COMMISSION OF THE EUROPEAN COMMUNITIES

COM(75) 147 final

Brussels, 10 April 1975

Alteration of 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 EEC Treaty)

EXPLANATORY MEMORANDUM

1. The main objective of the directive dealing with Cosmetic Products which was sent to the Council in October 1972[1] was the elimination of trade barriers to ensure a better protection of consumers by forbidding the marketing of cosmetic products which are harmful to health. In putting into practice the latter principle the Commission had to decide whether to list substances that could be regarded as harmful, that is a negative list, or substances which could be regarded as safe, that is a positive list, both as used in formulated products.

It is necessary to have much more information about a substance to declare that it is safe to use than it is to declare that it is harmful; accordingly the Commission decided that it was appropriate to make a general list of forbidden substances, that is Annex II, and a limiting and positive list, that is Annex III, to the directive, only where the evidence was soundly based and complete. Where toxicological testing was not yet complete a time limit of three years was imposed for the review of a number of permitted substances and they were placed in Annex IV.

The form of the directive is such that it can be readily modified by the addition of further positive lists where these are thought necessary for the improved protection of public health. The Commission considers that as a first stage these lists could cover, for instance, antioxidants, colorants, hair dyes, preservatives and ultra violet filters.

In giving its advice on the Directive the European Parliament, both in its initial report[2] and its complementary report, recommended the rapid adoption of positive lists. The Economic and Social Committee[3] made a similar recommendation while recognising the problems which arise in the preparation of such lists.

---

[1] OJ No C 133, 23 December 1972

[2] OJ No C 62, 31 July 1973

[3] OJ No C 60/17, 26 July 1973

Since October 1972, the date of transmission of the proposal to the Council, the services of the Commission have, therefore, studied more deeply the toxicological characteristics of certain categories of substances. As a result of these studies and in taking note of the views expressed by the European Parliament, the Economic and Social Committee and consumer organisations, the Commission proposed to insert a new Article 11 "bis" in the proposition in order to add subsequently positive lists for certain substances.

2. In compiling the negative list appearing in Annex II it was further extended by the first proposition of modification proposed by the Commission following the receipt of the advice of the European Parliament. In compiling this Annex II it was not desirable or practicable to include the many tens of thousands of substances existing which are harmful to health, but only those which in the opinion of the experts of the Member States and of the Commission had occured or could occur as such or as contaminants in cosmetic products. Annex II must, therefore, be interpreted as an extension of Article 2 of the directive by which the use of toxic substances in harmful concentrations would be forbidden.

The Commission, therefore, considers that Article 12, which allows immediate action to be taken in the event of further substances being introduced into the cosmetic field which are harmufl to health, is essential to the directive. It is, therefore, proposing a new version of this clause based on the agreement for safeguard clauses in directives in the field of technical barriers to trade.

3. Cosmetic products have a wide variety of uses and while it would be unreasonable to say that they should not be harmful under any conditions of misuse, it is necessary to provide for the possibility of damage to areas of the body contingent or capable of contacting the site of application. Thus a shampoo should not be harmful to the eyes, nor a dentifrice poisonous if swallowed. The Commission, therefore, proposes a new version of Article 2 in which forseeable conditions of use in the sense explained above are taken into account.

./.

4. In considering the possibilities of poisoning by a complete misuse of a product the Commission is of the opinion that there should be a requirement for the necessary information for prompt treatment to be available.

The ways in which anti-poison information is available vary in the Member States and the Commission does not consider that it should propose a harmonisation of these procedures which are peculiar to and are the responsibility of each Member State. Nevertheless, the Commission considers that it is appropriate to envisage at Community level dispositions which impose an obligation on the manufacturers to provide such information, imposing a parallel obligation on the relevant authorities, in order to respect trade secrets, to release to third parties only that information which is essential to the effective treatment of the condition. The Commission, therefore, proposes to add a further sub-paragraph to Article 7 giving effect to this requirement.

Alteration of

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

---

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

- a rewording of Article 2
- the addition of a further paragraph (number 3) to Article 7.
- a new Article 11 "bis".
- a rewording of Article 12.

Article 2

The following text shall replace the text of this article:

Cosmetics 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.

Article 7

The following paragraph is added to the text of this article:

3. Furthermore, a Member State may require that in order that prompt and appropriate treatment is available for cases of poisoning, adequate and sufficient information regarding harmful substances contained in cosmetic products is made available to the competent authority who shall ensure that this information shall only be used for the purposes of treatment.

Article 11 "bis"

One year at the latest after the expiry of the period provided for in Article 14, paragraph 1, for the implementation by the Member States

./.

of the present directive, the Commission, on the basis of results of the latest scientific and technical research, will send to the Council appropriate propositions establishing lists of permitted substances.

Article 12

The following text shall replace the text of this article:

1. Where a Member State finds that a cosmetic product, although satisfying the requirements of this Directive, presents a health or safety risk, it may, temporarily, prohibit within its territory the placing on the market of that cosmetic product. It shall immediately inform the Commission and the other Member States of this action and give reasons therefore.

2. The Commission shall within six weeks consult with the Member State concerned, then express without delay its opinion and take the appropriate steps.

3. According to the procedure laid down in Article 11 of the Directive of 27 June 1967 it shall be immediately decided if technical amendments to the Annex(s) of the Directive are necessary. The Member State can maintain its interdiction until a decision has been taken, either by the Council or by the Commission according to the aforementioned procedure.