European Communities

EUROPEAN PARLIAMENT

Working Documents

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7 May 1980 **DOCUMENT 1-145/80**

Report

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

on the proposal from the Commission of the European Communities to the Council (Doc. 199/79) for a Directive amending for the first time Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products

Rapporteur: Mrs U. SCHLEICHER

By letter of 22 May 1979 the President of the Council of the European Communities requested the European Parliament, pursuant to Article 100 of the EEC Treaty, to deliver an opinion on the proposal from the Commission of the European Communities to the Council for a directive amending for the first time Directive 76/768/EEC of 27 July 1976 on the approximation of laws of the Member States relating to cosmetic products.

The President of the European Parliament referred this proposal to the Committee on the Environment, Public Heath and Consumer Protection as the committee responsible on 19 July 1979.

On 25 September 1979 the Committee appointed Mrs Schleicher rapporteur.

It considered this proposal at its meetings of 20 December 1979 and 24 and 25 April 1980 when it adopted the motion for a resolution unanimously.

Present: Mr Alber, acting Chairman; Mrs Schleicher, rapporteur; Mr Adam (deputizing for Mr O'Connell), Mr Ceravolo (deputizing for Mr Segre), Mr Forth (deputizing for Miss Hooper), Mrs Fuillet, Mr Ghergo, Mrs Maij-Weggen, Mr Mertens, Mr Muntingh, Mr Newton Dunn, Mr Provan (deputizing for Mr Johnson), Mr Remilly, Mrs Scrivener, Mrs Seibel-Emmerling, Mr Sherlock, Mrs Spaak and Mrs Squarcialupi.

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The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament the following motion for a resolution, together with explanatory statement:

MOTION FOR A RESOLUTION

embodying the opinion of the European Parliament on the proposal from the Commission of the European Communities to the Council for a directive amending for the first time Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council ;[1]
- having been consulted by the Council pursuant to Article 100 of the EEC Treaty (Doc. 199/79);
- having regard to the report by the Economic and Social Committee;
- having regard to the report by the Committee on the Environment, Public Health and Consumer Protection (Doc. 1-145/80);

1. Recognizes the need for the adoption of this first amending directive as the 1979 deadline laid down in the basic directive already had to be extended for a full year and is now due to expire on 31 December 1980;

2. Would have been very much in favour of this first amending directive being consolidated with the second and third amending directives now being prepared in order to reduce the costs and effort of transposing them into national law, and urgently requests the Commission to ensure that the amending directives now in the process of preparation can be consolidated;

3. Suggests that consideration be given to whether the 31 December 1982 deadline for the revision of the annexes and the fixing of maximum trace levels for the substances is not again too short in view of the difficult material involved, and whether it should not have been fixed at 31 December 1984 from the outset;

[1] OJ No C 165 2.7.79 p.52

4. Considers that in general terms it is important, to set realistic deadlines for:

   (a) transposing the directive into national law,

   (b) adapting products to the market, and

   (c) fixing maximum permitted trace levels;

5. Approves the introduction of a positive list of preservatives in the interests of effective consumer protection;

6. Notes however that, in the past, the system of positive lists has resulted in uncertainty, and consequently urges that paragraph 2 of Annex 4 (the positive list of preservatives) be amended to read: 'The substances listed may be used in different concentrations for other purposes';

7. Recognizes the need to update the list as quickly as possible and asks the Commission if this could not be done by formal means other than amending directives;

8. Requests the Commission to change Article 6(1)(b) of the basic directive to oblige products to carry an indication of number where it is conventional trade practice so to do, but to permit exemptions from the requirement to indicate quantity if the total quantity is under 5 grammes or 5 millilitres or the number of times of usage is indicated;

9. Notes that the term 'marketing' is used nine times in the basic directive and twice in the amending directive and that as a result of differences of interpretation and translation in the various Member States, distortions of competition persist and new distortions have arisen which stand in the way of the efforts to harmonize the rules;

10. Calls on the Commission to remove these differences of application by either precisely defining the relevant stage in the marketing process or inserting the words 'for the first time' to make the text clearer;

11. Calls on the Commission to see to it that the basic directive adopted in 1976 is embodied in the national legislation of all the Member States;

12. Approves, subject to the observations made above the proposal for a directive and requests the Commission to incorporate the following amendments pursuant to Article 149 (2) of the EEC Treaty.

