COMMISSION DIRECTIVE 2000/41/EC

of 19 June 2000

postponing for a second time the date after which animal tests are prohibited for ingredients or combinations of ingredients of 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 2000/11/EC [2], and in particular Article 4(1)(i) thereof,

After consulting the Scientific Committee on cosmetic products and non-food products intended for consumers,

Whereas:

(1) The main objective of Directive 76/768/EEC is to protect public health. To this end it is indispensable to carry out certain toxicological tests to evaluate the safety for human health of ingredients and combinations of ingredients used in cosmetic products.

(2) Pursuant to Article 4(1)(i) of Directive 76/768/EEC Member States should prohibit the marketing of cosmetic products containing ingredients or combinations of ingredients tested on animals after 30 June 2000 in order to meet the requirements of the Directive.

(3) The second subparagraph of this provision also provides that the Commission should submit draft measures to postpone the date of implementation of this provision if there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines.

(4) In the absence of any scientifically validated alternative methods to animal experiments and any pertinent toxicity test guidelines in the field of alternative methods adopted by the OECD, it was necessary to postpone the date provided for in Article 4(1)(i) of Directive 76/768/EEC for the first time by Commission Directive 97/18/EC in compliance with the second subparagraph of this provision.

(5) Three alternative methods have been validated in Europe to date. It is unlikely that the scientific state of the art will change significantly before 30 June 2000. Therefore, the date provided for in Article 4(1)(i) of Directive 76/768/EEC should be postponed for a second time in compliance with the second subparagraph of this provision and Article 2 of Directive 97/18/EC.

(6) These three methods are being incorporated into Community law through their entry onto Annex V to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [3], as last amended by Commission Directive 2000/33/EC [4].

(7) Council Directive 86/609/EEC [5] of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [6] provides that an animal test shall not be carried out if an alternative method is available.

(8) These methods are therefore mandatory for use in all sectors including that of cosmetics.

(9) The Commission has proposed a Directive amending for the seventh time Directive 76/768/EEC in order to solve definitively the issue of experiments on animals in the cosmetic products sector. Such a proposal should be adopted by co-decision procedure involving the European Parliament and the Council.

(10) Taking into account that it can be expected that validated alternative methods will become available for other tests in the next two years and that the proposed Directive shall be adopted by that point of time, it is appropriate to postpone for the last time the date to 30 June 2002.

(11) 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

The date of '30 June 2000' shall be replaced by '30 June 2002' in the first sentence of Article 4(1)(i) of Directive 76/768/EEC.

[1] OJ L 262, 27.9.1976, p. 169.
[2] OJ L 65, 14.3.2000, p. 22.
[3] OJ L 114, 1.5.1997, p. 43.
[4] OJ L 196, 16.8.1967, p. 1.
[5] OJ L 136, 8.6.2000, p. 90.
[6] OJ L 358, 18.12.1986, p. 1.