

COMMISSION DIRECTIVE 2004/94/EC
of 15 September 2004
amending Council Directive 76/768/EEC as regards Annex IX
(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 approximation of the laws of the Member States relating to cosmetic products⁽¹⁾, in particular the second subparagraph of Article 4a(1) thereof,

After consulting the Scientific Committee on Cosmetic products and Non-food Products intended for consumers,

Whereas:

- (1) The contents of Annex IX to Directive 76/768/EEC should be established for the purpose of listing those alternative methods to animal testing that have been validated by the European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre and that are not listed in 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⁽²⁾.
- (2) As animal testing may not be replaced completely by an alternative method, it should be mentioned in Annex IX whether the alternative method fully or partially replaces animal testing.
- (3) Directive 76/768/EEC should therefore be amended accordingly.
- (4) There are at present, no alternative methods validated by ECVAM, other than those listed in Annex V to Council Directive 67/548/EEC.
- (5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The text in the Annex to this Directive is inserted in the Annex IX to Directive 76/768/EEC.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 21 September 2004 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

3. Member States shall communicate to the Commission the text of the main 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 Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 15 September 2004.

For the Commission

Olli REHN

Member of the Commission

⁽¹⁾ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2004/88/EC (OJ L 287, 8.9.2004, p. 5).

⁽²⁾ OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1).

ANNEX

The following text is inserted in Annex IX to Directive 76/768/EEC:

'ANNEX IX

LIST OF VALIDATED ALTERNATIVE METHODS TO ANIMAL TESTING

This Annex lists the alternative methods validated by the European Centre on Validation of Alternative Methods (ECVAM) of the Joint Research Centre available to meet the requirements of this Directive and which are not listed in Annex V to Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. As animal testing may not be replaced completely by an alternative method, it should be mentioned in Annex IX whether the alternative method fully or partially replaces animal testing.

Reference number	Validated alternative methods	Nature of replacement full or partial
A	B	C