

# European Communities

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EUROPEAN PARLIAMENT

## Working Documents

1973-1974

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4 May 1973

DOCUMENT 35/73

### Report

drawn up on behalf of the Committee on Public Health and the Environments

on the proposal from the Commission of the European Communities to the  
Council (Doc. 209/72) for a directive on the approximation of Member States'  
legislation on cosmetic products

**Rapporteur: Mrs Elisabeth ORTH**

PE 32.179/fin.

By letter of 22 November 1972 the President of the Council of the European Communities requested the European Parliament, in accordance with Article 100 of the EEC Treaty, to deliver an opinion on the proposal of the Commission of the European Communities to the Council for a directive on Member States' legislation on cosmetic products.

On 11 December 1972 Parliament referred this proposal to the Committee on Social Affairs and Health Protection as the committee responsible and to the Legal Affairs Committee for its opinion.

On 22 November 1972 the Committee on Social Affairs and Health Protection appointed Mrs ORTH rapporteur.

It discussed the proposal at its meetings of 18 December 1972 and 26 February and 10 April 1973.

On 10 April 1973 the Committee on Public Health and the Environment unanimously adopted the motion for a resolution and the explanatory statement.

The following were present : Mr DELLA BRIOTTA, chairman; Mr JAHN and Mr SCOTT-HOPKINS, vice-chairmen; Mrs ORTH, rapporteur; Mr BREGEGERE, Mr CHRISTENSEN, Mr DURAND (deputizing for Mr DURIEUX), Sir Anthony ESMONDE, Mr MARTENS, Mr MULLER, Mr WALKHOFF.

The opinion of the Legal Affairs Committee is annexed to this report.

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The Committee on Public Health and the Environment hereby submits the following motion for a resolution to the European Parliament, 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 on the approximation of Member States' legislation on cosmetic products

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council<sup>1</sup>,
  - having been consulted by the Council pursuant to Article 100 of the EEC Treaty (Doc. 209/72),
  - having regard to the report of the Committee on Public Health and the Environment and the opinion of the Legal Affairs Committee (Doc. 35 /73),
1. Welcomes the Commission's proposal for a directive replacing the present legislation on cosmetic products, which varies from one Member State to another, by fully harmonized Community provisions;
  2. Regrets, however, that the Commission has submitted this proposal for a directive more than two years later than called for in the General Programme of 28 May 1969 for the elimination of technical barriers to trade<sup>2</sup>;
  3. Finds it disappointing that in drafting its proposal for a directive, the Commission afforded manufacturers the opportunity to state their views but failed to consult the consumers' associations although the proposed directive is primarily concerned with matters of consumer protection and public health;
  4. Agrees with the Commission that the most important objectives of Community legislation on cosmetic products are to preserve public health and an adequate measure of consumer protection and that these objectives must be achieved by measures which make the fullest possible allowance for economic and technological requirements;

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<sup>1</sup>OJ No. C 133, 23.12.1972, p. 16

<sup>2</sup>OJ No. C 76, 17.6.1969, p. 1

5. Points out, however, that economic and technological requirements should be taken into consideration only inasfar as they do not affect the overriding considerations of public health and consumer protection;
6. Strongly supports, in the interests of more effective protection of consumers' health, the system of compulsory positive lists hitherto adopted at Community level, and consequently calls upon the Commission to apply this system in the field of cosmetic products within the next five years;
7. Has strong misgivings about authorizing the substances listed in Annex IV, whose innocuousness has not yet been finally established; regards the 3-year transitional period laid down in Article 5 as an absolute maximum, and urges the Commission to do everything possible to decide within this time-limit whether the substances concerned are to be finally authorized or prohibited;
8. Insists that the information to the consumer given on containers or labels be printed in at least the language of the country of destination;
9. Requests the Commission to ensure that the measures required to supervise the proper implementation of the provisions contained in the proposed directive should be adopted concurrently with the introduction of the directive;
10. Welcomes the rule which protects the manufacturer by stipulating that the detailed grounds on which any individual measure is taken on the basis of the directive to limit or prohibit the marketing of cosmetic products must be notified to the persons concerned, together with a caution as to their rights;
11. Requests the Commission to incorporate the following amendments in its proposal, pursuant to Article 149(2) of the EEC Treaty;
12. Requests its committee to ascertain whether the Commission of the European Communities alters its proposal to reflect the amendments of the European Parliament and to report back if necessary;
13. Instructs its President to forward this motion for a resolution and the report of its committee to the Council and Commission of the European Communities.

Proposal from the Commission of the European  
Communities to the Council for a directive on  
the approximation of Member States' legislation  
on cosmetic products

Preamble and recitals Nos. 1 and 2 unchanged

Recital No. 2A (new)

2A. Cosmetic products were included in the  
third phase of the General Programme of 28 May  
1969 for eliminating technical obstacles to  
trade arising from differences in provisions  
laid down by law, regulation or administrative  
action.

Recitals Nos. 3 - 9 unchanged

Article 1

1. Cosmetic products shall mean  
substances or preparations intended  
for external use on the different  
parts of the human body (skin, hair,  
nails, lips and intimate areas) or  
on the teeth and dentures and the  
mucosa of the oral cavity for the  
sole or primary purpose of perfuming,  
cleaning and caring for the said  
parts of the body, improving their  
appearance or affecting body odour.

