

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(81) 653 final

Brussels, 11 November 1981

Proposal for a
COUNCIL DIRECTIVE

amending 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(81) 653 final

EXPLANATORY MEMORANDUM

1. The proposal amends for the fourth time Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. Its purpose is to authorize two substances (nicomethanol hydrofluoride and 6-methyl coumarin) for use in cosmetic products subject to certain restrictions and conditions (entry in Annex III).
2. Directive 76/768/EEC authorizes a number of fluorine compounds for use in oral hygiene products up to a maximum concentration of 0.5% calculated as F in the finished cosmetic product and subject to certain conditions of use and warnings which must be printed on the label. According to the file submitted by the manufacturer, nicomethanol hydrofluoride appears to have some advantage in fixing fluorine on tooth enamel while at the same time it has no toxicity or pharmacological action under normal conditions of use and even beyond. It is therefore proposed that it be added to the list of fluorine compounds already authorized by the Directive, under the same conditions.
3. In the United States 6-methyl coumarin has been prohibited in cosmetic products because it can induce photosensitization reactions. For the same reason the International Fragrance Association (IFRA) recommends that 6-methyl coumarin should not be used as a raw material for perfumery. However, the Council of Europe (1) allows the presence of 6-methyl coumarin in foods up to a concentration of 30 ppm. As far as cosmetic products are concerned, it is therefore proposed that the use of 6-methyl coumarin be authorized solely in oral hygiene products, where there is no risk of photosensitization, and at a maximum concentration of 30 ppm in the finished product, the limit authorized for foodstuffs, which corresponds to normal practice in the Community.

(1) Blue book. Natural flavouring substances, their sources and added artificial flavouring substances. 1974 edition.

4. In drafting the proposal, the Commission obtained the opinion of national experts and consulted industry and consumers.

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

Proposal for a Council Directive amending 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 18 November 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 Council Directive 76/768/EEC ⁽¹⁾, as last amended by Directive 79/661/EEC ⁽²⁾, should be further amended to take account of the results of the most recent scientific and technical research;

Whereas according to these results the use of nicomethanol hydrofluoride and 6-methyl coumarin in cosmetic products may be authorized under certain conditions,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The following substances are hereby added to Annex III Part 1 to Directive 76/768/EEC:

Reference No	Substance	Restrictions			Conditions of use and warning 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
—	nicomethanol hydrofluoride	oral hygiene products	0.15 % calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15 %		contains nicomethanol hydrofluoride
—	6-methyl coumarin	oral hygiene products	0.003 %		

⁽¹⁾ OJ No L 262, 27. 9. 1976, p. 169.

⁽²⁾ OJ No L 192, 31. 7. 1979, p. 35.

Article 2

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 April 1982. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.
