

Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

amending Council Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annexes II and VII thereto to technical progress

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

After consulting the Scientific Committee on Consumer Products,

Whereas:

- (1) The Scientific Committee on Consumer Products ("SCCP") concluded in its opinion of 20 June 2006 that "*Although 4-aminobenzoic acid (PABA) is presently permitted and used as a sunscreen, it became apparent in the process of evaluation of the dossier that much of the information did not conform to current standards and guidelines*". In order to carry out a proper risk assessment of 4-aminobenzoic acid the SCCP required a new dossier with additional safety data conform to modern standards and SCCP guidelines to be submitted by cosmetics industry before 1 July 2007.
- (2) The Commission received information from the cosmetics industry that there is no longer interest in using 4-aminobenzoic acid in cosmetic products in the Community market. It appears that the cosmetics industry does not intend to defend the use of PABA as it has not submitted any additional safety data required by the opinion of the SCCP of 20 June 2006.
- (3) Without a proper risk assessment 4-aminobenzoic acid can not be considered safe for use as UV-filter in cosmetics and should therefore be deleted from Annex VII and listed in Annex II to Directive 76/768/EEC.
- (4) Regarding Diethylamino hydroxybenzoyl hexyl benzoate, the SCCP concluded in its opinion of 15 April 2008 that the use of this substance at a maximum concentration of 10% in cosmetic products, including sunscreen products, does not pose a risk to the

¹ OJ L 262, 27.9.1976, p. 169. [no longer necessary]

consumer. In order to extend the scope of the allowed use of this substance column "c" of entry 28 should be amended in Annex VII.

- (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

Annexes II and VII to Directive 76/768/EEC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by **[Day, Month, Year = Six months after the entry into force of the Directive]** 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 the provisions set out in point 3 of the Annex to this Directive from **[Day, Month, Year = Six months after the entry into force of the Directive]**.

They shall apply the provisions set out in points 1 and 2 of the Annex to this Directive from **[Day, Month, Year = Nine months after the entry into force of the Directive]**.

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 3

This Directive shall enter into force on the twentieth 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, [...]

For the Commission
[...]

Member of the Commission

ANNEX

Directive 76/768/EEC is amended as follows:

- (1) In Annex II, entry 167 “Esters of 4-aminobenzoic acid, with the free amino group, with the exception of that given in Annex VII, Part 2” is replaced by “4-aminobenzoic acid and its esters, with the free amino group”.
- (2) In Annex VII, entry 1 is deleted.
- (3) In Annex VII, in entry 28 the words “in sunscreen products” are deleted from column “c”.