2. unchanged

3. deleted

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1. This text is available in Dutch, French, German and Italian only - for  
full text see OJ No. C133, 23 December 1972, p.16.

Article 2

Cosmetic products marketed in the Community may not, in normal use, cause harm to human health.

Article 3 unchanged

Article 4 unchanged

Article 5

Member States permit temporarily, at the most for a period of three years from the issue of this directive, the marketing of products which

- (a) contain the substances listed in Part One of Annex IV;
- (b) contain the colourants listed in Part Two of Annex IV in so far as these products are intended for application to the area of the eyes, lips or oral cavity.

Article 6

unchanged

1. unchanged

2. unchanged

3. Special precautions for use, particularly those listed in the column headed 'Compulsory indication of directions for use and warnings printed on labels' in Annexes III and IV, shall be clearly printed on the container. If this is impossible for practical reasons, the directions shall be printed on the outside wrapping and on an accompanying leaflet; in such cases, however, a shorter version, referring to these directions, shall be printed on the container.

4. The labels and wrappings of the products mentioned in Article 1, as well as advertisements for such products, shall not show any designations, trade marks, drawings or other signs, descriptions or other statements that claim properties which the products do not in fact possess or attribute effects which are not



justified or adequately proven by  
scientific knowledge.

Article 7

1. deleted

2. They shall require, however,  
that the information referred to in  
Article 6 is printed in at least  
the language(s) of the country.

Article 8 unchanged

Article 9

1. unchanged

2. unchanged

3. By the same procedure and on the basis of the results of scientific and technical research, the substances and colourants listed in Parts 1 and 2 of Annex IV and provisionally permitted, shall, after expiry of the time-limit laid down in Article 5,
- be definitively assigned to Annexes II or III;
  - deleted
  - or struck from all the annexes to this directive.

Article 10 unchanged

Article 11

1. unchanged

2. unchanged

3. The Commission shall decide on measures for immediate implementation. Should these not be in keeping with the committee's opinion, however, the Council shall be notified without delay. In such cases, the Commission may defer the implementation of the measures it has decided for up to one month following their notification.

Within one month the Council may, acting by a qualified majority, take a different decision.

#### Article 12

1. If a Member State establishes that a cosmetic product is a health hazard although it complies with the provisions of this directive and is used as directed, the said Member State may prohibit the sale, distribution or use of the product for a period of not more than one year. The Member State shall forthwith notify the other Member States and the Commission of this measure and of the grounds on which it was taken.

2. Within a period of six weeks, the Commission shall consult the Member States concerned. It shall give its opinion forthwith and take the requisite measures. On the Commission's initiative a decision shall be taken, in accordance with Article 100 of the EEC Treaty or Article 11 of this directive, whether the directive must be changed. If necessary, the requisite changes shall be laid down in new directives. The period laid down in paragraph 1 shall be prolonged until the completion of this procedure, but the prolongation may not exceed one year.

Article 13 unchanged

Article 14

1. unchanged

2. deleted

3. Member States shall notify the Commission of the text of draft legislation in the field covered by this directive and of the reasons therefor. This notification shall be given no later than six months before the scheduled date of entry into force.

Article 15 unchanged

Annex I unchanged

ANNEX II<sup>1</sup>

unchanged

plus:

426. Hormones

(a) - Oestrone

- Oestradiol and its esters

- Oestriol and its esters

(b) - Progesterone

- Ethisterone

(= 17 $\beta$  - hydroxy - 17 $\alpha$  -  
pregn - 4 - en - 20 - yn -  
3 - on)

427. Selenium disulphide

Annex III unchanged

Annex IV unchanged

ANNEX V

deleted

<sup>1</sup> If appropriate, the substances mentioned in the annex to this report should be added to the prohibited lists in Annexes II, III and IV (see Section 3 of the explanatory statement).

EXPLANATORY STATEMENTI. General

1. By presenting its proposed directive on cosmetic products, the Commission has met an urgent need, although at a very late stage. The urgency of this directive is explained by the fact that until recently few Community countries had taken comprehensive legal measures for cosmetic products.

2. In its explanatory statement, the Commission stresses that the proposed directive is primarily intended to protect human health. It is therefore all the more surprising that - contrary to usual practice - representatives of the Comité de Liaison des Syndicats de la Parfumerie were invited to all the meetings while representatives of the consumer associations were in no case asked for their opinions.

This criticism cannot be answered by the mere fact that the Consumers' Contact Group suspended its activities in February 1972, since in the debate on 20 September 1972 Mr Borschette indicated that the Commission maintained regular contacts with the five organizations belonging to the Contact Group. He also stated that contacts were maintained with the national consumer organizations so that it was perfectly feasible to ascertain the views of the various bodies concerned.

3. One result of this state of affairs is that an additional list supplementing the Annexes<sup>1</sup> has been disregarded. Your committee should consider whether this list, which is now submitted, should be added to the one which already exists. Your committee has always examined all proposed directives from the angle of protection of public health and of the consumer. Economic and technical criteria should only be included in the considerations to the extent that they do not encroach upon the primary interests of public health and consumer protection.

