

# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(87) 156 final

Brussels, 9 April 1987

Proposal for a  
FIFTH COUNCIL DIRECTIVE

adapting to technical progress Annex III to Directive 76/768/EEC  
on the approximation of the laws of the Member States relating  
to cosmetic products

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(submitted to the Council by the Commission)

COM(87) 156 final

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Cosmetology

EXPLANATORY MEMORANDUM

1. The aim of the proposal is to authorize, under certain conditions and subject to certain restrictions, the use of benzoyl peroxide in lotions, creams and gels for cleaning and improving the appearance of greasy skin.
  
2. The use of benzoyl peroxide in cosmetic products is neither prohibited nor restricted by Directive 76/768/EEC. Two Member States have invoked the safeguard clause in order to prohibit the use of benzoyl peroxide in cosmetic products on the grounds of its irritating and sensitising properties. In the opinions<sup>1</sup> it delivered on 29 November 1983 and 17 December 1984, the Scientific Committee on Cosmetology accepted the use of benzoyl peroxide in cosmetic products at a maximum concentration of 3% in the finished product, provided that certain warnings appeared on the labelling, although several members took the view that benzoyl peroxide should be used only under medical supervision. In the meantime, the industry has reduced the concentration used to 2%. Following the opinion of the Scientific Committee on Cosmetology, the Commission referred a draft to the Committee for the Adaptation to Technical Progress of Directive 76/768/EEC for its opinion. This draft authorizes the use of benzoyl peroxide in certain cosmetic products with a maximum concentration of 2% in the finished product, provided that the set of mandatory warnings appears on the labelling and subject to certain requirements, in particular that the finished product must not be presented in such a way as to claim or imply that it can cure and prevent acne; this would be an improvement on the present situation from the public health viewpoint. The Committee was unable to deliver an opinion because the delegations are divided on whether products containing benzoyl peroxide should be classified as cosmetics or medicinal products. Failing an opinion from the Committee, it is up to the Commission, pursuant to Article 10 of Directive 76/768/EEC, to refer a proposal to the Council, which will have to decide by a qualified majority within three months of the proposal being submitted to it.

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1 Report EUR 10305

Proposal for a  
FIFTH COUNCIL DIRECTIVE

adapting to technical progress Annexe III to  
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,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products<sup>1</sup>, as last amended by Directive 87/137/EEC<sup>2</sup>, and in particular Article 8(2) thereof,

Having regard to the proposal from the Commission,

Whereas, on the basis of the results of the most recent scientific and technical research, the use of benzoyl peroxide to improve the appearance of greasy skin may be authorized under certain conditions;

Whereas the Committee for the Adaptation to Technical Progress of the Directives for Removal of Technical Barriers to Trade in the Cosmetics Sector was unable to deliver an opinion on the proposed measures referred to it by the Commission,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The following is hereby added to Annex III, part 1 of Directive 76/768/EEC/

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1 OJ No. L 262, 27.9.1976, p. 169  
2 OJ No. L 56, 26.2.1987, p. 20

a	b	c	d	e	f
53	Benzoyl peroxide	Lotions, creams and gels for cleaning and improving the appearance of greasy skin	2%	<ul style="list-style-type: none"><li>- In accordance with the definition of a cosmetic product in Article 1(1), it may not be stated or implied that the finished product can cure or prevent acne.</li> <li>- Not to be used in ethanol preparations</li></ul>	<ul style="list-style-type: none"><li>- Contains benzoyl peroxide.</li><li>- Avoid all contact with the eyes and mouth.</li><li>- Discontinue use if irritation occurs.</li><li>- Avoid prolonged exposure to the sun.</li></ul>

Article 2

1. Member States shall take all necessary measures to ensure that from 1 January 1990 neither manufacturers nor importers established in the Community place on the market products which do not satisfy the requirements of this Directive.
2. Member States shall take all necessary measures to ensure that the products referred to in paragraph 1 can no longer be sold or disposed of to the final consumer after 31 December 1991.

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 1988 and shall forthwith inform the Commission thereof.
2. Member States shall communicate the text of the provisions of national law which they adopt in the field governed by this Directive to the Commission.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

- I. Quelle est la justification principale de la mesure ? (1)
- II. Caractéristiques des entreprises concernées  
En particulier :
- Y a-t-il un grand nombre de PME ? oui
  - note t'on des concentrations dans des régions :
    - éligibles aux aides régionales des E.M. ? néant
    - éligibles au Feder ? néant
- III. Quelles sont les obligations imposées directement aux entreprises ?  
néant
- IV. Quelles sont les obligations susceptibles d'être imposées indirectement aux entreprises via les autorités locales ?  
néant
- V. Y a-t-il des mesures spéciales pour les PME ?
- Lesquelles ? néant
- VI. Quel est l'effet prévisible ? néant
- sur la compétitivité des entreprises ? //
  - sur l'emploi ? //
- VII. Les partenaires sociaux ont-ils été consultés ? oui
- avis des partenaires sociaux : accord

(1) This proposal will allow, under certain conditions and restrictions, the use of benzoyl peroxide in the manufacture of cosmetics. Only a few businesses will be affected and, since the change amounts to a relaxation, these effects will be beneficial. The proposal has no other implications for business competitiveness or employment.