II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 17 May 1982

amending for the second time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(82/368/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the implementation of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (4), as amended by Directive 79/661/EEC (5), showed that certain amendments should be made to Annexes II, III, IV and V;

Whereas, in order to protect public health, measures should be taken with regard to mandatory warnings on the labels of cosmetic products containing thioglycollic acid, its salts and esters;

Whereas the use of hydrogen peroxide is not restricted to oxydizing colouring agents for hair dyeing; whereas the use of this substance should therefore also be authorized for hair care products, with the requirement that certain warnings be printed on the label to safeguard health;

Whereas in certain circumstances it is not necessary to mention the formaldehyde content on the label when this substance is not used as an ingredient of a cosmetic product but is inevitably present as a residue from the processing of raw materials;

Whereas the field of application and/or use of hydroquinone should be specified;

Whereas the maximum authorized concentration of potassium or sodium hydroxide in depilatories should be specified;

Whereas a decision may be taken with regard to the substances listed in Part I of Annex IV to Directive 76/768/EEC, in accordance with Article 5 thereof;

Whereas Parts 2 and 3 of Annex IV to the same Directive do not correspond with the list of colouring

(1) OJ No C 165, 2. 7. 1979, p. 52.
(2) OJ No C 175, 14. 7. 1980, p. 88.
(3) OJ No C 83, 2. 4. 1980, p. 7.
(4) OJ No L 262, 27. 9. 1976, p. 169.
(5) OJ No L 192, 31. 7. 1979, p. 35.

agents actually used in the preparation of cosmetic products; whereas this list should therefore be updated;

Whereas a list of substances authorized for use as preservatives can be drawn up on the basis of the latest scientific and technical research;

Whereas a procedure for updating the Annexes rapidly should be introduced;

Whereas the presence of traces of substances which cosmetic products must not contain according to Annex II to Directive 76/768/EEC is technologically inevitable with correct manufacturing processes; whereas therefore certain provisions should be made in this connection;

Whereas the English, German and Dutch versions of Directive 76/768/EEC of 27 July 1976 contain typographical errors which should be corrected,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC shall be amended in accordance with the provisions set out hereinafter.

Article 2

Annex II shall be amended as follows:

— replace the title by:

'List of substances which must not form part of the composition of cosmetic products';

— replace '46 Barium salts' by:

'Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Annex III, Part 1, lakes prepared from barium sulphate and pigments prepared from the colouring agents listed in Annex III, Part 2 and Annex IV, Parts 2 and 3 and marked 1 (Ba)';

— replace '191 Hydrofluoric acid' by:

'Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Annex III, Part 1';

— replace '221 Mercury and its compounds' by:

'Mercury and its compounds, with the exception of those listed in Annex V and Annex VI, Part 2';

— at 268 delete 'Phenol and its alkali salts, excluding the exceptions listed in Annex III' and replace by 'Picric acid';

— replace '321 Thiourea and its derivatives, with the exception of those listed in Annex IV, Part 1' by:

'Thiourea and its derivatives, with the exception of the one listed in Annex III, Part 1';

— replace '350 Tetrabromosalicylanilides' by:

'Tetrabromosalicylanilides except as impurities of tribromosalicylanilide according to the criteria laid down in Annex IV, Part 1';

— replace '351 Dibromosalicylanilides, e.g. metabromsalan (*) and dibromsalan (*)' by:

'Dibromosalicylanilides, except as impurities of tribromosalicylanilide according to the criteria laid down in Annex IV, Part 1';

— replace '360 Sassafras officinale Nees oil containing safrole' by:

'Safrole except for normal content in the natural essences used and provided the concentration does not exceed:

100 ppm in the finished product,

50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children'.

Article 3

1. Part 1 of Annex III shall be replaced by the Annex given in Annex 1 to this Directive.

2. Part 2 of Annex III shall be amended as follows:

(a) **Reds**

— In the third and sixth columns delete:

— 'E 180' against colouring agent No 10 corresponding to colour index number 15 850,

— 'E 420' against colouring agent No 26 corresponding to colour index number 77 015.

— In the second column, replace:

'15 630 (Ba)' by '15 630: 1 (Ba)',
'15 630 (Sr)' by '15 630: 3 (Sr)',
'15 865 (Sr)' by '15 865: 3 (Sr)',
'45 170 (Ba)' by '45 170: 1 (Ba)'.

(b) **Oranges and yellows**

For colouring agent No 23, replace the colour index number '45 395' in the second column by '45 396'.

(c) **Greens and blues**

For colouring agent No 4 corresponding to colour index number 44 090 enter the number 'E 142' in the third and sixth columns.

(d) **Violets, browns, blacks and whites**

— Delete colouring agent No 8 corresponding to colour index number 77 005.

— In the third and sixth columns delete 'Part of E 153' and 'E 153' respectively for colouring agents Nos 12 and 13 corresponding to colour index numbers 77 266 and 77 267.

— Add reference number '26' and enter 'Part of E 153' and 'E 153' respectively in the third and sixth columns corresponding to this reference number.

(e) **Footnote** (4)

Add the following sentence:

'They shall continue to be subject to the general criteria set out in Annex III to the Directive of 1962 concerning colouring matter, where the "E" number has been deleted in that Directive.'

