

## ECONOMIC AND SOCIAL COMMITTEE

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COSMETIC PRODUCTS

Brussels, 6 December 1979

R E P O R T  
of the  
Section for Industry, Commerce, Crafts and Services  
on the  
Proposal for a Council Directive Amending, For the First  
Time, Council Directive 76/768/EEC of 27 July 1976 on  
the Approximation of the Laws of the Member States  
Relating to Cosmetic Products  
(Doc. COM(79) 250 final)

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Rapporteur : Mr MASPRONE

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## I. INTRODUCTION

In a letter dated 8 June 1979, the Council of the European Communities asked the Economic and Social Committee for an Opinion of the

Proposal for a Council Directive amending, for the First Time, Council Directive 76/768/EEC of 27 July 1976 on the Approximation of the Laws of the Member States relating to Cosmetic Products (Doc. COM(79) 250 final).

On 26 June 1979 the Committee's Bureau instructed the Section for Industry, Commerce, Crafts and Services to draw up an Opinion and a Report on the matter.

The Section instructed the Study Group on Technical Barriers to draft the Opinion and the Report.

## II. GIST OF THE DRAFT DIRECTIVE

The proposal is designed to :

- 1) correct certain errors in Council Directive 76/768/EEC of 27 July 1976, chiefly in connection with index numbers for colouring agents;
- 2) tighten up the above Directive. Implementation revealed the need to tighten up, if not improve certain provisions;

- 3) comply with Article 5 which stipulates that on expiry of a period of three years from notification, the substances and colouring agents listed in Annex IV shall :
  - either be definitively permitted;
  - or definitively prohibited (Annex II);
  - or retained for a further period of three years in Annex IV;
  - or deleted from all Annexes to this Directive.
- 4) draw up a list of substances which may be used as preservatives;
- 5) adapt the Annexes to technical progress, under the usual procedure.

### III. GENERAL COMMENTS

1. The Section welcomes the amendments to the parent Directive of 27 July 1976 on cosmetic products. The amendments already provided for in the parent Directive are necessary in order (a) to correct certain errors which it contained and (b) to take account of technical progress in this field. The fact that these amendments have taken longer than originally envisaged is understandable in view of the complexity of the problems (this is pointed out specifically in the parent Directive).

2. In its previous Opinion on cosmetics the Committee approved the structure of the parent Directive but asked the Commission to start immediately to build up an approved list by stages, starting with whatever groups of substances seemed most important from the point of view of health; at the same time it pointed to

the difficulties which the compilation of such a list could entail. For this reason the Section is pleased to note that the proposed amendment are a first step in this direction.

3. Prohibited substances. The new clause tolerates traces of the prohibited substances listed in Annex II provided that they are technically unavoidable and do not render the product unsafe. This clause seemed necessary since the Directive stipulated that cosmetic products must not contain Annex II substances, whereas the idea had been to ban the use of these substances in the manufacture of cosmetics. The proposed solution seems the best.

The Commission further undertakes to propose maximum concentrations for these substances by 31 December 1982 at the latest.

Some members are of the view that when these maximum concentrations are fixed the opportunity should be taken to obtain information about the specific problems of cosmetics production and marketing.

Some members think that it will be very difficult to adhere to this undertaking because of the complexity of the problem and in particular the difficulty of pinpointing the substances which can be present in the form of traces, taking into account the current state of chemical analysis techniques and the progress which is continually being made.

Other members point out that the proposal put forward by the Commission is to move towards liberalization since the banned substances would be permitted in the form of traces which are "technically unavoidable when correct manufacturing techniques are used". In their view, however, this expression is meaningless to those responsible for carrying out inspections. The expression is, therefore, not acceptable to these members, on health grounds, unless maximum permissible concentrations of the banned substances (based on toxicological data) are also laid down as soon as possible. It would not, however, appear to be possible to lay down these figures by the proposed date. Until such time as maximum permissible concentrations are determined a vague wording could always be exploited in the case of infringements.

4. Other uses of products. The proposal for a Directive permits the use of preservatives in higher concentrations if they are used for other purposes (such as fungicides or antiseptics). Some members consider that this is a dangerous practice as the restrictions on the use of preservatives have been determined in the light of toxicological data and the toxicity of preparations containing more than the permitted concentrations is a matter for speculation. Furthermore, when a substance is used as an antiseptic it is no longer a cosmetic product but a medical preparation. Any product which is regarded as both a cosmetic product and a medical preparation will inevitably cause legal difficulties. Authorizing the use of higher concentrations of these substances will cause difficult problems both as regards public health and inspections. This issue is being considered by the Council of Europe which has not been able to reach a decision on the matter. The other uses of the preservatives should, therefore, be examined, specified and set out in an exhaustive list which should be drawn up as soon as possible.

