TWENTY-SECOND COMMISSION DIRECTIVE 98/16/EC

of 5 March 1998

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 [1] on the approximation of the laws of the Member States relating to cosmetic products, as last amended by Commission Directive 97/45/EC [2], and in particular Article 8(2) thereof,

Whereas Commission Directive 97/1/EC [3] temporarily prohibited, as a precautionary measure, the use of bovine, ovine and caprine tissues and fluids from the encephalon, the spinal cord and the eyes, and ingredients derived therefrom; this Directive was to be reviewed following the examination of the elements on which it was based, and generally adapted in the light of the development of scientific knowledge;

Whereas Commission Decision 97/534/EC of 30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies [4], defines specified risk materials, provides for their elimination at source and prohibits their import into the Community;

Whereas Directive 76/768/EEC requires Member States to ensure that only cosmetic products which conform to the provisions of this Directive may be put on the market in the EU and whereas, more particularly, Member States shall prohibit the marketing of cosmetic products containing substances listed in Annex II;

Whereas these provisions apply to all cosmetic products to be placed on the market in the Community, nothwithstanding the origin of the product or the raw materials contained therein; whereas, thereby, the compliance with Community law of cosmetic products, starting materials and intermediate products which are imported into the Community to be used in the manufacture of cosmetic products is controlled and checked;

Whereas Directive 76/768/EEC should be amended to align the list of prohibited animal materials to that contained in the Decision 97/534/EC;

Whereas the opinion of the Scientific Committee on Cosmetology of 24 June 1997 stated that tallow derivatives such as fatty acids, glycerine, fatty acid esters and soaps, used in the production of cosmetic products, are considered safe provided that, as a minimum, they have been obtained by certain specified methods which have been strictly certified, and that other tallow derivatives such as fatty alcohols and fatty amides produced from the abovementioned derivatives and subsequently processed are regarded as safe;

Whereas, according to this scientific opinion, it is possible to grant a derogation for tallow derivatives; this derogation also applies to other derivatives of tallow such as fatty alcohols, fatty amines and fatty amides, and materials made from the abovementioned that are manufactured according to the methods indicated in the Annex and subjected to additional subsequent treatments;

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;

Whereas Member States have the right to maintain in force until 1 April 1998 those measures adopted in concordance with Directive 97/1/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

Member States shall take the necessary measures to ensure that the cosmetic products containing the substances set out in the Annex cannot be placed on the market from 1 April 1998. This does not apply to products produced before 1 April 1998. Member States may retain in force those measures implementing Directive 97/1/EC until 1 April 1998.

[1] OJ L 262, 27. 9. 1976, p. 169.
[2] OJ L 196, 24. 7. 1997, p. 77.
[3] OJ L 16, 18. 1. 1997, p. 85.
[4] OJ L 216, 8. 8. 1997, p. 95.