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COVER NOTE

From: Secretary-General of the European Commission,
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 15 July 2020

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
the European Union

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Subject: COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and
III to Regulation (EC) No 1223/2009 of the European Parliament and of the
Council on cosmetic products

Delegations will find attached document [...] (2020) XXX draft - D067529/01.

Encl.: [...] (2020) XXX draft - D067529/01



Brussels, **XXX**
[...](2020) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

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

(Text with EEA relevance)

Commission Regulation (EU) .../... of XXX amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard 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 health risks of the use of hair dyes were of concern.
- (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) Having succeeded the SCCP pursuant to Commission Decision 2008/721/EC³, the Scientific Committee on Consumer Safety (SCCS) assessed the safety of individual hair dye substances for which updated files had been submitted by the industry.
- (5) As a result of the assessment by the SCCS, in order to ensure the safety of hair dye products for human health it is necessary to prohibit the use of three hair dye substances, 1,2,4-Trihydroxybenzene⁴, 2-[(4-Amino-2-nitrophenyl)-amino]-benzoic acid⁵ and 4-Amino-3-hydroxytoluene⁶, based on the final opinions given by the SCCS on their safety. In addition, in light of the final opinions by the SCCS on other six hair dye substances, Dimethylpiperazinium Aminopyrazolopyridine HCl⁷, Methylimidazoliumpropyl p-phenylenediamine HCl⁸, HC Orange No. 6⁹, Acid Orange

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 September 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).

⁴ SCCS/1598/18

⁵ SCCS/1497/12

⁶ SCCS/1400/11

⁷ SCCS/1584/17

⁸ SCCS/1609/19

7¹⁰, Tetrabromophenol Blue¹¹ and *Indigofera Tinctoria*¹², it is appropriate to limit their maximum concentrations for use in hair dye products.

- (6) The definition of a hair product laid down in point (1)(c) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009 excludes the application of hair dye substances on eyelashes, based on a different level of risk of applying a cosmetic product on the hair on the head as compared to applying the same product on eyelashes. A specific safety assessment was therefore needed for the application of hair dye substances on eyelashes.
- (7) The substance 2-Methoxymethyl-p-Phenylenediamine and its sulfate are listed under entry 292 in Annex III to Regulation (EC) No 1223/2009. Taking into account the conclusions of the latest SCCS opinion¹³ on the use of those substances on eyelashes, the field of application of the restriction to which they are subject should be extended to products intended for colouring eyelashes.
- (8) In order to avoid any risk related to self-application by consumers of products intended for colouring eyelashes that contain 2-Methoxymethyl-p-Phenylenediamine and its sulfate, those products should be allowed for professional use only.
- (9) In order to inform consumers and professionals about possible adverse effects of the use of hair dyes and products intended for colouring eyelashes with the aim to lower the risk of skin sensitisation to those products, appropriate warnings should be printed on their labels.
- (10) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (11) It is appropriate to provide for reasonable periods of time in order for the industry to adapt to the new requirements and to phase out cosmetic products which do not comply with those requirements.
- (12) 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

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*.

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

⁹ SCCS/1579/16
¹⁰ SCCS/1536/14
¹¹ SCCS/1610/19
¹² SCCS/1615/20
¹³ SCCS/1603/18

Done at Brussels,

*For the Commission
The President
Ursula von der Leyen*