
16.255		
45.170		
45.370		
45.380		
45.410		
45.430		

— the following footnote is added:

(5) The following shall also be permitted: the barium, strontium and zirconium lakes or salts of these colouring agents, insoluble in 0·1 N-hydrochloric acid at 37 °C in accordance with a method which will have to be determined as provided for in Article 8.

Article 4

1. The following is added to Part 1 of Annex IV:

Reference number	Substances	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
—	Silver nitrate		4 %		For products intended to dye eyelashes and eyebrows: contains silver nitrate. Rinse eyes immediately if product comes into contract with them

2. Part 2 of Annex IV is amended as follows:

— the following colour index numbers are deleted:

15.500: 1 (Ba)

15.585: 1 (Ba);

— reference (5) is inserted before the following colour index number:

27.290;

— the following footnote is added:

(5) The following shall also be permitted: the barium, strontium and zirconium lakes or salts of these colouring agents, insoluble in 0·1 N-hydrochloric acid at 37 °C in accordance with a method which will have to be determined as provided for in Article 8.

Article 5

In Annex V the wording relating to substances Nos 5 and 6 is replaced by:

'5. Strontium and its salts, with the exception of those used in the colouring agents listed under reference (5), in Part 2 of Annex III and Part 2 of Annex IV.'

6. Zirconium and its compounds, with the exception of complexes mentioned by name in Part 1 of Annex III and zirconium salts used in the colouring agents listed under reference (5), in Part 2 of Annex III and Part 2 of Annex IV.

Article 6

Annex VII, in the form of the Annex hereto is added, listing the substances permitted as sunscreen agents in the manufacture of cosmetic products under the conditions laid down in that Annex and the preamble thereto.

Article 7

The following items are added to Article 4:

'(g) sunscreen agents, other than those listed in Part 1 of Annex VII;

(h) sunscreen agents listed in Part 1 of Annex VII, if the indicated limits are exceeded and the indicated conditions are not fulfilled.'

Article 8

The following text is added to Article 5:

'Until 31 December 1986, Member States shall permit the marketing of cosmetic products containing the sunscreen agents listed in Part 2 of Annex VII, within the limits and under the conditions laid down therein.

On 1 January 1987, these sunscreen agents shall, in accordance with the procedure laid down in Article 10, either be:

— definitively permitted (Part 1 of Annex VII), or

— definitively prohibited (Annex II), or

— retained for a period specified in Part 2 of Annex VII, or

— deleted from all Annexes.'

Article 9

1. Paragraph 1 (c) of Article 6 is replaced by:

'(c) the date of minimum durability. The date of minimum durability of a cosmetic product shall be the date until which the product, under appropriate conditions of storage and use, retains its specific characteristics and, in particular, remains in conformity with Article 2. It shall be indicated by the words: "Best used before the end of . . ." followed by either:

— the date itself, or

— details of where the date appears on the packaging.

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

The date shall be clearly expressed and comprise the month and the year in that order. Indication of the date of durability shall not be mandatory for cosmetic products whose durability exceeds 24 months.'

2. Paragraph 1 (e) of Article 6 is replaced by:

'(e) the manufacturing batch number or the product identification reference. However, where this is impossible for practical reasons, the product shall be identified by means of information displayed on the outer packaging or, by other more appropriate and indelible means, even if invisible.'

Article 10

1. Member States shall take all the requisite measures to ensure that, with effect from 1 January 1987, neither manufacturers nor importers established in the Community shall place at the disposal of third parties products which do not meet the requirements of this Directive.

2. Member States shall adopt all the requisite measures to ensure that, by 31 December 1988 at the latest, the products referred to in the first paragraph are no longer marketed.

Article 11

Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive by 31 December 1984 at the latest. They shall forthwith inform the Commission thereof.

Article 12

This Directive is addressed to the Member States.

ANNEX

ANNEX VII

List of sunscreen agents which cosmetic products may contain

Sunscreen agents are substances which, when applied topically, are specifically intended to filter certain ultraviolet rays in order to protect the skin from certain harmful effects of the sun.