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES [1]	AMENDED TEXT

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

Preamble unchanged

Articles 1 - 6 unchanged

Article 7	Article 7
Article 4 is amended to read as follows:	Article 4 is amended to read as follows:
"1. Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:	"1. Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing <u>for the first time</u> of cosmetic products containing:
(a) (unchanged)	**unchanged**
(b) (unchanged)	**unchanged**
(c) (unchanged)	**unchanged**
(d) (unchanged)	**unchanged**
(e) preservatives other than those listed in the first part of Annex VI	**unchanged**
(f) preservatives listed in the first part of Annex VI beyond the limits and outside the conditions laid down.	unchanged
2. The presence of traces of the substances listed in Annex II may be allowed provided that it is technically unavoidable when correct manufacturing techniques are used and that it conforms with Article 2 of this directive. The maximum authorized concentrations of these substances will be fixed - in accordance with the procedure provided for in Article 10 - by 31 December 1982 at the latest. On the other hand, the use of the substances listed in Annex II in the manufacture of cosmetic products is prohibited."	2. The presence of traces of the substances listed in Annex II may be allowed provided that it is technically unavoidable when correct manufacturing techniques are used and that it conforms with Article 2 of this directive. The maximum authorized concentrations of these substances will be fixed - in accordance with the procedure provided for in Article 10 - by <u>31 December 1984</u> at the latest. On the other hand, the use of the substances listed in Annex II in the manufacture of cosmetic products is prohibited."

[1] Full text see O.J. No C 165, 2.7.79 p.52

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT
	Article 8 New article The first paragraph of Article 6 is amended to read as follows:
	1. Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if their packaging, containers or labels bear the following information in indelible, easily legible and visible lettering:
	(a) (unchanged)
	(b) the nominal content at the time of packaging and an indication of number in the case of products where it is conventional trade practice to do so; however, small packs and free samples may be exempted from the requirement to indicate quantity if the total quantity is under 5 grammes or 5 millilitres and the number of times of usage is indicated.
	(c) (unchanged)
	(d) (unchanged)
	(e) (unchanged)
	2. (unchanged)
Article 8	Article 9
Article 5 is amended to read as follows:	Article 5 is amended to read as follows:
"Until 31 December 1982, Member States shall accept the marketing of cosmetic products containing:	"Until 31 December 1984, Member States shall accept the marketing for the first time of cosmetic products containing:
(a) (unchanged)	unchanged
(b) (unchanged)	unchanged
(c) (unchanged)	unchanged
(d) the preservatives listed in the second part of Annex VI within the limits and conditions laid down.	unchanged
On 1 January 1983, these substances, colouring agents and preservatives shall:	On 1 January 1985, these substances, colouring agents and preservatives shall:

TEXT PROPOSED BY THE COMMISSION OF THE EUROPEAN COMMUNITIES	AMENDED TEXT
- either be definitively permitted,	unchanged
- or definitively prohibited (Annex II),	
- or retained for a further period as specified in Annex IV or VI,	
- or deleted from all Annexes to this directive."	
Articles 9 - 12	Articles 10 - 13
unchanged	unchanged
ANNEXES 1 - 3 unchanged	
ANNEX 4	**ANNEX 4**
ANNEX VI	**ANNEX VI**
LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN	**LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN**
PREAMBLE	**PREAMBLE**
1. Preservatives are substances which may be added to cosmetic products, in the maximum concentrations authorized by this Annex, for the primary purpose of inhibiting the development of micro-organisms in such products.	unchanged
2. The substances marked with an asterisk may also be added to cosmetic products in higher concentrations for specific purposes, e.g. as deodorants in soaps or as anti-dandruff agents in shampoos. In addition to their preservative function, therefore, they can also have antiseptic, antifungal or other properties.	2. The substances listed may be used in different concentrations for other purposes.
3. Other substances used in the formulation of cosmetic products also have anti-microbial properties and thus help in the preservation of the products, as, for instance, many essential oils and some alcohols. These substances are not included in this annex	unchanged
4. For the purposes of this list:	unchanged
- "Salts" is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolomines; salts of the anions chloride, bromide, sulphate, acetate.	
- "Esters" is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.	
The lists of permitted substances are unchanged.	
ANNEXES 5 - 7 unchanged.	