II. Examination of the provisions of the draft directive

4. Article 1 defines cosmetic substances. This definition includes substances or preparations which are intended to come into external contact with the different parts of the human body or with the teeth or mucosa of the oral cavity 'for the sole or primary purpose of protecting and caring for the said parts of the body'.

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<sup>1</sup> This supplementary proposal from the German Delegation to the European Communities is annexed to this report.

Inclusion of the notion of 'protection' in the definition makes the demarcation between cosmetic and pharmaceutical products imprecise and indeed almost impossible. This definition should therefore be omitted, especially as the notion of 'care' includes all substances which are applied or rubbed in to protect the skin against external influences, e.g. mosquito repellents, oils, emulsions or sprays to protect the skin against bright sunlight, baby creams and powders to prevent skin irritation of infants.

5. On the other hand the definition contained in the proposed directive should include substances used to clean dentures; these substances may affect the human organism through the dentures treated with them. It is therefore reasonable to make them subject to the same requirements as substances used to clean and care for natural teeth.

6. The directive should not cover cosmetic products containing the substances listed in Annex V (hormones and selenium disulphide). This Annex too does not clearly delimit the sphere of application of the directive because the negative list is not exhaustive. At all events, on the basis of the provisions of Article 1(3), the legal treatment of cosmetic substances containing hormones or selenium disulphide would differ in individual Member States. There is in fact a risk that, on the basis of Article 1(3), producers may remove beyond the scope of the Community provisions all cosmetic substances to which a trace of oestrone is added, e.g. face cream.

For these reasons your committee has decided, by 5 votes to 3 with 3 abstentions, that Article 1(3) should be deleted and the substances listed in Annex V transferred to Annex II (prohibited substances).

7. Article 2 contains the important fundamental stipulation that cosmetic products marketed in the Community shall not cause harm to human health when used 'as directed'. The question arises whether 'use as directed' in itself covers all possible prohibitions or whether the following addition should be made: 'as directed or for foreseeable purposes'. The manufacturer would then be required to ensure that a cosmetic product cannot be harmful to health if it is used otherwise than directed but in a manner which could be foreseen by him. Cases in which damage is caused by incorrect or abnormal use or use contrary to the instructions supplied, are not covered by the concept of 'foreseeable use' according to the relevant jurisprudence and literature.

Your committee has decided, by 5 votes to 4 with 2 abstentions, against the addition proposed by the rapporteur, the majority taking the view that better justice to the rapporteur's scruples would be done by stipulating 'normal use'. The Commission is asked to change the text of Article 2 accordingly.

8. The list of 425 prohibited substances shows all substances which may not be used; conversely all substances not included in this list are permitted (Article 4). The question then arises whether this list is complete; in fact it is not, since Germany has already presented a supplement to it (see annex to this report). It would be desirable to prepare a positive list, i.e. a list of substances which are permitted in the manufacture of cosmetics. The manufacturers' argument that this would prevent the development of new preparations appears untenable since a list of this kind would in no way prohibit combinations of the permitted substances in a different manner. As a result of technical progress new products are brought onto the market in rapid succession; there is therefore a risk to the consumer since evidence of the harmful nature of these cosmetics is in practice only obtained after they have been available to consumers for an extensive period.

The situation was reversed under the system of a positive list used hitherto and always advocated by your committee; manufacturers were first required to provide evidence of the safety of new products before bringing them onto the market. This prevented experiments with new products at the expense of the consumer's health. Your committee should therefore favour the system of a positive list which has been adopted in the past at Community level.

Since, however, your committee is aware of the practical difficulties entailed by immediate application of the system of a positive list to cosmetic products, it has voted for a transitional period of five years during which the system of a negative list provided for in Article 4(a) can be tolerated. With this reservation, it approves Article 4 of the proposal for a directive.

Your committee has emphasized in paragraph 6 of the motion for a resolution its demand for the subsequent application of the system of a positive list.

9. Article 5 contains a transitional provision which your committee should examine carefully. It stipulates that cosmetics containing the substances listed in Annex IV may still be used in Member States for three years. These are substances and colourants whose safety has not yet been fully proved. They therefore constitute a risk to public health. To eliminate that risk, your committee should require the deletion of Article 5.

After lengthy discussion, your committee adopted the following view. The transitional period of three years provided for should be regarded as a maximum period; if possible, an earlier decision should be made on the final authorization or prohibition of these substances in order to remove the consumer's uncertainty. The retention in Annex IV for a further three-year



period of cosmetic products that are 'provisionally permitted' should be rejected. Accordingly, the second point in Article 9 (3) must be deleted.

Your committee has clearly stated its attitude on this question in paragraph 7 of the motion for a resolution.

10. Article 6(2) requires a final date to be indicated for the use of products which do not have an unlimited shelf life. Your committee takes the view that the consumer may conclude that if no date is indicated cosmetic products have an unlimited shelf life.

Paragraph 3 requires the special precautions for use to be indicated on the container. If this is impossible for practical reasons, details must be given on the outer packet or on an accompanying leaflet. Your committee insists on the need to give these indications on the outer packet and on the accompanying leaflet in all cases. This is the only way of enabling consumers to purchase cosmetic products with a full knowledge of their content.

