

Commission Directive 2009/159/EU of 16 December 2009 amending, for the purpose of adaptation to technical progress, Annex III to Council Directive 76/768/EEC concerning cosmetic products (Text with EEA relevance)

COMMISSION DIRECTIVE 2009/159/EU

of 16 December 2009

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on European Union and 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<sup>(1)</sup>, 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 31 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 reaction products of oxidative hair dyes due to the incompleteness of the dossier submitted by the industry. The cosmetics industry provided the missing data by the end of September 2009.
- (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 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 31 hair dye substances listed in Part 2 of Annex III, on the basis of risk assessment of their reaction products, and its implementation

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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.

- (6) Directive 76/768/EEC should therefore be amended accordingly.
- (7) 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.](#)