TWENTY-FOURTH COMMISSION DIRECTIVE 2000/6/EC

of 29 February 2000

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 98/62/EC [2], and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers,

Whereas:

(1) Tallow derivatives, such as fatty acids, glycerine, esters of fatty acids and soaps and fatty alcohols, fatty amines and fatty amides derived therefrom, are considered safe for use in the manufacture of cosmetic products with regard to the risk of contracting transmissible spongiform encephalopathies if they are prepared in strict accordance with specific physico-chemical processes in which temperature is the decisive parameter on which the corresponding pressure conditions depend. Annex II to the abovementioned Directive should therefore be amended accordingly.

(2) Harmful secondary effects have been shown to arise following prolonged use of hydroquinone as skin-lightening cream. This particular use of hydroquinone must not therefore be authorised, meaning that Part I of Annex III to the abovementioned Directive needs to be amended. Studies also show that the concentration of hydroquinone used in hair dyes does not have harmful effects for health if it does not exceed 0,3 %. Part I of Annex III to the abovementioned Directive must be amended accordingly.

(3) On the basis of new scientific data, benzalkonium chloride, bromide and saccharinate have recently been added to the list of substances which may be used as preservatives in the manufacture of cosmetic products set out in Part 1 of Annex VI to the abovementioned Directive. In the light of experience, it is also acceptable for these benzalkonium salts to be used for other purposes in cosmetic products, according to the length of their carbon chain, provided that the maximum authorised concentrations are observed. These specific characteristics therefore justify their inclusion in the list Part 1 of Annex III.

(4) The cosmetics industry has supplied new scientific data based on studies of the percutaneous absorption of acqueous solutions of boric acid, borates and tetraborates at various pH numbers and at various concentrations showing that the requirement that pH should be neutral or slightly alkaline in order to minimise the percutaneous absorption of these boron derivatives is not justified. The list of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down, set out in Part 1 of Annex III, should therefore be amended accordingly.

(5) In the concentrations in which it is normally used as a preservative in cosmetic products intended to be removed by rinsing, benzylhemiformal is not likely to cause harmful effects for human health. Therefore it should be removed from Part 2 of Annex VI to the abovementioned Directive which sets out the list of preservatives provisionally allowed in cosmetic products and included in Part 1 of Annex VI which contains the list of preservatives allowed in cosmetic products.

[1] OJ L 262, 27.9.1976, p. 169.
[2] OJ L 253, 15.9.1998, p. 20.

(6) In the concentrations in which it is normally used as a preservative in cosmetic products, 3-iodo-2-propynyl butylcarbamate is not likely to have harmful effects on human health. Therefore, it should be removed from the list in Part 2 of Annex VI and entered in the list in Part 1 of Annex VI.

(7) In the concentrations in which it is normally used as a UV filter for sunscreen cream, 4-dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA) is not likely to have harmful effects on the health of users. Therefore, it should be removed from Part 2 of Annex VII to the abovementioned Directive which sets out the list of UV filters that cosmetic products may provisionally contain and entered in Part 1 of Annex VII which contains the list of UV filters allowed in cosmetic products.

(8) In the concentrations in which it is normally used as a UV filter for sunscreen cream, 2-hydroxy-4-methoxybenzophenone-5-sulfonic acid (benzophenone-5) and its sodium salt is not likely to give rise to harmful effects for human health. Therefore, 2-hydroxy-4-methoxybenzophenone-5-sulfonic (benzophenone-5) and its sodium salt should be removed from Part 2 of Annex VII and entered in Part 1 of Annex VII.

(9) 4-isopropyl-benzyl salicylate is no longer used as a UV filter for sunscreen products. Consequently, 4-isopropyl-benzyl salicylate must be removed from Part 2 of Annex VII.

(10) Within the concentration limits and under the conditions adopted by the cosmetic industry for its use as a UV filter for sunscreen products, 2,2'-methylene-bis-6-(2H-benzotriazol-2-yl)-4-tetra-methyl-butyl-1,1,3,3-phenol, is not likely to produce harmful effects for the health of users. Therefore, it may be included in the list in Part 1 of Annex VII.

(11) Within the concentration limits and under the conditions adopted by the cosmetic industry for its use as a UV filter for sunscreen products, the monosodium salt of 2-2'-bis-(1,4-phenylene)1H-benzimidazole-4,6-disulfonic acid is not likely to have harmful effects on the health of users. Therefore, it may be included in the list in Part 1 of Annex VII.

(12) Within the concentration limits and under the conditions adopted by the cosmetic industry for its use as a UV filter for sunscreen products, (1,3,5)-triazine-2,4-bis-((4-(2-ethyl-hexy-loxy)-2-hydroxy)-phenyl)-6-(4-methoxyphenyl) is not likely to have harmful effects on the health of users. Therefore, it may be included in the list in Part 1 of Annex VII.

(13) 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 indicated in the Annex to this Directive.

Article 2

Member States shall adopt the necessary measures to ensure that cosmetic products containing the substances listed in Annexes II, III, VI and VII to Directive 76/768/EEC, as set out in the Annex to this Directive, which are supplied to the final consumer after 1 January 2001, comply with the provisions of this Directive.