This problem is inevitable with incomplete approved lists and can only be adequately resolved by the compilation of a complete approved list as called for by the Committee Opinion of 23 and 24 May 1973.

Several substances can function as preservatives in cosmetic preparations and some substances with preservative properties can also give cosmetic preparations other properties; deodorant, dandruff prevention, perfume, combing out agent for hair etc.; furthermore, without any risk to the user, it is often necessary to specify higher concentrations than those necessary to ensure the keeping properties of the product. The user is then protected by the fact that the manufacturer must comply with Article 2 of the Directive of 27 July 1976 which stipulates that : "Cosmetic products put on the market within the Community must not be liable to cause damage to human health when they are applied under normal conditions of use."

Inspection laboratories which detect higher than the prescribed percentages of listed preservatives which always be able to ask the manufacturers to justify this situation.

#### IV. SPECIFIC COMMENTS

1. Procedure for Adapting to Technical Progress (Article 9).  
The proposal that the Commission should adapt the Annexes, after consulting the Committee on Adaptation of Directives to Technical Progress, meets the wish expressed repeatedly by the Committee. Moreover, in its 1972 Study the Committee called for an extension of this procedure so as to speed up amendments to Directives dictated by advances in research and the discovery of new techniques in this sector.

The Section would, however, stress the need to introduce changes in the membership of the Adaptation Committee to enable it to include representatives of sectors concerned.

At all events, the Section urges that the consultation between the working party and the interested groups, i.e. manufacturers and users, be continued prior to the submission of any new proposed amendments to the Council or the Adaptation Committee.

2. Annex IV. The Section welcomes the fact that the Commission has been able to cut from 33 to 4 the number of substances provisionally allowed in Annex IV, Part I, by reclassifying these substances in the other Annexes.

It deplores the failure to settle the question of methyl alcohol because the EEC has not yet been able to harmonize alcohol taxes, methanol being used in some Member States as a denaturant.

Some members wish to make the following comments :

1. Preamble - eighth paragraph

Although substances may carry a C.I. number, they are not always considered as colouring agents. The proposed changes to Annex 4 take this into account and it should also be indicated in this preamble.

2. Article 4, paragraph (2) (d)

C.I. number 77718 corresponds to talcum, which should not be considered as a colouring agent.

3. Article 6

Article 7, paragraph (1) (e)

Article 7, paragraph (1) (f)

Article 8, paragraph (d)

The text of these Articles should make clear what is meant by preservatives. It will give a legal status to the preamble of Annex IV. It is therefore proposed to add the words :

"preservatives as defined in the preamble to Annex IV"  
to these three Articles.

4. Annex III, Part 1, title

Allowance should be made for the unavoidable presence of traces of these substances occurring in cosmetic products in which they are banned and to which they were not



deliberately added. The Italian text seem to be clear on this. It is suggested to use the title : "Substances the use of which is forbidden in cosmetic products".

5. Annex III, Part 1, No. 2

Thioglycolic acid is never present in the acid form. Consumers should not be misled, as this could even lead to accidents in the case of spillage (as an acid needs to be neutralized with a base). For this reason it is suggested to put in column (f) "Contains a thioglycolate - Follow the instructions".

6. Annex III, Part 1, No. 14

The use as a skin lightener exists in several Member States and would be forbidden if the text were not changed. Column (c) should specify two uses :

1. Oxidation hair dye;
2. Skin lightener.

7. Annex III, Part 1, No. 26

Only water-soluble salts need limitation on safety grounds and column (b) should therefore read "water-soluble zinc salts".

8. Annex IV, Part 1, additional substances

Two additional listings should be made in Annex IV, Part 1. The substances listed in Part 2, Nos. 6 and 7 (p-hydrobenzoic acid, their salts and esters) should be listed in Part 1 as Nr. 12 with an asterisk. The substances listed in Part 2, No. 34 (paraformaldehyde) should be listed in Part 1 as No. 13 with an asterisk. These additions as permitted preservatives were agreed upon during previous official discussions at the EEC working party but not included by the Commission due to lack of time.

9. Annex VI, Part 2, No. 2

The limitations for boric acid as described in Annex III, Part 1, No. 1 are adequate and should also be used for Annex VI. Inconsistences between Annexes III and VI should be avoided.

10. Annex VI, Part 2, No. 12

The nitrate salts are widely used in the industry. In the text of the original Directive under Annex V, salts of acetate, nitrate and borate were covered. In the present

text, acetate is covered by the preamble, but borate and nitrate have to be mentioned. It is therefore proposed to put in the column marked "substances" the following text : "Phenylmercury and its salts (including borate and nitrate)".

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