

IND/183

COSMETICS
(5th Amendment)

Brussels, 8 June 1982

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 Fifth Time Directive 76/768/EEC
on the Approximation of the Laws of the Member States
relating to Cosmetic Products
(COM(81) 774 final)

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I. INTRODUCTION

On 29 January 1982 the President of the Council of the European Communities asked the ESC for an Opinion on the

Proposal for a Council Directive Amending for the Fifth Time Directive 76/768/EEC on the Approximation of the Laws of the Member States relating to Cosmetic Products.

On 26 January 1982 the Committee Bureau instructed the Section for Industry, Commerce, Crafts and Services to draw up an Opinion and a Report on the matter.

The Section for Industry, Commerce, Crafts and Services instructed the Study Group on Technical Barriers to prepare the corresponding Draft Opinion and Draft Report.

II. BACKGROUND: LEGAL CONTEXT AND REASONS FOR THE AMENDMENT OF THE DIRECTIVE

The basic Directive of 27 July 1976

1. The basic purpose of the Directive is to safeguard human health

This is covered by Article 2: "Cosmetic products ... must not be liable to cause damage to human health ...".

It is generally accepted that the most efficient way to protect consumer health is a system based exclusively on approved lists of permitted substances (see the Council's reply to Parliamentary Question No. 646/76, OJ C 127 of 31 May 1977). However, given the present stage of research, and the concern to use methods which allow for economic and technological requirements, the Directive regulates the substances used in cosmetics by a mixed system of prohibited and approved lists.

What the mixed system means:

- a) Some substances are prohibited: these are contained in a prohibited list (Annex II).
- b) Some substances are allowed in limited quantities and with special criteria for their use; these are contained in a general approved list.

Authorized substances which are not subject to a review clause are contained in Annex III; those with provisional authorization in Annex IV.

- c) Strict approved lists are used for three categories of substances: colouring agents, preservatives and sun filters. In these categories, only substances which appear in the corresponding lists are authorized.

d) With the exception of colouring agents, preservatives and sun filters, all categories of product whose substances appear on neither the prohibited nor the general approved list are permitted subject to the conditions of Article 2.

2. The safeguard clause

As it is possible that cosmetic products launched on the market may fulfil the requirements of the Directive and its annexes while still constituting a danger to human health, the Directive lays down a procedure by which a Member State can provisionally prohibit or restrict the marketing of the suspect product(s) (Art. 12).

3. Substances not covered by approximation

Some substances on which Member States differed when the basic Directive was drawn up were excluded from the Directive, and their authorization was left up to individual Member States. These substances are listed in Annex V of the Directive.

4. Consultation of interested parties

Neither consumers nor workers were consulted when the basic Directive was drawn up. Only the views of the industry were heard.

Amendments to the framework Directive have all been made in consultation with COLIPA (the European Liaison Committee for the Perfume and Cosmetics Industry) and the Consumers' Consultative Committee, but workers have never been consulted.

A knowledge of the precautions to take when handling potentially harmful products may be crucial, and this applies first and foremost to hairdressers, beauticians and the like.

Some members thus feel that consultation of the Consultative Committee for Occupational Hygiene would be highly desirable.

In any case, some members observe that the Committee issued an Opinion on the framework Directive and its amendments.

III. GIST OF THE PROPOSAL FOR A FIFTH AMENDMENT TO THE BASIC - DIRECTIVE

This amendment deals with the problems raised by hair dyes.

1. Treatment of hair dyes in the basic Directive

These substances are not yet the subject of a strict approved list.

Some of them are authorized by the general approved list (Annex III) under headings no. 9: diaminobenzenes, no. 10: diaminotoluenes and no. 11: diaminophenols.

One of them was not covered by approximation. This is 1,4-diaminobenzene, included in Annex V, under no. 4: para-diaminobenzene.

The other substances are implicitly authorized by their non-appearance in Annex II.

2. Purpose of the fifth amendment

The fifth amendment aims to:

- a) allow the free movement of 1,4-diaminobenzene (currently in Annex V);
- b) take appropriate measures for the ten hair dyes on which several Member States have exercised the safeguard clause:
 1. 1-methoxy-2,4-diaminobenzene (2,4-diamino-anisole)
 2. 1-methoxy-2,5-diaminobenzene (2,5-diamino-anisole)
 3. 1,4-diamino-2-nitrobenzene (2-nitro-p-phenylenediamine)
 4. 1,2-diamino-4-nitrobenzene (4-nitro-o-phenylenediamine)
 5. 1-methyl-2,4-diaminobenzene (2,4-diaminotoluene)
 6. 1-methyl-2,5-diaminobenzene (2,5-diaminotoluene)
 7. 1,2-diaminobenzene (o-phenylenediamine)
 8. 1,3-diaminobenzene (m-phenylenediamine)
 9. 1-hydroxy-2-amino-4-nitrobenzene (2-amino-4-nitrophenol)
 10. 1-hydroxy-2-amino-5-nitrobenzene (2-amino-5-nitrophenol).

