

**COMMISSION OF THE EUROPEAN COMMUNITIES**

**COM(73) 1733 final**

**Brussels, 17 October 1973**

**Amendment to the proposal for a Council  
directive on the approximation of the laws  
of Member States relating to cosmetic products**

**(Presented by the Commission to the Council pursuant to  
the second paragraph of Article 149 of the E.E.C. Treaty)**

**COM(73) 1733 final**

EXPLANATORY MEMORANDUM

As part of the General Programme for the removal of technical obstacles to trade adopted by the Council on 28 May 1969<sup>1</sup>, the Commission addressed to the Council on 19 October 1972 a proposal for a Directive on the approximation of the laws of the Member States relating to cosmetic products.

The European Parliament delivered its opinion on this proposal for a Directive during its session of 6 July 1973<sup>2</sup>. The Commission has carefully examined the comments contained in the opinion and has decided to take appropriate action on some of them, and, to this end, in pursuance of Article 149, second paragraph of the Treaty, to put forward the following proposals for amendments to the original proposal for a Directive:

- Article 6 (3) and (4);
- Article 11 (2);
- Article 12;
- Article 14;

These proposals for amendments are intended to give greater clarity to certain requirements relating to the labelling and presentation for sale of cosmetic products, to make clearer and more practical the Community safeguard procedure provided for cases in which a cosmetic product which complies with these provisions constitutes a hazard to human health. They are also intended to remove from the proposal the additional period provided for the sale of old stocks.

Furthermore they are for the purpose of amending, in connection with the Community's enlargement, the distribution of votes in the Committee's procedure.

The Commission also proposes the amendment and expansion of Annexes II (List of substances which cosmetic products must not contain), III, Part 1 (List of substances which cosmetic products must not contain, except subject to the restrictions laid down) and IV, Part 1 (List of substances provisionally allowed).

In formulating the last mentioned proposals for amendments, the Commission has taken account of the opinions of the experts who assist it in drawing up the technical annexes to the proposal for a Directive.

<sup>1</sup> OJ No C-76, 17 June 1969    <sup>2</sup> OJ No C 62, 31 July 1973.

AMENDMENTS TO

the proposal for a Council Directive on the approximation of the laws of Member States relating to cosmetic products  
the Commission on 19 October 1972

The proposal for a Directive forwarded to the Council on 19 October 1972 is amended by the following:

- amendments to Article 6 (3) and (4);
- a correction to Article 11 (2);
- the rewording of Article 12;
- deletion of Article 14 (2);
- amendments to Annexes II, III and IV.

Article 6

The text of paragraphs (3) and (4) is expanded as follows:

3. The special precautions of use, and, in particular, those indicated in the column "Conditions of use and warnings which must appear on the label" in Annexes III and IV shall appear legibly on the container; where this is impossible for practical reasons, these indications shall appear on the outside packaging and on an enclosed leaflet, but in this case an abbreviated external indication must appear on the container, referring to the indications mentioned.
4. The use, both in the labelling and in the presentation for sale of the products covered by Article 1 and in the publicity concerning them, in whatever form this may be, of names, trademarks, images or other signs, visual, cinematographic or other displays, suggesting a characteristic which the products considered do not possess, or attributing thereto effects which are not, or are insufficiently established scientifically, shall be prohibited.

Article 11

~~The text of the second paragraph shall be amended as follows:~~

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall render its Opinion on this draft within a period of time which the Chairman may fix according to the urgency of the matter in hand. It shall act by a majority of 41 votes, the votes of the Member States being weighted as laid down in Article 148 (2) of the Treaty. The Chairman shall not vote.

Article 12

The text of this Article is replaced by the following:

1. If a Member State ascertains that a cosmetic product constitutes a hazard to health, although conforming to the requirements of this Directive and being used as directed, this State may, for a maximum period of one year, prohibit in its territory the sale, putting into circulation or use of the cosmetic product in question. It shall immediately communicate this to the other Member States and to the Commission, accompanied by a statement of grounds.
2. The Commission shall consult the Member States involved within six weeks. It shall deliver its opinion without delay and take the necessary measures. On the initiative of the Commission it shall be decided without delay, in accordance with the procedure provided for in Article 100 of the EEC Treaty or with that specified in Article 11 of this Directive, whether the Directive must be amended. If necessary, the necessary amendments shall be adopted by Directive. The time limit referred to in Paragraph (1) shall be extended until the procedure initiated has been completed, but not for more than one year.

Article 14

Section 2 is deleted.

Annex II -- list of substances which cosmetic products must not contain.

The following substances have been added to the list:

426. Diphenhydramine (2 Benzhydroxy-N,Dimethylethylamine) and its salts.
427. p-tert butyl phenol and its allergenic derivatives.
428. p-tert butyl pyrocatechin
429. Dihydrotachisterol (AT 10)

430. Thiourea
431. Derivatives of thiourea, except those expressly mentioned in Annex IV.
432. Dioxane (1.4 diethylene dioxide).
433. Morpholine.
434. Preparations based on pyrethrum.
435. Pyrimino-anisole moleate.
436. Paribenzamine.
437. Tetrachlorosalicylanilide.
438. Dichlorosalicylanilide.
439. Tetrabromosalicylanilide.
440. Dibromosalicylamide.
441. Bithionol.
442. Thiramic monosulphides.
443. Thiramic disulphides.
444. Dimethylformamide.
445. Xylidines (all isomers).
446. Benzylidene acetone.
447. Coniferyl benzoate, except for normal content in natural essences used.
448. Furocumarin, except for normal content in natural essences used.
449. Laurel oil.
450. Sassafras oil containing safrole.
451. Iodothymol.

Annex III: Part 1

List of substances which cosmetic products must not contain, except subject to the restrictions laid down.

Item No 27-- Hexachlorophene-- is deleted.

The words "and muds" are deleted on Page 4, note (1), beginning of second paragraph.

The substances quoted below are added.

Reference Number	Product	Restrictions			Conditions of use and warnings which must be printed on the label
		Use	Maximum permissible concentration	Other limitations and requirements	
a	b	c	d	e	f
27	Quinine and its salts	(a) shampoos (b) hair lotions	0.5% } expressed 0.2% } as quinine base		contains quinine
28	Hydroxy-8-quinoline and its sulphate		0.3% expressed as base	not for use in anti-sunburn products, post sunbathing products and baby powders	
11	Formaldehyde			prohibited in aerosols	
29	Nitro methane	solely as corrosion inhibitor for aerosol packs	0.3%		

Annex IV: Part 1

List of provisionally acceptable substances.

The following is added to item 22 - xylocaine:

Reference number	Product	Restrictions		Conditions of use and warnings to be printed on the label
		Use	Maximum permissible concentration	
a	b	c	d	e
22	xylocaine (lidocaine USP)  (lignocaine BP)	after shave lotion  after sun lotion	0.1%  allowed	
The following substances have been added:				
23	hexachlorophane	(a) soaps and shampoos (b) aerosol sprays (c) body deodorants (d) other uses	1%  0.15%  0.5%  0.1%	contains hexachlorophane not for use on children below the age of 10       Products for intimate hygiene not to be used during pregnancy
			other restrictions prohibited in cosmetic products for use on children below the age of 10	
24			maximum content 100 ppm in the finished product	