

Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress

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 products¹, and in particular Article 8(2) thereof,

Whereas:

- (1) Directive 76/768/EEC prohibits the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (hereinafter, CMR), of category 1, 2 and 3, under Annex I 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 substances². However, the use of substances classified in category 3 pursuant to Directive 67/548/EEC may be allowed subject to evaluation and approval by the Scientific Committee on Consumer Products (SCCP).
- (2) In so far as the SCCP considers that glyoxal, a substance classified as CMR of category 3 under Annex I to Directive 67/548/EEC represents a negligible risk when present up to 100 ppm in cosmetic products, Annex III to Directive 76/768/EEC needs to be amended accordingly.
- (3) Directive 76/768/EEC should therefore be amended accordingly.
- (4) In order to ensure a smooth progression from the existing formulae of cosmetic products to formulae which comply with the requirements laid down in this Directive, it is necessary to provide for appropriate transitional periods.
- (5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

¹ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive [reference should be introduced at the time of publication].

² OJ L 196, 16.8.1967, p.1. Directive as last amended by Directive [reference to be included at the time of publication].

HAS ADOPTED THIS DIRECTIVE:

Article 1

Part 1 of Annex III to Directive 76/768/EEC is amended in accordance with the Annex to this Directive.

Article 2

Member States shall take all necessary measures to ensure that products which fail to comply with this Directive are not sold or disposed of to the final consumer after [Day, Month, Year = **twelve months** after the publication of the Directive³].

Article 3

1. Member States shall adopt and publish, by [Day, Month, Year = **Six months** after the publication of the Directive⁴] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [Day, Month, Year = **nine months** after the publication of the Directive⁵].

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.

2. 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 4

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

³ Date to be included.

⁴ Date to be included.

⁵ Date to be included.

Done at Brussels, [...]

*For the Commission
Günter Verheugen
Vice-President*

ANNEX

In Part 1 of Annex III to Directive 76/768/EEC the following entry for glyoxal is added:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
A	b	c	D	e	f
"[reference number to be included]"	Glyoxal CAS 107-22-2 EU 203-474-9		100 mg/kg"		