11. Article 6(4) attempts to make provision for protection against misleading advertising. The proposed solution prohibiting the 'claim to properties which the products do not in fact possess' on labels, packets and in advertising for cosmetic products does not satisfactorily cover the area involved.

It is regrettable that only 'descriptions, trade marks, illustrations or other illustrative or non-illustrative signs' are subject to this prohibition. We wonder whether the adjectives 'illustrative or non-illustrative' could not be deleted as superfluous since the notion of other signs is equally comprehensive. On the other hand it seems more serious that this provision does not cover television advertising, since short publicity films (presentations) are often involved. In order to avoid misleading advertising of this kind Article 6(4) should preferably read 'signs, descriptions or other statements.'

In addition, the provision is also incomplete to the extent that it only relates to misleading claims in respect of characteristics. In the cosmetic products sector which is still the subject of much scientific discussion, advertising based on scientifically unproven effects attributed to cosmetic products plays a considerable part. Article 6(4) should therefore be further amended as follows: '... that claim properties... or attribute effects which are not justified or adequately proven by scientific knowledge.'

12. In Article 7(2) the word 'may' should be replaced by the word 'shall' since it is too much to expect the consumer always to understand correctly information given to him in a foreign language.

13. Article 9(1) contains provisions on how the following are to be established:

- details of sampling;
- methods of analysis required to check the composition of cosmetic products;
- criteria of bacteriological purity;
- methods of testing the criteria of bacteriological purity.

This takes place according to a procedure involving the committee envisaged in Article 10 for adjusting, in the light of technical progress, the directive on removing technical obstacles to trade in the field of cosmetic products.

Your committee demands, in accordance with its previous attitude on similar cases, that the points listed above be established no later than at the time of entry into force of the directive, in order that effective control can be exercised right from the start, for without such control the directive would be no more than a dead letter.

This demand is also set forth in paragraph 9 of the motion for a resolution.

14. Article 10 provides for the creation of a 'Committee on directives to eliminate technical barriers to trade in the cosmetics sector'. Despite its basic objections to an excessive number of committees of this kind, your Committee would agree to the provisions of Article 10, if the working procedure laid down in Article 11 for this new committee were amended according to the requirement on which we have insisted for many years. Article 11 should therefore be amended in the normal manner which the plenary assembly has always approved to prevent the powers of the Commission from being still further reduced.

15. Article 12 lays down a procedure enabling Member States to temporarily prohibit the marketing or use of a cosmetic product on their territory if it is found to constitute a risk to human health. This formulation limits the rights enjoyed by Member States under Article 36 of the EEC Treaty to the extent that the Member State is no longer able to act independently in such cases. The required limitation or prohibition of cosmetic products recognized dangerous to health is only possible 30 days after a corresponding application has been made and then only for the territory of the Member State lodging such application. In the other Member States the dangerous substance will remain on the market as before. Your committee therefore advocates the following new wording of Article 12:

'1. If a Member State establishes that a cosmetic product is a health hazard although it complies with the provisions of this directive and is

used as directed, the said Member State may prohibit the sale, distribution or use of the product for a period of not more than one year. The Member State shall forthwith notify the other Member States and the Commission of this measure and of the grounds on which it was taken.

2. Within a period six weeks, the Commission shall consult the Member States concerned. It shall give its opinion forthwith and take the requisite measures. On the Commission's initiative a decision shall be taken, in accordance with Article 100 of the EEC Treaty or Article 11 of this directive, whether the directive must be changed. If necessary, the requisite changes shall be laid down in new directives. The period laid down in paragraph 1 shall be prolonged until the completion of this procedure, but the prolongation may not exceed one year.'

16. Article 13 is designed to protect the manufacturer of cosmetic products. It lays down that the detailed grounds for every individual measure taken on the basis of the directive to limit or prohibit the marketing of these products shall be given and the measure notified to the persons concerned, together with a caution as to their rights and the time allowed for an appeal.

This provision, particularly as regards the caution on rights, reflects the wish expressed by your committee on more than one similar occasion in the past and is consequently welcomed.

17. Article 14(2) stipulates a transitional period of three years after publication of the directive during which Member States shall have the possibility of authorizing the sale on their territory of cosmetic products which do not comply with the provisions of the directive.

Quite apart from the fact that distortions of competition may occur during this transitional period if Member States make differing use of this possibility, the risk to consumer's health will be continued for a still longer period by the use of cosmetic products which do not comply with the directive.

Your Committee therefore recommends deletion of Article 14(2).

18. Article 14(3) requires Member States to forward to the Commission the text of national legislation in the field covered by the directive. But there is no provision for this to be done at a sufficiently early stage to enable the Commission to indicate its views in good time.

Your committee therefore requires this provision to be worded as follows in accordance with the Commission's previous practice: 'Member States shall notify the Commission of the text of draft legislation in the field

covered by this directive and of the reasons therefor. This notification shall be given no later than six months before the scheduled date of entry into force.'