These ten substances are authorized by headings 9 and 10 of Annex III of the basic Directive.

3. To clarify the situation, the Commission asked the Scientific Committee on Cosmetology to give their opinion on the eleven suspect hair dyes

The gist of the Opinion is as follows:

1-4 diaminobenzene: No negative evidence - the Committee recommends that use of it continue.

Substances 3 and 5: Carcinogenic substances in animals, incomplete evidence - the Committee recommends they be banned.

Substance 7: Very little evidence, substance not used - the Committee recommends it be banned.

Substances 6 and 8: No carcinogenic potential in animals - the Committee recommends that use of them continue.

Substances 1, 2, 4, 9 and 10: most of these substances act as mutagens on bacteria, and tests on carcinogenic potential were unsatisfactory - the Committee recommends use of them be continued provisionally until 31 December 1985, while awaiting the results of additional research.

4. On the basis of the Scientific Committee's Opinion, the Commission proposes:

1. banning substances 5 and 7 as recommended by the Scientific Committee. These substances are therefore transferred to Annex II.
2. allowing the free movement of 1,4-diaminobenzene (or para-diaminobenzene) by transferring it from Annex V to Annex III.
3. taking no specific measures for the other substances, as they are already authorized by Annex III.
4. deferring its decision on substance 3, while awaiting further toxicological evidence.

IV. GENERAL COMMENTS

1. The Section endorses the banning of substances 5 and 7, and the authorization of the free movement of 1,4-diaminobenzene, as these proposals are in line with the recommendations of the Scientific Committee.

2. Although the proposal concentrates only on the future of substances 5, 7 and 1,4-diaminobenzene, the Section notes that its implications are in fact much wider.

For by leaving diaminobenzenes and diaminotoluenes in Annex III (general approved list), the proposal authorizes substances 1, 2, 4, 6, 8, 9 and 10 without providing for a review clause.

The Section notes that the Scientific Committee on Cosmetology recommends that substances 1, 2, 4, 9 and 10 be only retained provisionally, until 31 December 1985. These substances should therefore be subject to a review clause.

3.1. The Section notes that the Commission is taking no decision on substance 3, while the Scientific Committee recommends it be banned.

3.2. Some members point out that this substance is of great economic and technological importance: around 6 tonnes of it are used every year. This represents a total sale of 38 million units of permanent dye and around 20 million units of temporary or semi-permanent dye. The dye is used in 600 different formulas for dye products. A ban on it would reduce the range of dye shades available. Moreover, the development of substitutes is proving a long and difficult process.

3.3. Other members feel that it is disturbing, to say the least, that a directive which has human health as one of its basic aims puts economic interests before health protection.

These members urge that a decision be taken as soon as possible. If it is not, the Scientific Committee's recommendation would suggest that retention of this substance in Annex III may be incompatible with Article 2 of the framework Directive.

3.4. One member calls for the banning of Substance 3. Other members wish to stress that there is absolutely no question of their wanting to put health protection at risk. This is why they urge that the results of the toxicological tests be made known as soon as possible, so that a reasoned decision can be made on this substance.

4. The Section raises the problem posed by the legal uncertainty which could result from the consequences of the enforcement by some Member States of the safeguard clause. In the present case, the Commission will communicate its decision on all the authorized substances (i.e. 1, 2, 4, 6, 8, 9 and 10) to the Member States concerned.

If these countries find the authorization unacceptable, they may present a detailed justification to the Commission seeking to retain their own ban. If the Commission finds this justification insufficient, it will start legal proceedings against the countries concerned. Cases will be brought before the Court of Justice.

Countries which have exercised the safeguard clause on substance 3 will be allowed to retain their ban on it until the Commission reaches a decision.

5. The Section feels that an approved list of colouring materials for hair dyes is urgently needed, to (a) ensure protection of consumer and worker health, (b) ensure greater certainty in the legal position of manufacturers, and (c) simplify the task of the Commission.

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