18th COMMISSION DIRECTIVE 95/34/EC

of 10 July 1995

adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products [1], as last amended by Commission Directive 94/32/EC [2], and in particular Article 8 (2) thereof,

After consultation of the Scientific Committee on Cosmetology,

Whereas furocoumarines are recognized to be photomutagenic and photocarcinogenic; whereas the Scientific Committee on Cosmetology has not been able to conclude from the available scientific, technical and epidemiological data that the association of protective filters with furocoumarines would guarantee the safety of sun protection and bronzing products containing furocoumarines above a minimum level; whereas, in order to protect public health, it is therefore necessary to limit furocoumarines to less than 1 mg/kg in these products;

Whereas 4-tert-Butyl-3-methoxy-2,6-dinitrotoluene (Musk Ambrette), is recognized to be a potent photoallergen; whereas, on the basis of recent scientific research, use of this substance in cosmetic products poses a risk to human health; whereas it is therefore necessary to prohibit its use;

Whereas toxicological evaluation of Diisobutyl-phenoxy-ethoxy-ethyldimethylbenyl-ammonium chloride (Benzethonium), shows that this ingredient is toxic to a significant degree; whereas the safety margin for human health, when this ingredient is used in cosmetic products, is inadequate; whereas it is therefore necessary to prohibit its use;

Whereas cells, tissues or products of human origin are liable to transmit the Creutzfelt-Jakob disease, human spongiform encephalopathy, and certain virus diseases; whereas it is therefore necessary, given the current state of scientific knowledge, to prohibit their use in cosmetic products;

Whereas recent toxicological studies of 3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein*); show a net clastogenic effect *in vitro*; whereas the safety margin is low, especially where children are concerned; whereas it is therefore necessary to prohibit its use;

Whereas, on the basis of the latest scientific and technical research, 2-Cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester may be used as ultraviolet filter in cosmetic products;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 76/768/EEC is hereby amended as shown in the Annex hereto.

Article 2

1. Member States shall take all the necessary measures to ensure that as from 1 July 1996 for the substances set out in the Annex, neither manufacturers nor importers established in the Community shall place on the market products which do not comply with the requirements of this Directive.

2. Member States shall take the necessary measures to ensure that the products referred to in paragraph 1 containing the substances set out in the Annex shall not be sold or otherwise supplied to the final consumer after 30 June 1997.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 30 June 1996. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

[1] OJ No L 262, 27. 9. 1976, p. 169.
[2] OJ No L 181, 15. 7. 1994, p. 31.