### III. Examination of the opinion of the Legal Affairs Committee

19. Your committee has examined the opinion drafted by Mr HUNAULT on behalf of the Legal Affairs Committee (PE 32.160/fin.). This opinion is annexed to the present report.

20. The Legal Affairs Committee agrees to the Commission's choice of Article 100 of the EEC Treaty as the legal foundation for its proposal for a directive. The Legal Affairs Committee further points out that cosmetic products have been included in the third phase of the General Programme of 28 May 1969 for removing technical obstacles to trade arising from differences in provisions laid down by law, regulation or administrative action. In order to draw attention to this background of the directive, the Legal Affairs Committee considers it expedient to incorporate a last recital in the preamble with the following wording: 'Cosmetic products have been included in the third phase of the General Programme of 28 May 1969 for removing technical obstacles to trade arising from differences in provisions laid down by law, regulation or administrative action.'

Your committee is in agreement, but considers it better to introduce this addition between the second and the third recitals of the Commission's proposed text.

21. The Legal Affairs Committee states that Annex I, to which Article 1(2) refers, contains a not exhaustive list of cosmetic products which fit the definition and fall within the sphere of application of the directive. Since, however, a directive of this kind can have no legal consequences, Article 1(2) and Annex I could, from the legal point of view, be omitted, as the definition contained in Article 1(1) is sufficient.

Your committee notes that the Legal Affairs Committee does not explicitly demand the deletion of the provisions referred to. In your committee's view, they can still contribute to a clarification of the text; it therefore advocates their retention.

22. For the same reasons as your committee (see paragraph 6 of Explanatory Statement), the Legal Affairs Committee takes the view that the substances listed in Annex V (hormones and selenium disulphide) do not fall within the sphere of application of the directive. It therefore demands the deletion of Article 1(3) and of Annex V.

23. In agreement with your committee (see paragraph 8 of Explanatory Statement) the Legal Affairs Committee criticizes the fact that Annex II contains a negative list, i.e. lists the substances that must not be contained in cosmetic products. In its view a positive list would render the consumer better service. It therefore explicitly calls upon the Commission to remodel

its proposal for a directive in such a way as to base it upon a positive list.

Your committee, which in principle shares this point of view, has reproduced this demand in slightly modified form in paragraph 6 of the motion for a resolution.

24. The Legal Affairs Committee disapproves of the transitional period of three years provided for in Article 5. In its view, the substances listed in Annex IV should not be employed in cosmetic products until they have been proved to be innocuous. It therefore demands the deletion of Article 5.

For practical reasons, your committee has only been able to take this demand partially into account (see paragraph 8 of Explanatory Statement).

25. The Legal Affairs Committee agrees with your committee that the information referred to in Article 6 must be printed in the language or languages of the country of destination. Article 7(2) must therefore be worded so as to give it binding force.

26. The Legal Affairs Committee also shares the attitude of your committee on Article 12(1) (see paragraph 15 of Explanatory Statement). In connection with the general criterion contained in Article 3, the Legal Affairs Committee is dismayed by the fact that a Member State is not allowed to withdraw immediately a product directly harmful to health but is forced to initiate a cumbersome procedure lasting at least thirty days.

27. The Legal Affairs Committee rejects the transitional period of 36 months, provided for in Article 14(2), during which Member States may permit the marketing on their territories of cosmetic products that do not comply with the provisions of the directive. It therefore advocates the deletion of Article 14(2).

This demand also reflects the attitude of your committee (see paragraph 17 of Explanatory Statement).

28. Finally, the Legal Affairs Committee advocates a modification of Article 14(3) to the effect that Member States notify the Commission not only of legal provisions already adopted but also of provisions envisaged for the future in the field of cosmetic products.

Your committee also supports this recommendation (see paragraph 18 of Explanatory Statement).

Supplementary proposal by the German delegation

The Federal Republic of Germany suggests inclusion of the following additional substances in the list of prohibited substances contained in Annexes II, III and IV.

Re Annex II (list of substances which must not be present in cosmetic products)

- diphenohydramine
  - p-tert.-butylphenol and derivatives
  - p-tert.-butylpyrocatechin
  - dihydro-tachysterine (AT 10)
  - thio-urea compounds
  - dioxane
  - morpholin
  - pyrethrum preparations
  - pyrianisamine-maleate
  - pyribenzamine
  - salicylanilide tetrachloride )
  - salicylanilide dichloride )
  - salicylanilide tetrabromide )
  - salicylanilide dibromide )
  - bithionol
  - thiuram-monosulphide
  - thiuram-disulphide
  - dimethyl-formamide
  - xylylidine (all isomers)
  - benzylidene acetone
  - coniferyl benzoate
  - furocumarine, except when naturally present in etheric oils
  - laurel oil, fatty
  - safrol
  - sassafras oil containing safrol
  - terpentine oil containing peroxide
- nor as impurities in a permitted halogenated salicylanilide

The following amendments are also proposed:

Inclusion in this list of No. 33 from Annex III, Part 1: monoglycerine esters of p-aminobenzoic acid  
and No. 8, xylocaine, from Annex IV, Part 1

Re Annex III, Part 1

(list of substances which must not be present in cosmetic products except for specified limited uses)