Other substances used in the formulation of cosmetic products can also absorb certain ultraviolet rays. They are not included in the list because absorption of ultraviolet rays is not their main function.

PART 1

List of sunscreen agents which cosmetic products may contain

Reference number	Substances	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must appear on the label
a	b	c	d	e
1	p-Aminobenzoic acid	5 %		
2	3-(4-Trimethyl-ammoniobenzylidene) camphor methosulphate	6 %		
3	Homomethyl salicylate (3,3,5-trimethyl-cyclohexyl salicylate)	10 %		
4	Phenyl salicylate	4 %		
5	2-Hydroxy-4-methoxybenzo-phenone	10 %		
6	2-Amino-6-hydroxypurine (guanine)	2 %		

PART 2

List of sunscreen agents which cosmetic products may provisionally contain

Reference number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must appear on the label
a	b	c	d	e
1	N-propoxylated ethyl p-aminobenzoate	5 %		
2	Ethoxylated ethyl p-aminobenzoate	10 %		
3	Amyl p-dimethyl-aminobenzoate	5 %		
4	Glyceryl p-aminobenzoate	5 %	without benzocane	
5	2 Ethylhexyl p-dimethyl-aminobenzoate	8 %		
6	2 Ethylhexyl salicylate	5 %		
7	Benzyl salicylate	7 %		
8	3,3,5-Trimethylcyclohexyl-N-acethylanthranilate (homomen-thyl-N-acetyl-anthranilate)	2 %		

Reference number	Substances	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must appeat on the label
a	b	c	d	e
9	Potassium cinnamate	2 %		
10	p-Methoxycinnamic acid salts (potassium and di-ethanolamine)	8 % (expressed as acid)		
11	Propyl p-methoxycinnamate	3 %		
12	Salicylic acid salts (potassium and triethanolamine)	5 %	The pH of the finished product must be such that the acid is not liberated	Not to be used for children under three years of age
13	Iso-amyl p-methoxycinnamate	10 %		
14	2-Ethoxyethyl p-methoxycinnamate	10 %		
15	2-Ethoxyethyl p-methoxycinnamate	5 %		
16	Digalloyl trioleate	4 %		
17	2,2',4,4'-Tetrahydroxy-benzophenone	10 %		
18	2-Hydroxy-4-methoxy-4'-methylbenzophenone	4 %		
19	2-Hydroxy-4-methoxy-benzophenone 5-sulphonic acid and sodium salt	5 % (expressed as acid)		
20	2-Ethylhexyl-4'-phenyl-benzophenone-2-carboxylate	10 %		
21	2-Phenylbenzimidazole-5 sulphonic acid and its potassium and triethanolamine salts	8 % (expressed as acid)		
22	β-Imidazole-4(5)-acrylic acid and its ethyl ester	5 % (expressed as acid)		
23	2-Phenyl-5-methylbenzoxazole	4 %		
24	Sodium 3,4-dimethoxyphenylglyoxylate	5 %		
25	Dianisoylmethane	6 %		

Reference number	Substances	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must appear on the label
a	b	c	d	e
26	5-(3,3-Dimethyl-2-norborn-yliden)3-pentene-2-one	3 %		
27	3-(3-Sulpho-4'-methyl benzylidene) camphor	6 %		
28	3-(4'-Sulphobenzylidene)	6 %		
29	3-(4'-Methylbenzylidene)-d, 1-camphor	6 %		
30	3-Benzylidene-d, 1-camphor	6 %		
31	Methoxybenzylidene cyano-acetic acid and its n-hexyl ester	5 %		
32	4-Isopropyldibenzoylmethane	5 %		
33	p-Isopropylbenzyl salicylate	4 %		
34	Cyclohexyl p-methoxycinnamate	1 %		
35	2-(p-Toluyl)-benzoxazole	10 %		
36	ter-Butyl-4-methoxy-4-dibenzoylmethane	5 %		