EUROPEAN COMMISSION

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2011/0164 (NLE)

Proposal for a

COUNCIL DIRECTIVE

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

The attached proposal for a Council Directive concerns the use of hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide, in tooth whitening or bleaching products, in the framework of the Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products. It aims at implementing within Directive 76/768/EEC an opinion of the Scientific Committee on Consumer Safety of 2007.

Indeed, in December 2007, the Scientific Committee on Consumer Products, which has been replaced by the Scientific Committee on Consumer Safety (hereinafter SCCS) pursuant to Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, delivered an opinion on hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products.

A draft Commission Directive aiming to implement within Directive 76/768/EEC the above-mentioned scientific opinion was submitted to the Standing Committee on Cosmetic Products on 6 May 2010 for vote by written procedure. The Committee did not deliver an opinion within the time-limit laid down by its Chairman: 16 Member States expressly voted in favour and 6 Member States were considered to have given tacitly their agreement, as they did not express opposition or intention to abstain within the timeline set in the written procedure (243 votes in favour) and 5 Member States voted against (102 votes against).

Consequently, pursuant to Article 8(2) read in conjunction with Article 10 of Directive 76/768/EEC and in accordance with Article 5 of Council Decision 1999/468/EC modified by Council Decision 2006/512/EC, the Commission is required to submit to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by qualified majority, and to inform the European Parliament.

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(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

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,

Having regard to the proposal from the European Commission,

Whereas:

(1) The use of hydrogen peroxide is already subject to restrictions and conditions laid down in Annex III, Part 1 to Directive 76/768/EEC.

(2) The Scientific Committee on Consumer Products, which has been replaced by the Scientific Committee on Consumer Safety (hereinafter SCCS) pursuant to Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC[2], has confirmed that a maximum concentration of 0.1% of hydrogen peroxide present in oral products or released from other compounds or mixtures in those products is safe. It should therefore be possible to continue to use hydrogen peroxide in that concentration in oral products, including tooth whitening or bleaching products.

(3) The SCCS considers that the use of tooth whitening or bleaching products containing more than 0.1% and up to 6% of hydrogen peroxide present or released from other compounds or mixtures in these products may be safe if the following conditions are satisfied. An appropriate clinical examination is necessary to ensure the absence of risk factors or other oral pathology of concern and the exposure to these products should be limited in a manner that ensures that the products are used only as intended in terms of frequency and duration of application. These conditions should be fulfilled in order to avoid reasonably foreseeable misuse.

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1 OJ L 262, 27.9.1976, p. 169.
2 OJ L 241, 10.9.2008, p. 21.

(4) Therefore, those products should be regulated in a way that ensures that they are not directly available to the consumer. For each cycle of use of those products, the first use should be limited to dental practitioners as defined under Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications[3] or under their direct supervision if an equivalent level of safety is ensured. Dental practitioners should then provide access to those products for the rest of the cycle of use.

(5) An appropriate labelling regarding the concentration in hydrogen peroxide of the tooth whitening or bleaching products containing more than 0.1% of this substance should be provided for in order to ensure the appropriate use of these products. For this purpose, the exact concentration in percentage of hydrogen peroxide present or released from other compounds and mixtures in those products should be clearly indicated on the label.

(6) Directive 76/768/EEC should therefore be amended accordingly.

(7) The Standing Committee on Cosmetic Products has not delivered an opinion within the time-limit laid down by its Chairman,

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

Transposition

1. Member States shall adopt and publish, by [Day, Month, Year = 12 months after the publication of the Directive[4]] 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 [Day, Month, Year = 12 months + 1 day after the publication of the Directive[5]].

   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.

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3 OJ L 255, 30.9.2005, p.22.
4 Date to be included.
5 Date to be included.

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 Council
The President

ANNEX

In Part 1 of Annex III to Directive 76/768/EEC, reference number 12 is replaced by the following:

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	
"12	Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair care mixtures	(a) 12 % of H_2O_2 (40 volumes), present or released		(a) wear suitable gloves (a) (b) (c) (e) Contains hydrogen peroxide Avoid contact with eyes Rinse immediately if product comes into contact with them.
		b) Skin care mixtures	(b) 4% of H_2O_2, present or released		
		(c) Nail hardening mixtures	(c) 2% of H_2O_2, present or released		
		(d) Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products	(d) ≤ 0.1% of H_2O_2, present or released		
		(e) tooth whitening or bleaching products	(e) >0.1% ≤ 6% of H_2O_2, present or released	(e) To be only sold to dental practitioners. For each cycle of use,	(e) Concentration of H_2O_2 present or released indicated in percentage. Not to be used on a

				1st use by dental practitioners as defined under Directive 2005/36/EC * or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use. Not to be used on a person under 18 years of age	person under 18 years of age To be only sold to dental practitioners. For each cycle of use, the first use to be only done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use.

* OJ L 255, 30.9.2005, p. 22 “