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EUROPEAN COMMISSION

Brussels,
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Draft

COMMISSION DIRECTIVE ../.../EU

of [...]

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

(Text with EEA relevance)

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COMMISSION DIRECTIVE/EU

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

After consulting the Scientific Committee on Consumer Safety,

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- (2) The Scientific Committee on Consumer Products, which has been replaced by the Scientific Committee on Consumer Safety (hereinafter SCCS) pursuant to Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of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/EC², 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.

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 such 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 qualifications³ or under their direct supervision if an equivalent level of safety is ensured. Dental practitioners should then decide to use the product on consumers for the first time and should only provide access to those products for the rest of the cycle of use.
- (5) The SCCS considers that concentration levels above 6% of hydrogen peroxide present in tooth whitening or bleaching products or released from other compounds or mixtures in these products are not safe in products used by the consumer. Therefore these products should be regulated in a way that ensures that they are not directly available to the consumer. In order to ensure their safe use, these products should only be used by dental practitioners as defined under Directive 2005/36/EC or under their direct supervision if an equivalent level of safety is ensured.
- (6) 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.
- (7) Directive 76/768/EEC should therefore be amended accordingly.
- (8) In part 1 of Annex III, reference number 12 on the regulation of hydrogen peroxide present or released from other compounds or mixtures in tooth whitening or bleaching products should be reconsidered in four years at the latest in the light of new scientific data available.
- (9) 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 [Day, Month, Year = 12 months after the publication of the Directive⁴] at the latest, the laws, regulations and administrative

³ OJ L 255, 30.9.2005, p.22.

⁴ Date to be included.

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 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 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

[...]

The President

⁵ Date to be included.

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	<p>(a) Hair care preparations</p> <p>(b) Skin care preparations</p> <p>(c) Nail hardening preparations</p> <p>(d) Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products</p>	<p>(a) 12 % of H₂O₂ (40 volumes), present or released</p> <p>(b) 4% of H₂O₂, present or released</p> <p>(c) 2% of H₂O₂, present or released</p> <p>(d) 0.1% of H₂O₂, present or released</p>		<p>(a) wear suitable gloves</p> <p>(a) (b) (c) (e) Contains hydrogen peroxide</p> <p>Avoid contact with eyes</p> <p>Rinse immediately if product comes into contact with them.</p>

⁶ OJ L 255, 30.9.2005, p. 22.

		(e) tooth whitening or bleaching products	(e) 1. >0.1% - ≤ 6% of H ₂ O ₂ present or released 2. >6% of H ₂ O ₂ present or released	(e) 1. To be only sold to dental practitioners. For each cycle of use, 1 st use by dental practitioners as defined under Directive 2005/36/EC ⁶ or under their direct supervision if an equivalent level of safety is ensured. Not to be used on a person under 18 years of age 2. To be only sold to dental practitioners. To be only used by dental practitioners as defined under Directive 2005/36/EC or under their direct supervision if an equivalent level of safety is ensured. Not to be used on a	(e) 1. Concentration of H ₂ O ₂ present or released indicated in percentage. Not to be used on a 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. 2. Concentration of H ₂ O ₂ present or released indicated in percentage. Not to be used on a person under 18 years of age To be only sold to dental practitioners. To be only used by dental practitioners or under their direct supervision if an equivalent level of safety is ensured.”
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				person under 18 years of age	
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