B

EXPLANATORY STATEMENT

1. The main objective of the basic directive of 1976 is the harmonization of the various health protection rules on cosmetics. Pursuant to the directive, only those cosmetics which, if used normally, are not liable to harm human health may be put on the market in the Community.

The objective of this amending directive is to correct mistakes in the text of the Council Directive of 27 July 1976 and to clarify some of the provisions of the latter, as practice has shown that some of its provisions require clarification and improvement. In addition all the annexes are to be adapted to technical progress in accordance with the Technical Progress Committee procedure;

2. The 1976 directive contains, among other things, an extensive list of substances (361) which may not be used in cosmetic products (so-called negative lists). Other annexes to the directive contain lists of substances which may be used only for specific purposes or subject to certain maximum concentration levels. Several of these substances were provisionally permitted until 31 July 1979. It was categorically stated that on expiry of the three-year period a decision should be taken on whether these substances and colouring agents should be:

- definitively permitted
- definitively prohibited
- provisionally permitted for a further three years or
- deleted from all annexes to the directive.

3. The deadline was extended until 31 December 1980 since it was not possible to take a decision on the individual substances by the time the original deadline expired. As the original deadline has now expired it is unfortunately necessary to deal with this second amending directive as quickly as possible, although third and fourth amending directives are already being drafted. Given the present flood of directives and amendments the Committee on the Environment, Public Health and Consumer Protection should try to ensure that in future amending directives are not published at excessively short intervals so that it can keep track of existing directives and related national laws and keep down the costs entailed, which is also in the interests of the consumer. In future, any necessary amending directives - for example to adapt the annexes to technical progress - must be coordinated and consolidated. It is particularly with this in mind that the committee would ask the Commission to ensure that the deadlines in this amending directive are set realistically. The committee would also ask the Commission to ensure that those directives already in the process of preparation can be dealt with together, so that national legislative procedures can be rationalized.

4. Although the deadline for transposing the directive into national law expired on 31 December 1978, some Member States, namely Italy, Ireland and the Netherlands have not yet complied. In the interests of comprehensive consumer protection the Commission is urged to ensure that these countries transpose the directive into national law without delay.

5. Despite the comprehensive provisions of the 1976 directive on the use of permitted substances, consideration was given at the time to the possibility of drawing up further lists of permitted substances:

- hair dyes,
- preservatives,
- ultra-violet filters,
- anti-oxidants.

Positive lists of this kind allow only those substances specifically mentioned in the lists to be used in a given area.

6. The only positive list contained in the 1976 directive is that for colouring agents coming into contact with the mucous membranes; in other words, only those colouring agents listed in Annexes III, Part 2 and IV, Part 2 may be used in cosmetic products coming into contact with the mucous membranes. The amending directive contains a new positive list of preservatives. As most of these substances are permitted only provisionally in the interests of safety, the committee would ask the Commission, for the reasons outlined above, to allow realistic periods for safety checks to be carried out on the products before they are definitively permitted. In the interests of improved consumer protection, the committee welcomes the fact that the positive lists will make it easier in future to identify and determine the conditions of use of preservatives used in the manufacture of cosmetic products.