The following substances already shown in the German proposed list (Doc. III/957/71) should be included in this Annex:

Substance	Field of use	Limitations	
		Max. permitted concentration	Other limitations and criteria
Boric acid	a) face and shaving lotions	(not yet fixed)	not in child-care compounds
	Body and foot powders		
	b) as tube protection agent for hair dyes	0.08%	
Quinine and its salts	hair lotions	0.2%	
8-hydroxy-quinoline and sulphate thereof		0.3%	not in anti-sunburn products and products for use after sunbathing
iodine thymol		(not yet fixed)	not in anti-sunburn products
amyl acetate butyl acetate			in sprays <sup>+</sup> up to 2%
diethanol amine			in sprays up to 0.2% <sup>+</sup>
formaldehyde and formaldehyde depot substances			not in sprays <sup>+</sup>
hexachlorophene	a) soaps +	1%	
	b) sprays	0.1%	
	c) other uses	0.5%	
methyl acetate			not in sprays <sup>+</sup>

+ fine atomizing



Substance	Field of use	Limitations	
		Max. permitted concentration	Other limitations and criteria
Nitromethane	as corrosion inhibitor for aerosol cans	0.3%	
salicyl-aldehyde salicyl-alcohol thiosalicylic acid			not in anti-sunburn products
thioglycolic acid and salts thereof			not in sprays <sup>+</sup>
benzyl salicylate	as aromatic substance	1%	
heptin-carbonic acid methyl ester	as aromatic substance	0.01%	
perubalsam	as aromatic substance	0.1%	may cause allergic reaction

<sup>+</sup> fine atomizing

The following changes (underlined) are also proposed:

- No. 11 formaldehyde: field of use:  
a) use as nail hardener  
b) use as preservative except in mouth washes  
c) delete
- No. 14 sodium nitrite: field of use:  
as corrosion inhibitor in sprays
- No. 15 picric acid: field of use:  
sprays
- No. 16 calcium hydroxide  
and  
No. 20 sodium hydroxide  
Warning on label:  
Avoid contact with eyes: danger to sight  
Keep away from children
- No. 17 pyrogallol: field of use: hair dyes

Re Annex III, Part 2

(limiting list of colourants which may be present in cosmetic substances liable to come into contact with the mucosa in the context of the proposed limitations).

The following amendments (underlined) correspond to the results arrived at by the 26th Conference of the 'Colourants Committee' of the German Research Association in October 1971:

a) Red

Serial number	Colour index number	Designation according to communication 3 of Colourants Committee	Field of use	Limitations	
				Max. concentration	Purity criteria
1	12.085	C-red 1	a) <u>lip-sticks</u>	3%	
			b) <u>other uses</u>	<u>none</u>	
5	15.525	C-red 8		<u>no barium salt colourant</u>	
6	15.580	C-ext. red 40		<u>delete colourant from list</u>	
9	15.850	C-red 12		<u>no barium salt colourant</u>	
10	15.865	C-red 13		<u>no barium salt colourant</u>	
22	75.470	C-red 50			<u>free from salmonella</u>
26	45.425	C-red 35			<u>free from iodine ions organically bound iodine 41.5 - 45.5% fluorescin not more than 1% moniodine-fluorescin not more than 5%</u>

d) Violet, brown, black and white

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2	42.640	C-Violet 10 previously: C-ext. Violet 15	Delete 'aluminium lacquer'
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10	77.266	C-Black 4	<u>no carbo veget.</u> <u>medicinalis</u>
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Re Annex IV, part 1

(List of provisionally permitted substances for the authorization of which justification must be provided within three years)

The following substances listed in Doc. III/957/71 should be included in this annex:

resorcun monoacetate (acetyl resorcin)

4-chloro-1, 3-dihydroxybenzol (4-chlororesorcin)

4-n-hexyl-1, 3-dihydroxybenzol (4-n-hexyl resorcin)

ethylene glycol

ethylene glycol ester

chloracetamide (for preservation of shampoos only: 0.3%)

tribromosalicylcanilide

tert.-butyl alcohol

1,2 butylene oxide

2,3 buylene oxide

propylene oxide

salicylic acid

3,4,4' trichloro-carbanilide: field of use and max. permitted concentration

a) in soaps: 2%

b) other uses: 1%

The following amendment (underlined) is also proposed to Doc. III/2255/71  
Annex IV - Part 1:

No. 1 lead acetate field of use: hair dyes

No. 19 ethyl mercury thiosalicylate field of use: for eye cosmetics only

Re Annex IV, part 2

(List of provisionally permitted colourants for the authorization of which justification must be provided within 3 years)

The following proposed amendments correspond to the results arrived at by the 26th Conference of the 'Colourants Committee' of the German Research Association:

(a) Red

Serial number	Colour index number	Designation according to communication 3 of Colourants Committee	Proposed amendment
1	12.120	C-ext. red 1	<u>Delete</u> this colourant from list
3	12.350	C-ext. red 4	<u>Delete</u> this colourant from list
4	12.385	C-ext. red 5	<u>Delete</u> this colourant from list
10	Schultz number: 1.386	C-red 51	<u>Delete</u> this colourant from list

The following two substances should be transferred from Annex III, Part 2, to this Annex:

(a)

Serial No. in Annex II, 2	Colour index number	Designation according to communication 3 of Colourants Committee	Limitations
12	16.185	C-red 46	

(b) Orange and yellow

22	45.396	C-orange 7	as hitherto
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OPINION OF THE LEGAL AFFAIRS COMMITTEE

Rapporteur for the opinion: Mr Xavier HUNAUT

The Legal Affairs Committee appointed Mr Hunaut rapporteur for an opinion on 7 December 1972.

