

Commission Directive 2009/129/EC of 9 October 2009 amending Council Directive 76/768/EEC concerning cosmetic products for the purposes of adapting Annex III thereto to technical progress (Text with EEA relevance)

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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,

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) The compounds containing fluorine are currently regulated under reference numbers 26 to 43, and reference numbers 47 and 56 in Part 1 of Annex III to Directive 76/768/EEC. Their maximum authorised concentration in toothpastes refers to the content of elemental fluorine (0,15 % calculated as F, i.e. 1 500 ppm).
- (2) The Scientific Committee on Consumer Products replaced by the Scientific Committee on Consumer Safety (hereinafter 'SCCS')⁽²⁾ stated in its opinion SCCP/0882/08 that the maximum permitted concentration of 0,15 % (1 500 F ppm) fluoride does not pose a safety concern when used by children under the age of six years, based on the available scientific evidence. The data used were generated from studies primarily on sodium fluoride.
- (3) Based on the scientific conclusions of the SCCS, 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⁽³⁾ introduced for the regulated compounds containing fluorine a requirement for warning which must be printed on the label of toothpastes containing fluoride. This requirement refers to the content of fluoride instead of elemental fluorine. As a result, not all fluorine containing compounds listed in Part 1 of Annex III to Directive 76/768/EEC were covered by the introduced labelling requirement.
- (4) Upon request of the Commission, the SCCS clarified that in opinions SCCNFP/0653/03 and SCCP/0882/05, it was pointed out that an extrapolation to other compounds containing fluorine listed in Part 1 of Annex III to Directive 76/768/EEC could only be made with respect to fluorosis. However, for the purpose of the reference to compounds containing fluorine in Part 1 of Annex III to Directive 76/768/EEC, introduced by

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Directive 2007/53/EC, the SCCS considered that the terms ‘fluorine’ and ‘fluoride’ were equivalent and interchangeable.

- (5) To ensure legal certainty, it is necessary to clarify that the labelling requirement refers to all 20 compounds containing fluorine listed in Part 1 of Annex III to Directive 76/768/EEC, and not only to those containing fluoride.
- (6) Therefore, the condition for labelling which must be printed on the label of toothpastes containing fluorine compounds listed in Part 1 of Annex III to Directive 76/768/EEC should refer to the content of fluorine instead of fluoride. Directive 76/768/EEC should therefore be amended accordingly.
- (7) In view of a smooth transition, Member States should not prohibit the marketing of products complying with this Directive before its date of application.
- (8) 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 to Directive 76/768/EEC is amended in accordance with the Annex to this Directive.

Article 2

1 Member States shall adopt and publish, by 15 April 2010 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.

They shall apply those provisions from 15 October 2010.

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

Member States shall not prohibit the marketing of toothpaste labelled in accordance with the provisions transposing this Directive before the date set out in the second subparagraph of Article 2(1).

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 9 October 2009.

For the Commission

Günter VERHEUGEN

Vice-President

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ANNEX

In column 'f' corresponding to reference numbers 26 to 43, 47 and 56 of Part 1 of Annex III to Directive 76/768/EEC, the text after the first sentence is replaced by the following sentences:

For any toothpaste with compounds containing fluorine in a concentration of 0,1 to 0,15 % calculated as F 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 minimise swallowing. In case of intake of fluoride from other sources consult a dentist or doctor".

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- (1) [OJ L 262, 27.9.1976, p. 169.](#)
- (2) The name of the committee was changed by Commission Decision 2008/721/EC ([OJ L 241, 10.9.2008, p. 21](#)).
- (3) [OJ L 226, 30.8.2007, p. 19.](#)