7. However, the committee regrets the fact that the Commission is now introducing positive lists without giving details in its explanatory memorandum of its experience with the directive to date. For instance, it would have been interesting to learn whether in the period after the entry into force of the directive any injuries or other harmful effects on health have occurred which might necessitate further changes. The introduction of the positive list system gives rise to a fundamental problem: if a substance is mentioned in a positive list as an anti-oxidant there is a danger that its use for other purposes might be prohibited on the basis of the positive-list principle. However, most chemical substances are used for a variety of different purposes. If other areas of application are not to be excluded, every list should specify that the substances mentioned may be used in different concentrations for other purposes.

8. Article 4(a) of the basic directive prohibits the sale of cosmetic products which contain any substance listed in Annex II. From the technical point of view, however, it is virtually impossible to prevent traces of the substances occurring even if the substances themselves are not used, as the methods of analysis are only now able to detect even the slightest traces. The amendment to Article 4 of the basic directive set out in Article 7 of the amending directive is necessary for this reason. Article 7 puts the situation right by specifying that, while the use of substances listed in Annex 2 is prohibited, the presence of traces of these substances may be allowed. The committee welcomes this clarification and regards the Commission's more far-reaching proposal to fix the maximum permitted trace levels by 1982 pursuant to the second sentence of Article 4(2) as desirable from the point of view of consumer protection. As regards the 1982 deadline, the committee would ask the Commission to take the above remarks into account. The committee wonders whether it is at all possible to establish a comprehensive list of maximum trace levels for 362 substances in the short time left up to the end of 1982, as in order to establish masimum levels it will also be necessary to lay down for all the Member States appropriate and comparable methods of analysis for detecting traces and determining their concentration.

Some of these methods of analysis do not yet exist and considerable time would be necessary to develop them. Despite the committee's positive attitude towards the idea of fixing masimum trace levels, it is debatable whether the results of such an exercise justify the cost or whether the need to protect the consumer is not in fact perfectly adequately satisfied in the first sentence of Article 7(2), which permits the presence of traces only if this is compatible with Article 2 of the directive, i.e. no cosmetic products are sold which if applied normally are likely to harm human health.

9. The vague term 'marketing' has, unfortunately, caused confusion on the sales markets. Some Member States felt compelled to introduce more precise rules which have not contributed to the harmonization. In some cases the marketing stage is taken to mean the introduction of the product by the manufacturer or importer (i.e. the first marketing stage after manufacture) while in others it is taken to include even the final stage of distribution. As a result, the disposal on the market of products which no longer comply with the latest provisions is dealt with differently in most Member States.

If the Commission does not define this concept clearly in future rules in order to leave the individual Member States the possibility of adapting the rules to their own requirements and to avoid being too perfectionist, steps must be taken to ensure that the Member States are not subsequently bound by a specific definition of the concept in the Community directive.

10. The labelling provisions set out in Article 6 of the basic directive conflict to some extent with directives on the prepackaging of products and with national laws. The Commission has stated that the wording is unclear in parts and that it is prepared to review it. The committee therefore suggests that a more satisfactory solution would be to exempt from the requirement to indicate small quantities of, say, under 5 grammes or millilitres in the case of small packs and free samples and to require an indication of the number of items in the case of products where it is conventional trade practice to do so.

11. Most of the transitional periods laid down in the basic directive were not adhered to. In particular, the substances provisionally permitted could not be satisfactorily tested in such a short time. The committee fears that the deadlines set in the amending directive will not be adhered to either and that it will not be possible to conduct satisfactory tests on the substances provisionally permitted in the short time laid down by the Commission. The committee would therefore stress again that it would like to see the Commission set more realistic deadlines in future for testing substances provisionally permitted.

Furthermore, the transitional periods for substances which are no longer permitted or for changing the rules governing labelling should take more account of practicalities.

The different procedures applied in the various countries in the past have led to distortions of competition. In principle, it should be permitted in future to sell existing stocks of products which meet health criteria. The introduction of new rules on labelling should not mean that all products already on the market have to be withdrawn.

Luxembourg
P.O.B. 1601