

**Proposal for a Directive of the European Parliament and of the Council amending for the seventh time Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products**

(2000/C 311 E/06)

(Text with EEA relevance)

COM(2000) 189 final — 2000/0077(COD)

(Submitted by the Commission on 6 April 2000)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Council Directive 76/768/EEC <sup>(1)</sup>, as last amended by Commission Directive 2000/11/EC <sup>(2)</sup>, has comprehensively harmonised the national laws relating to cosmetic products. The main objective of the Directive is to protect public health. To this end it is indispensable to carry out certain toxicological tests to evaluate the safety of cosmetic products for human health.
- (2) In accordance with Directive 76/768/EEC, it is essential that the aim of abolishing animal experiments be pursued and that the prohibition of such experiments becomes effective on the territory of the Member States.
- (3) The safety of finished cosmetic products can already be assessed from knowledge about the safety of the ingredients which they contain and by methods which do not involve the use of animals. Therefore animal tests with finished cosmetic products should be prohibited.
- (4) It will progressively but slowly be possible to ensure the safety of the ingredients and combinations of ingredients used in cosmetic products, at least for the acute effects, without recourse to animal experiments, by using alternative methods validated at Community level, or approved as being scientifically validated, by the European Centre for the Validation of Alternative

Methods (ECVAM). After consulting the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) as regards the applicability of the validated alternative methods to the field of cosmetic products, the Commission will have immediately to publish the validated or approved methods recognised as being applicable to such ingredients. In order to achieve the highest possible degree of animal protection, a deadline has to be foreseen, when a definitive prohibition should be introduced. However, the date of implementation of this prohibition should be postponed if there has been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated as offering an equivalent level of protection for the consumer.

- (5) All efforts must be made to ensure that the ethical requirement of animal welfare is recognised world-wide. To this end, the Commission should endeavour to obtain the rapid acceptance by the Organisation for Economic Co-operation and Development (OECD) of alternative methods validated at Community level. Furthermore, in the framework of bilateral agreements with third countries, the Commission should make efforts to obtain recognition of the results of tests carried out in the Community using alternative methods so as not to obstruct the export of cosmetic products for which such methods have been used.
- (6) It should be possible to claim on a cosmetic product that no experiment on animals was ever carried out on the finished cosmetic product and/or its ingredients and combinations of ingredients including for the purposes outside the scope of Directive 76/768/EEC. The Commission, in consultation with the Member States, should produce guidelines with the aim of providing clarity and practical guidance to the cosmetic industry, European regulators and above-all the consumer with respect to claims relating to animal testing within the cosmetic sector. These guidelines should aim to ensure that common criteria are applied in the use of claims and that an aligned understanding of the claims is reached, and in particular that such claims do not mislead the consumer.
- (7) Since the measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(3)</sup>, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision,

<sup>(1)</sup> OJ L 262, 27.9.1976, p. 169.

<sup>(2)</sup> OJ L 65, 14.3.2000, p. 22.

<sup>(3)</sup> OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

Council Directive 76/768/EEC is hereby amended as follows:

1. Article 4(1)(i) is deleted.
2. The following Article 4a is added:

*'Article 4a*

1. Member States shall take all necessary measures to prohibit the performance on their territory of animal tests in order to meet the requirements of this Directive:

- (a) for tests performed on finished cosmetic products (from 1 December 2001);
- (b) for tests performed on ingredients or combinations of ingredients, as soon as an alternative method has been published by the Commission, after endorsement of its scientific validity by the European Centre for the Validation of Alternative Methods (ECVAM) and the ECVAM Scientific Advisory Committee, following consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, and in any case (from 1 December 2004). However, if there has been insufficient progress in developing satisfactory methods to replace animal testing scientifically validated as offering an equivalent level of protection for the consumer, the Commission shall, by (1 June 2004), submit draft measures to postpone the date of implementation of this provision for a sufficient period, and in any case for no more than two years, in accordance with the procedure laid down in Article 10.

2. For the purposes of this Directive, "finished cosmetic product" means the cosmetic product intended to be supplied in its existing state to the final consumer.

3. The Commission shall present an annual report to the European Parliament and the Council on progress in the development, validation and legal acceptance of alternative methods to those involving experiments on animals until the entry into force of the prohibition referred to in paragraph 1(b). That report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The Commission shall pay particular attention to the development, validation and legal acceptance of experimental methods which do not use live animals.'

3. Article 6(3) is amended as follows:

- (a) The last sentence of Article 6(3) is deleted.
- (b) The following second subparagraph is added:

'Furthermore, the manufacturer or the person responsible for placing the product on the Community market may

only take advantage, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the product, of the fact that no animal tests have been carried out provided neither the finished product, nor its prototype, nor any of the ingredients contained in it have ever been the subject of such tests including for purposes outside the scope of this Directive. The Commission, in consultation with the Member States, shall for this purpose publish guidelines on the implementation of this principle.'

4. In Article 8(2) and Article 8a(3), the title 'Scientific Committee on Cosmetology' is replaced by the title 'Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers'.
5. In Article 9(1), the title 'Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector' is replaced by the title 'Standing Committee on Cosmetic Products'.
6. Article 10 is replaced by the following text:

*'Article 10*

1. The Commission shall be assisted by the Committee.
2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.
3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.'

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than (1 December 2001). They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

This Directive shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.

*Article 4*

This Directive is addressed to the Member States.