COMMISSION DIRECTIVE 97/18/EC

of 17 April 1997

postponing 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 1996 on the approximation of the laws of the Member States relating to cosmetic products [1], as last amended by Commission Directive 97/1/EC [2], and in particular Article 4 (1) (i) thereof;

After consulting the Scientific Committee on Cosmetology,

Whereas the main objective of Directive 76/768/EEC is to protect public health; whereas, to this end, it is indispensable to carry out the certain toxicological tests to evaluate the safety for human health of ingredients and combinations of ingredients used in cosmetic product formulations,

Whereas pursuant to Article 4 (1) (i) of Directive 76/768/EEC Member States must ban the placing on the market of cosmetic products containing ingredients or combinations of ingredients tested on animals after 1 January 1998 in order to meet the requirements of the Directive;

Whereas the second sentence of this provision provides that the Commission shall submit draft measures to postpone the date of implementation 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;

Whereas progress has been made in research into alternative methods of testing, in particular in the fields of percutaneous absorption and local risks to the eyes and skin; whereas it has not yet been possible to validate scientifically any alternative testing method; whereas the OECD has not yet adopted pertinent guidelines for toxicity tests in the field of alternative testing methods;

Whereas it is unlikely that the state of the art will change before 1 January 1998; whereas, therefore, the date provided for in Article 4 (1) (i) of Directive 76/768/EEC should be postponed, in compliance with the second sentence of this provision;

Whereas Directive 76/768/EEC provides that the date be postponed for a sufficient period, and in any case for no less than two years; whereas, therefore, it is necessary to stipulate a date later than 1 January 2000; whereas at this stage it is extremely difficult to foresee the date by which certain alternative methods for testing certain ingredients or combinations of ingredients for the presence of certain risks for human health will have been scientifically validated;

Whereas, however, it can be foreseen that alternative methods will progressively become available in regard to percutaneous absorption, photoirritation, eye irritation and skin irritation;

Whereas, likewise, taking into account the provision's objective, scientific reassessment should not be excessively delayed; whereas, therefore, it is necessary to lay down at this stage a date before which it can be foreseen that no alternative method of testing will have been adequately scientifically validated;

Whereas it is therefore appropriate to postpone the date to 30 June 2000;

Whereas, in these circumstances, it is not possible to lay down a time limit offering the certainty that it will be possible to implement the ban on animal experiments on a specified date; whereas, therefore, the Commission is not in a position to exercise its powers under Article 4 (1) (i) of the Directive except in part;

Whereas it is therefore necessary to provide that the Commission shall submit new draft measures under the conditions provided for in this Article;

Whereas postponement of the date shall not be prejudicial to the objective of reducing the number of test animals and their suffering wherever possible, notably through the use of screening tests;

Whereas everything must be done to ensure that alternative methods to animal experiments are developed, validated and accepted; whereas, pursuant to the provisions of Article 130f (3) of the Treaty and the Fourth Framework Programme for Research, the Commission must take the necessary measures to promote research into and the validation of alternative methods to animal experiments in the field of ingredients and combinations of ingredients used in cosmetic product formulations;

[1] OJ No L 262, 27. 9. 1976, p. 169.
[2] OJ No L 16, 18. 1. 1997, p. 85.