

EN

EN

EN

Draft

COMMISSION DIRECTIVE/EC

of [...]

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

(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 Safety,

Whereas:

- (1) According to the safety assessment strategy for hair dye substances, it was agreed with the Member States and stakeholders that the date of 31 December 2007 would be appropriate for the submission to the Scientific Committee on Consumer Safety (hereinafter “SCCS”) of the scientific data on the reaction products formed by oxidative hair dye substances on the scalp and their safety for the consumer.
- (2) Presently, there are 29 oxidative and 2 non-oxidative hair dye substances which are provisionally allowed for use in cosmetic products until 31 December 2009 under the restrictions and conditions laid down in Part 2 of Annex III to Directive 76/768/EEC. The requested scientific data on the safety of reaction products formed by oxidative hair dye substances were submitted by the cosmetics industry to the SCCS before the agreed deadline of 31 December 2007.
- (3) The submitted safety data were evaluated by the SCCS. In January 2009, the SCCS concluded in its opinion that it is not in the position to finally assess the risk of reactions products of oxidative hair dyes due to the incompleteness of the dossier submitted by the industry. The cosmetics industry responded to this opinion that it envisages to provide the missing data by September 2009 at the latest.
- (4) In view of the above, the risk assessment of the submitted additional data and the final opinion given by the SCCS on the safety of the reaction products will still require a

¹ OJ L 262, 27.9.1976, p. 169.

period of time exceeding the provisional deadline of 31 December 2009 for the substances listed in Part 2 of Annex III.

- (5) Therefore, the definitive regulation of 29 oxidative hair dye substances listed in Part 2 of Annex III, on the basis of risk assessment of their reaction products, and its implementation into the laws of Member States will not take place before the provisional deadline. Consequently, their provisional use in cosmetic products under the current restrictions and conditions laid down in Part 2 of Annex III should be extended. The new prolonged deadline of 31 December 2010 is considered sufficient for the definitive regulation of these substances in Part 1 of Annex III.
- (6) For non-oxidative hair dye substances HC Orange No. 2 and 2-hydroxyethylamino-5-nitroanisole, listed under reference numbers 26 and 29 in Part 2 of Annex III, the SCCS gave its final opinions on their safety. The SCCS recommended maximum authorized concentrations in the finished cosmetic product of 1,0% for HC Orange No. 2 and of 0,2% for 2-hydroxyethylamino-5-nitroanisole. Therefore, these two hair dye substances can be definitively regulated in Part 1 of Annex III.
- (7) Directive 76/768/EEC should therefore be amended accordingly.
- (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 31 December 2009 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 the provisions set out in point 1 of the Annex to this Directive from 1 January 2010.

They shall apply the provisions set out in points 2 and 3 of the Annex from **[insert concrete date = 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 Part 2 of Annex III in column “g” of the entries relating to reference numbers 3, 4, 5, 6, 10, 11, 12, 16, 19, 20, 21, 22, 25, 26, 27, 29, 31, 32, 33, 34, 35, 36, 37, 38, 39, 44, 48, 49, 50, 55, and 56 the date ‘31.12.2009’ is replaced by ‘31.12.2010’.
2. In Part 1 of Annex III the following entries are added:

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
“[X] ² ”	<p>1-(beta-Aminoethyl)amino-4-(beta-hydroxyethyl)oxy-2-nitrobenzene and its salts</p> <p>HC Orange No. 2</p> <p>CAS No 85765-48-6</p> <p>EINECS 416-410-1</p>	Hair dye substance in non-oxidative hair dye products	1,0 %	<p>- Do not use with nitrosating systems</p> <p>- Maximum nitrosamine content: 50µg/kg</p> <p>- Keep in nitrite-free containers</p>	 <p>Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy. Do not colour your hair if:</p> <ul style="list-style-type: none"> - You have a rash on your face or sensitive, irritated and damaged scalp. - You have ever experienced any reaction after colouring your hair. - You have experienced a reaction to a temporary “black henna” tattoo in the past.
[Y] ³	<p>2-[(2-Methoxy-4-nitrophenyl)amino]ethanol and its salts</p> <p>2-Hydroxyethylamino-5-nitroanisole</p> <p>CAS No 66095-81-6</p> <p>EINECS 266-138-0</p>	Hair dye substance in non-oxidative hair dye products	0,2%	<p>- Do not use with nitrosating systems</p> <p>- Maximum nitrosamine content: 50µg/kg</p> <p>- Keep in nitrite-free containers</p>	 <p>Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy. Do not colour your hair if:</p> <ul style="list-style-type: none"> - You have a rash on your face or sensitive, irritated and damaged scalp. - You have ever experienced any reaction after colouring your hair. - You have experienced a reaction to a temporary “black henna” tattoo in the past.”

² The relevant reference number will be introduced at the time of the publication.

³ The relevant reference number will be introduced at the time of the publication.

3. In Part 2 of Annex III the entries relating to reference numbers 26 and 29 are deleted.