

DIRECTIVES

COMMISSION DIRECTIVE 2007/53/EC

of 29 August 2007

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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Article 2

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 products ⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Products,

Whereas:

- (1) Fluorine compounds are currently listed in and subject to restrictions and conditions laid down in Annex III, Part 1 of Directive 76/768/EEC. The Scientific Committee on Consumer Products (SCCP) is of the opinion that if the sole source of fluoride exposure is toothpaste containing fluoride between 1 000 to 1 500 ppm, there is a minimal concern that children under the age of six will develop fluorosis, provided that such toothpaste is used as recommended. Therefore, reference numbers 26 to 43, and reference numbers 47 and 56 of Annex III, Part 1 should be amended accordingly.
- (2) Directive 76/768/EEC should therefore be amended accordingly.
- (3) 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

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

1. Member States shall adopt and publish, by 19 April 2008 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 together with a correlation table of those provisions and this Directive.

They shall apply those provisions from 19 January 2009.

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 texts of the main provisions of domestic law which they adopt in the field governed by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 29 August 2007.

For the Commission
Günter VERHEUGEN
Vice-President

⁽¹⁾ OJ L 262, 27.9.1976, p. 169. Directive last amended by Commission Directive 2007/22/EC (OJ L 101, 18.4.2007, p. 11).

ANNEX

In reference numbers 26 to 43, and reference numbers 47 and 56 of Part 1 of Annex III to Directive 76/768/EEC, the following text is added after each entry in column f:

‘For any toothpaste containing 0,1 to 0,15 % fluoride unless it is already labelled as contra-indicated for children (e.g. “for adult use only”) the following labelling is obligatory:

“Children of 6 years and younger: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist or doctor.”’
