IND/162
COSMETIC PRODUCTS

Brussels, 7 September 1981

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 third time Directive 76/768/EEC on the
Approximation of the Laws of the Member States relating
to Cosmetic Products
(COM(80) 917 final)

Rapporteur : Mr MASPRONE

I. INTRODUCTION

In a letter dated 10 February 1981, the Council of the European Communities asked the Economic and Social Committee for an Opinion on the

> Proposal for a Council Directive amending for the third time, Directive 76/768/EEC on the Approximation of the Laws of the Member States relating to Cosmetic Products.

On 24 February 1981 the Committee's Bureau instructed the Section for Industry, Commerce, Crafts and Services to draw up an Opinion and a Report on this matter.

The Section instructed the Study Group on Technical Barriers to prepare the draft documents.

II. GIST OF THE COMMISSION PROPOSAL

The aim of the Proposal is :

1) to authorize the use of barium, strontium and zirconium lakes or salts of a limited number of colouring agents;

2) to permit, under certain conditions, the use of two complexes of zirconium as anti-perspirants;

3) to make the use of silver nitrate in the manufacture of cosmetic products subject to certain restrictions and conditions, in the interests of health protection;

4) to draw up a list of permitted substances (approved list) for use as sunscreen agents;

5) to replace the expiry date by the minimum shelf-life (date of minimum durability);

6) to bring into line with the most recent developments in technology the way in which the manufacturing batch number or the product identification reference are indicated. It is not only the dimensions of the packaging which preclude identification of the goods but also the nature and shape of the packaging and the material of which it is made.

III. GENERAL COMMENTS

1. The Section welcomes the new amendments proposed by the Commission to the parent Directive of 27 July 1976 on cosmetic products.

These amendments have been considered necessary in order to identify the fields of application of the parent Directive and to take account of (a) the rules which have come into effect since its publication; (b) generally established scientific findings in this field since that date and (c) the technical applications of these findings.

2. The Committee issued an earlier Opinion approving the structure of the parent Directive. In its Opinion the Committee asked the Commission to draw up without delay a list of approved substances by stages, starting with the most important groups of substances from a health point of view. The Section is therefore pleased that the Commission has, inter alia, added an approved list of sun-protection agents to the list of preservatives proposed in the preceding amendment.

3. Problem of Recitals

Some recitals refer to "studies carried out" or "information received". Some members wanted to know who had assessed the value of these studies or this information. The Commission

replied that the Member States experts, following consultation with their respective Health Councils, had endorsed the toxicological value of information supplied by the industry. Some members thought that this should be borne in mind in the drafting of the recitals. Other members thought that the recitals should only mention the reasons for amendments, and not the amendments themselves.

Although Commission legal advisers had no objections to the proposed drafting, the Section proposed that these comments be taken into account by modifying the drafting of these recitals. The recitals themselves should only refer to studies and information, leaving the words "Authorization of barium, strontium and zirconium lakes and authorization of zirconium complexes as anti-perspirants" in the Articles of the Directive.

Although the Commission representative pointed out that it was often desirable to have a recital for each of the Articles of the Directive, some members considered that the recitals could be combined. At all events, the Section considered that the reference to new rules and new findings had to be interpreted along the lines set out in the second paragraph of point 1 of the "General Comments" above.

4. Problems of Barium, Strontium and Zirconium Lakes and Salts

Some members thought that reference to insolubility of lakes was adequate. Others agreed with the Commission representative, that insolubility was not an absolute concept, and that this should be taken into account in the drafting.

These comments mostly referred to the footnote on Articles 3 and 4.

Some members thought that under the proposed drafting and until the proposed method had been established, manufacturers could refuse to be monitored by the authorities and use the existing methods. In any case, the method for analysing the insolubility of barium, strontium and zirconium lakes and salts should be determined as soon as possible, so as to avoid technical barriers to trade. One possible way of satisfying the different points raised would be to reword the footnote to Articles 3 and 4 to read as follows :

> "The following shall also be permitted : the barium, strontium and zirconium lakes or salts of these colouring agents, insoluble in 0.1 N hydrochloric acid at 37° C. A method for assessing insolubility will be determined as provided for in Article 8".

5. Application Dates

Some members wanted harmonization of the dates on which various decisions provided for by the Directive came into force. For example, under the current drafting, the Decisions relating to lead acetate and sun filters would enter into force in 1984 and 1986 respectively. Other members thought, on the contrary, that even in the interests of harmonization, such decisions should not be postponed, unless there were technical reasons for doing so. Postponement would be detrimental to public health.

Other members insisted on the need to speed up the process of establishing approved lists. As the Directive was based on a system of approved and prohibited lists, many substances were still freely used today even though for some of them toxicological information was lacking.

The Section asked the Commission to review all dates of entry into force in the parent Directive 76/768/EEC and its three amendments, so that they were neither too far apart, in the interests of the consumer, nor too close together, so as to avoid causing excessive difficulties for manufacturers. It is particularly important that the Directive should set out precise information both for manufacturers and consumers.

