

Commission Implementing Directive 2012/21/EU of 2 August 2012 amending, for the purpose of adaptation to technical progress, Annexes II and III to Council Directive 76/768/EEC relating to cosmetic products (Text with EEA relevance)

COMMISSION IMPLEMENTING DIRECTIVE 2012/21/EU
of 2 August 2012

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(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 products⁽¹⁾, and in particular Article 8(2) thereof,

After consulting the Scientific Committee on Consumer Safety,

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/EC⁽²⁾, concluded that the potential risks were of concern. The SCCP 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 mutagenicity.
- (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/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⁽³⁾, assessed the safety of individual substances for which updated files had been submitted by industry.
- (5) The last step of the safety assessment strategy was to evaluate possible consumer health risk by reaction products formed by oxidative hair dye substances during the hair dyeing

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process. Based on the data yet available, the SCCS raised in its opinion of 21 September 2010 no major concern regarding genotoxicity and carcinogenicity of hair dyes and their reaction products currently used in the EU.

- (6) In the light of the risk assessment of the submitted safety data and the final opinions given by the SCCS on the safety of individual substances and of the reaction products, it is appropriate to include in Part 1 of Annex III to Directive 76/768/EEC 24 assessed hair dyes which are not regulated within Directive 76/768/EEC.
- (7) The substances Hydroxyethyl-2-Nitro-p-Toluidine and HC Red No 10 + HC Red No 11 were provisionally authorised for use in hair dye products until 31 December 2011 under the restrictions and conditions laid down in entries 10 and 50 in Part 2 of Annex III to Directive 76/768/EEC. Based on the final opinions given by the SCCS on their safety, Hydroxyethyl-2-Nitro-p-Toluidine and HC Red No 10 + HC Red No 11 can be considered safe in hair dye products and listed in Part 1 of Annex III to Directive 76/768/EEC.
- (8) Following the assessment by the SCCS concerning the substances 1-Naphthol and Resorcinol, listed in Part 1 of Annex III to Directive 76/768/EEC, their maximum authorised concentrations in the finished cosmetic product should be changed.
- (9) Concerning the substance HC Red No 16, the SCCS stated in its opinion of 14 December 2010 that based on the low margin of safety for the use in both oxidative and non-oxidative hair dye formulations, HC Red No 16 poses a risk to the health of the consumer. Therefore, HC Red No 16 should be listed in Annex II to Directive 76/768/EEC.
- (10) Directive 76/768/EEC should therefore be amended accordingly.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS DIRECTIVE:

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- (1) [OJ L 262, 27.9.1976, p. 169.](#)
- (2) [OJ L 66, 4.3.2004, p. 45.](#)
- (3) [OJ L 241, 10.9.2008, p. 21.](#)