



Brussels, **XXX**
[...] (2016) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

**amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and
of the Council on cosmetic products**

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products¹, and in particular Article 31(1) thereof,

Whereas:

- (1) Following the publication of a scientific study in 2001, entitled “Use of permanent hair dyes and bladder cancer risk”, the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, subsequently replaced by the Scientific Committee on Consumer Products (SCCP) pursuant to Commission Decision 2004/210/EC², concluded that the potential risks of the use of hair dyes were of concern. The SCCP, in its opinions, recommended that the Commission take further steps to control the use of hair dye substances.
- (2) The SCCP further recommended an overall safety assessment strategy for hair dye substances including the requirements for testing substances used in hair dye products for their potential genotoxicity or carcinogenicity.
- (3) Following the opinions of the SCCP, the Commission agreed with Member States and stakeholders on an overall strategy to regulate substances used in hair dye products according to which the industry was required to submit files, containing updated scientific data on the safety of hair dye substances, for a risk assessment by the SCCP.
- (4) The SCCP, subsequently replaced by the Scientific Committee on Consumer Safety (SCCS) pursuant to Commission Decision 2008/721/EC³, assessed the safety of individual hair dye substances for which updated files had been submitted by the industry.
- (5) As regards the evaluation of possible consumer health risks by reaction products formed by oxidative hair dye substances during the hair dyeing process, based on the data yet available, the SCCS, in its opinion of 21 September 2010, did not raise any

¹ OJ L 342, 22.12.2009, p. 59.

² Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment (OJ L 66, 4.3.2004, p. 45).

³ 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 (OJ L 241, 10.9.2008, p. 21).

major concern regarding genotoxicity and carcinogenicity of hair dyes and their reaction products currently used in the Union.

- (6) In order to ensure the safety of hair dye products for human health, it is appropriate to set up maximum concentrations of ten assessed hair dye substances and to list them in Annex III to Regulation (EC) No 1223/2009, by taking into account the final opinions given by the SCCS on their safety.
- (7) Since substances N,N'-bis-(2-hydroxyethyl)-2-nitro-p-phenylenediamine and 2,6-Dihydroxyethylaminotoluene are currently regulated under generic entries 8 and 9 of Annex III to Regulation (EC) No 1223/2009, separate reference numbers should be created for these substances, taking into account conclusions of the SCCS on their safety.
- (8) The definition of a hair product in Regulation (EC) No 1223/2009 excluded the application of hair dye substances on eyelashes. That exclusion was motivated by the fact that the level of risk is different when cosmetic products are applied on the hair on the head and on eyelashes. A specific safety assessment was therefore needed for the application of hair dye substances on eyelashes.
- (9) The SCCS, in its opinion on oxidative hair dye substances and hydrogen peroxide used in products to colour eyelashes of 25 March 2015, concluded that oxidative hair dye substances Toluene-2,5-diamine, p-Aminophenol, 2-Methylresorcinol, Tetraaminopyrimidine Sulfate, Hydroxyethyl-p-Phenylenediamine Sulfate and 2-Amino-3-Hydroxypyridine, listed in Annex III to Regulation (EC) No 1223/2009 and found safe for use in hair dye products, can be safely used by professionals in products intended for colouring eyelashes.
- (10) On the basis of the scientific assessment of those substances, their use should be allowed in products intended for colouring eyelashes. However, in order to avoid any risk connected with the self-application of products intended for colouring eyelashes by consumers, they should be allowed for professional use only. In order to allow professionals to inform consumers about possible adverse effects of the application of products intended for colouring eyelashes and to lower the risk of skin sensitisation to those products, appropriate warnings should be printed on their labels.
- (11) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (12) The application of the new requirements should be deferred to allow the industry to make the necessary adjustments to product formulations and labelling. In particular, undertakings should be granted twelve months from the entry into force of this Regulation to take the necessary measures to place on the market only products that comply with the new maximum concentrations and labelling requirements and to withdraw from the market the products that do not comply with those requirements.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [date = 12 months after the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission
The President
Jean-Claude Juncker*