6. Minimum durability - Article 9(1)

Some members thought that the term "minimum durability" should be precisely defined. They thought that it was the length of time for which a manufacturer guaranteed that his product :

a) conformed to Article 2, i.e. that harmful substances did not form during this period;

b) retained its primary function for which it was placed on the market;

c) retained its colour, scent, etc.....

Other members insisted that the main, if not the only, aim of this Directive was to protect the health of consumers. As such, the quality of products was of no concern and created difficulties both as regards regulation and verification.

The Section took the view that the concepts of colour and smell could relate only to the "primary function" of the product, e.g. colour for a lipstick, smell for a perfume.

One member thought that the term "minimum durability" did not properly express the desired concept as what was at issue was the maximum period during which the manufacturer could guarantee that the product would carry out its primary function.

Some members pointed out that the wording "best used before" might reduce the manufacturer's responsibility. Others thought that a Directive on product liability gave consumers most of the necessary guarantees.

The Commission representative pointed out that the expression in question was widely-used. If the term "to be used before" were substituted for "best used before" that would be tantamount to setting an expiry date. The Commission wanted to discontinue the use of the expiry date as it could not be justified for cosmetic products as it could be for pharmaceutical products.

Some members recognized that consumers were accustomed to this wording on food products. Whilst they might use such products shortly after the date of expiry, they did not greatly exceed this date.

Some members expressed their agreement with the concept of minimum durability and the wording "best used before". The Section urged that Article 2 be spelt out ("that is to say must not be liable to harm public health when they are applied under normal conditions of use".). The Section also considered that the term "specific characteristics" should be replaced by "primary function". The latter term included the necessary specific characteristics and took into account the observations on colour, scent, etc. Other members pointed out that though the "best used before" date could serve as a guideline for the consumer, in cases where changes in the product could have an effect on people's health, there was also a need to specify a deadline by which the product should be used. Several members came out in favour of the indication if both of these dates in the case of products having a minimum durability of less than 24 months.

As regards the period of durability requiring date stamping, some members thought that the period should be extended well beyond two years, as most cosmetics remained stable for longer than that.

Others thought that the few products which were not stable lost their primary function in less than two years and consequently should be marked. Those which remained stable would do so almost indefinitely. There would therefore be no objection to following the Commission's proposal and accepting a two-year period.

7. Marking of Batch Number - Article 9(2)

Some members thought that as the aim of such marking was to enable defective products to be withdrawn from the market, the consumer must be able to identify the batch number. The batch number and any other reference had to be clearly indicated.

Other members remarked that the Commission Proposal only authorized special means of marking which were, for example, only visible under ultra-violet light, where normal marking was impossible on practical grounds (small size of the cosmetic articles or nature and form of packaging). That was an improvement on the parent Directive which only specified marking on the outer packaging.

Other members said that in the event of certain products being withdrawn because of a danger, manufacturers would provide the necessary information to ensure that products with ambigious markings were also withdrawn.

The Section accepted the Commission Proposal, on the clear understanding that, as had always been the case, if a dangerous product were on the market, manufacturers would take all the necessary steps to warn consumers and to remove the risk of a dangerous product remaining on the market. That assurance was a better guarantee for the consumer than a marking.

8. Placing at the Disposal of Third Parties - Article 10

Some members remarked that there was an ambiguity, and that it could be considered that the Article related to disposal to countries outside the Community. All members agreed that products which did not conform to Article 2 of the parent Directive, i.e. were liable to harm health, could not be sold, even outside the Community. However, it would not be appropriate to prohibit the sale outside the Community of products which did not meet all the requirements of the Directive without reciprocal guarantees that those countries would not raise objections to the marketing on their territory of cosmetic products which did comply with the Directive.

The Section asked the Commission to review the drafting of the following passage :

"... neither manufacturers nor importers established in the Community shall place at the disposal of third parties products which do not meet the requirements of this Directive.",

in order to clarify the concept of placing on the market which the Section understood as referring only to the EEC domestic market. The Commission representative drew attention to a wording which had been adopted at the Council on the same subject but in respect of the second amendment to the Directive. The said wording should satisfy members.

9. Marking

As Article 9 of the Draft Directive proposed that some points in Article 6 of the parent Directive be reworded it was suggested that some exceptions to the obligation to indicate the nominal contents (Article 6 (1)(b)) be incorporated in the new version.

In the Section's view the following should be exempted from that obligation :

- free samples, provided they were labelled as such;

- individual doses/portions, provided they were labelled as such;

- products in respect of which the contents was normally indicated by means of the number of pieces.

It was also proposed that the exemption be extended to small packages containing less than 5 gr./ml.

IV. SPECIFIC COMMENTS

10. The Section asked the Commission to carefully revise the translations in the different languages.

For example, in Part I of Annex VII, product No. 3 is called homomethyl salicylate in some translations, but the product in question is homomenthyl salicylate.

11. In Article 7, paragraphs "g" and "h", the words "as defined in the preamble to Annex VII" should be added after "sunscreen agents".

The Section had already proposed a similar amendment as regards the preamble to Annex VI in its Report on the Proposal amending the Directive for the first time.

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