Article 4

1. Annex IV, Part 1 shall be replaced by the Annex given in Annex 2 to this Directive.

2. Annex IV, Part 2 shall be amended as follows:

(a) **Reds**

— Delete the following colouring agents:

Reference number	Colour index number
2	12 350
3	12 385
14	75 580

— For reference number 5 replace the numbers '15 500' and '15 500 (Ba)' in the second column by '17 200' and delete the reference to the field of application in the fourth column.

— For colouring agent No 6 replace '15 585 (Ba)' in the second column by '15 585 : 1 (Ba)'.

(b) **Oranges and yellows**

For reference number 2, replace colour index number '45 340' in the second column by '40 850' and add the number 'E 161g' in the third and sixth columns.

(d) **Violets, browns, blacks and whites**

Delete colouring agent No 8 corresponding to colour index number 77 718.

(e) **Footnote** (4)

Add the following sentence:

'They shall continue to be subject to the general criteria set out in Annex III to the said Directive, where the "E" number has been deleted in that Directive.'

3. Annex IV, Part 3 shall be replaced by the Annex given in Annex 3 to this Directive.

Article 5

In Annex V:

— Replace:

'2. Hexachlorophene (for all uses other than that stated in Part 1 of Annex III)'

by:

'2. Hexachlorophene (for all uses other than that stated in Annex VI, Part 1)';

— Replace:

'5. Strontium and its salts, with the exception of those used in the colouring agents listed in Part 2 of Annex III and Parts 2 and 3 of Annex IV'

by:

'5. Strontium and its salts, with the exception of strontium sulphide under the conditions laid down in Annex III, Part 1, and strontium salts used in the colouring agents listed in Annex III, Part 2 and Annex IV, Parts 2 and 3, and marked: 3 (Sr)';

— Replace:

'6. Zirconium and its derivatives'

by:

'6. Zirconium and its compounds';

— Add:

'10. Chloroform.

11. Hydroquinone, for use as a skin-lightener.'

Article 6

An Annex VI shall be added, listing the substances which may be used as preservatives in the manufacture of cosmetic products under the conditions set out in the said Annex and in the preamble thereto.

Article 7

Article 4 shall be amended as follows:

'*Article 4*

1. Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

(a) (unchanged)

(b) (unchanged)

(c) (unchanged)

(d) (unchanged)

(e) preservatives other than those listed in Annex VI, Part 1;

(f) preservatives listed in Annex VI, Part 1, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product.

2. The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2.'

Article 8

Article 5 shall be amended as follows:

'*Article 5*

Until 31 December 1985 Member States shall allow the marketing of cosmetic products containing:

(a) (unchanged)

(b) (unchanged)

(c) (unchanged)

(d) the preservatives listed in Annex VI, Part 2, within the limits and under the conditions laid down; however, these substances may be used in other concentrations for specific purposes apparent from the presentation of the product.

On 1 January 1986 these substances, colouring agents and preservatives shall be:

— definitively permitted,

— or definitively prohibited (Annex II),

— or retained for a period as specified in Annex IV or VI,

— or deleted from all Annexes to this Directive.'

Article 9

In Article 6 (1) (d) the words 'in Annexes III and IV' shall be replaced by the words 'in Annexes III, IV and VI'.

Article 10

Article 8 shall be replaced by the following:

'*Article 8*

1. (unchanged)

2. The amendments necessary for adapting Annexes II to VI to technical progress shall be adopted in accordance with the same procedure, after consultation of the Scientific Committee for Cosmetology at the initiative of the Commission or of a Member State.

However, in the case of Annexes III to VI this procedure will apply until 31 December 1988. No later than six months before that date, the Council acting unanimously on a Commission proposal shall take the appropriate measures.'

Article 11

The following Article shall be inserted:

'*Article 8a*

1. Notwithstanding Article 4 and without prejudice to Article 8 (2), a Member State may authorize the use within its territory of other substances not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization, subject to the following conditions:

(a) the authorization must be limited to a maximum period of three years;

(b) the Member State must carry out an official check on cosmetic products manufactured from the substance or preparation use of which it has authorized;

(c) cosmetic products thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the Commission and to the other Member States the next of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.

3. Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in a list of permitted substances of the substance given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. Within 18 months of submission of the request, a decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the Commission or of a Member State, of the Scientific Committee for Cosmetology and in accordance with the procedure laid down in Article 10 as to whether the substance in question may be included in a list of permitted substances or whether the national authorization should be revoked. Notwithstanding paragraph 1 (a), the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.'

Article 12

1. The English language version is corrected in accordance with Annex 5.

2. The German language version is corrected in accordance with Annex 6.

3. The Dutch language version is corrected in accordance with Annex 7.

Article 13

1. Member States shall take all necessary measures to ensure that as from 1 January 1986 neither manufacturers nor importers established in the Community place on the market products which do not satisfy the requirements of this Directive.

2. Member States shall take all necessary measures to ensure that the products referred to in the first paragraph can no longer be sold or disposed of to the final consumer after 31 December 1987.

Article 14

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with the provisions of this Directive not later than 31 December 1983 and shall forthwith inform the Commission thereof.

2. Member States shall ensure that the texts of the provisions of national law which they adopt in the field