The committee discussed the draft opinion at its meetings of 9 and 22 February 1973 and adopted it unanimously.

The following were present: Mr Brouwer, chairman and deputy rapporteur for the opinion, Mr Joseau-Marigné, vice-chairman, Mr Ballardini, Mr Brewis, Mr Broeksz, Mr Brugger, Mr Héger, Mr Koch, Mr Lucius, Mr Meister, Mrs Nielsen, Mrs Orth (deputizing for Mr Spénale), Mr Outers, Mr Reischl, Mr Vermeylen and Mr Walker Smith.

## I. Purpose and legal justification of the draft directive

1. Differences have been found to exist between the legal and administrative provisions laid down for cosmetic products in the Member States. These differences involve:

- a) the technical provisions governing the composition and the approval of cosmetic products,
- b) the definition of the boundary between cosmetic products on the one hand - to which legislation on cosmetics is applicable - and foodstuffs and pharmaceutical products on the other.

Intra-Community trade in cosmetic products is being hampered as a result.

The purpose of this proposal is to eliminate these differences by approximation of the relevant legal and administrative provisions.

2. The draft directive is based on Article 100 of the EEC Treaty.

Since the differences between national provisions are an obstacle to intracommunity trade, affecting as they do the organisation and operation of the Common Market, this Article does in fact provide the only justifiable legal basis.

3. In addition, cosmetic products are included in the third phase of the General Programme of 28 May 1969 for the elimination of technical barriers to trade resulting from differences between Member States' legal and administrative provisions<sup>1</sup>.

In order to clarify the background of the directive, it would be advisable to include in the preamble one last consideration worded as follows:

Bearing in mind the fact that cosmetic products are included in the third phase of the General Programme of 28 May 1969 for the elimination of technical barriers to trade resulting from differences between Member States' legal and administrative provisions.

<sup>1</sup> OJ C 76, 17.6.1969.

The Legal Affairs Committee has already pointed out on previous occasions that the deadlines fixed in the General Programme are not being respected. This proposal should in fact have been submitted by the Commission by 1 July 1970 and the Council should have adopted it by 1 January 1971.

## II. Purpose and content of the Draft Directive

4. Article 1(1) defines cosmetic products within the meaning of the draft directive.

Article 1(2) refers to Annex 1 which contains a general list of cosmetic products corresponding to the definition and considered to fall within the sphere of application of the directive.

A general list has only an illustrative value and cannot therefore have legal consequences in the strict sense of the term. Considered in this light, Article 1(2) and Annex I could have been omitted from the directive. The definition given in Article 1(1) is in itself perfectly adequate.

5. Article 1(3) refers to Annex V which contains a list of substances excluded from the scope of the directive.

Perusal of the text of this provision shows that the addition of one of the substances specified in Annex V to a cosmetic product can result in the product falling outside the scope of the directive. Such a provision may give rise to all kinds of **malpractices**. Your committee therefore considers that the substances listed in Annex V should also be covered by the directive. Article 1(3) should thus be deleted accordingly.

6. Article 2 states as a general criterion of the directive that cosmetic products must not constitute a risk to human health.

7. Article 3 indicates that the Commission has opted for the system of complete harmonisation, i.e. only products satisfying the requirements of the directive may be marketed. This system differs from that of optional harmonisation, in which Community legislation and national legislation co-exist.

In the past, the European Parliament has repeatedly advocated complete harmonisation, and your Committee therefore welcomes the nature of this directive.

The same observations apply to Article 6, which lays down compulsory requirements for packaging and labelling.

8. Article 4 is a prohibition and refers to Annexes II and III listing substances which must not be present in cosmetic products, or if they are tolerated, must not exceed a specific limit or may only be present under certain conditions.

Annex II is a list of products which must not be used in cosmetic products. In the opinion of your Committee, consumers would find a positive list more useful, i.e. a list of all the substances which cosmetic products may contain. The negative list proposed by the Commission in fact implies that, irrespective of the conditions mentioned in the other annexes, all substances not mentioned in Annex II may be included in cosmetic products. This is clearly not an adequate safeguard against the presence of toxic substances in cosmetic products. The Legal Affairs Committee is unreservedly in favour of Annex IV being replaced by a positive list. It further urges the Committee on Social Affairs and Public Health to move an amendment to this effect to Article 4. This shortcoming is also pointed out in an article published in January of this year in the Dutch 'Consumentengids'. (Consumers' Guide) and appended in the form of an Annex to this opinion.

9. Article 5 is a transitional provision and refers to Annex IV which contains a list of temporarily permitted substances.

According to the Commission's memorandum on Article 5 and Annex IV, a decision will be taken in three years time as to whether the substances specified in Annex V should be prohibited or definitively permitted.

So long however as uncertainty persists about the effects of these substances on the human organism their use must be prohibited. In the view of the Legal Affairs Committee Article 5 should therefore also be deleted from the directive.

10. Article 7, the fundamental provision which forms the basis of the directive, guarantees the free movement of cosmetic products which comply with the requirements of the directive.

Pursuant to Article 7(2), the indications referred to in Article 6 may be required in the respective national languages. It would be better to make the use of the national language compulsory. This opinion too is supported by the above-mentioned 'Consumentengids'.

11. Article 8 requires Member States to take the necessary measures to check whether products comply with the requirements of the directive either when they are brought on the market or while they are held in storage by the manufacturer, the importer or the middleman.

The Commission proposes that the arrangements for checking and the frequency of checks should be left to the discretion of the Member States. The technical checking methods, however, would be decided upon jointly at a later date.



12. Article 9 refers to the procedure by which methods of sampling and analysis must be determined. This provision also deals on the one hand with the adaptation of Annexes II and III to technical progress, and on the other with the definitive classification of the provisionally approved substances listed in Annex IV.

13. Article 10 makes provision for the appointment of a committee responsible for adapting the directive to technical progress and Article 11 goes on to indicate the procedure to be followed by this committee. Both provisions incorporate the standard formula given in the resolution on the adaptation to technical progress of the directive adopted by the Council on 28 May 1969<sup>1</sup>.

14. Article 12 (1) contains an escape clause for products which, although conforming to the directive, constitute a danger to human health.

These products can be banned from the market by every Member State by an abbreviated procedure of Article 11.

It should be noted that a product constituting a health hazard can only be taken off the market by a Member State thirty days after the matter has been brought to the committee's attention by the Commission, which means that an even longer period elapses between the Member State establishing the hazard and taking the product off the market. Considering the general criterion laid down in Article 3, your committee is somewhat surprised that the directive does not allow a Member State to take a product off the market as soon as it has been discovered to constitute a health hazard. Since this again is not a specifically legal problem, it suffices to draw this flaw to the attention of the Committee for Social Affairs and Health Protection.

15. Article 13 creates legal safeguards for individuals to prevent arbitrary measures being taken against them.

16. Pursuant to Article 14 (1), the provisions of the directive must be incorporated in the national legislation within eighteen months of publication.

Nonetheless, under Article 14 (2), products which do not comply with the regulations of the directive can be allowed on the market by Member States in their territory for a period of thirty-six months. According to the Commission's explanatory statement, this is to enable dealers to sell off their stocks of cosmetic products which do not comply with those regulations.

<sup>1</sup> OJC C 76, 17.6.1969, p.8

This aspect, however, is not made clear in the text of Article 14(2). As it stands, the provision states simply that the system of optional harmonization is to be applied for thirty-six months. In other words, if Article 14(2) is followed to the letter, not only products which comply with the regulations of the directive but also other cosmetic products can be brought on the market by Member States for a period of thirty-six months, irrespective of whether they are taken from old stocks.

After exhaustive discussion of this matter, your committee came to the conclusion that it would make better sense if the entire text of Article 14(2) could be deleted from the directive.

Finally Article 14(3) requires Member States to inform the Commission of the implementation of national provisions in the field covered by the directive.

Your committee also feels that the Commission must not only be notified of the provisions which are actually introduced in Member States' legislation but also of the provisions which Member States envisage for the future. It asks the Committee to consider the possibility of moving an amendment to this effect to Article 14(3).

17. Subject to the above observations, the Legal Affairs Committee can endorse the directive as a whole.

Article published in the Dutch 'CONSUMENTENGIDS'

(Consumers' Guide) of January 1973

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Such directives are also of great importance to consumers since, as we have seen, they belong under the heading of product legislation. This is why we were particularly interested in the European Commission's draft directive on cosmetics. It contains a list of substances which may not be used in cosmetics and a second list of substances which may only be used to a limited extent or only in so far as their harmful influence on health is not proven. Yet a product such as hexachlorophene, which was recently shown to be harmful, may still be used to a limited extent. Although nothing is known of their possibly harmful effect, new products may be used freely since they do not feature on the list. A creepy business.

We are definitely not happy with this directive. Instead of a list of substances which may not be used we should much prefer a list of substances which have been proved to be harmless and to remain so, and which therefore may be used. This list would be required for each group of articles, for it is quite conceivable that a substance may be harmless for instance in a foot care preparation yet not so innocent in a lipstick. The use of substances which do not figure on the list should be prohibited. This would give the consumer the protection so long denied him.

For years consumer organisations in Western Europe have been advocating a clear description of the composition of products on the package. The new directive from the European Commission does not make a statement of composition compulsory. Neither are there any regulations concerning standardisation, description of contents or indication of price per standard quantity. This is especially necessary in the field of cosmetics with its thousands of different bottles and pots, tubes and boxes.

It is also not obligatory to print directions for use or, where necessary, warnings in the language of the country in which the cosmetics are sold. Of course the different countries may stipulate, on the basis of the directive, use of the local language, but it would be better if the directive itself were to lay down such a requirement.

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