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Delegations will find attached document D041818/04.

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EUROPEAN  
COMMISSION

Brussels, **XXX**  
[...](2015) **XXX** draft

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

**of **XXX****

**amending Annex IV 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 Annex IV 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 to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products<sup>1</sup>, and in particular Article 31 (2) thereof,

Whereas:

- (1) Carbon Black is authorized as a colorant in cosmetics under entry 126 of Annex IV to Regulation (EC) No 1223/2009. The Scientific Committee on Consumer Safety ("SCCS") carried out a risk assessment of Carbon Black (nano) and adopted an opinion on 12 December 2013<sup>2</sup>, in which it concluded that the use of Carbon Black in its nano-structured form (with a primary particle size of 20 nm or larger) at a concentration up to 10 % w/w as a colorant in cosmetic products does not pose any risk of adverse effects in humans after application on healthy, intact skin.
- (2) Moreover, the SCCS indicated, in a further opinion of 23 September 2014 for clarification of the meaning of the term "sprayable applications/products" for the nano forms of Carbon Black CI 77266, Titanium Dioxide and Zinc Oxide<sup>3</sup>, that the opinion on Carbon Black (nano) does not apply to applications that might lead to exposure of the consumer's lungs to Carbon Black nanoparticles by inhalation.
- (3) The SCCS conclusions apply to Carbon Black (nano) with a defined purity and impurity profile. Furthermore, the purity criteria set out for non-nano Carbon Black are no longer up-to-date and should be removed, as Commission Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs<sup>4</sup> was repealed by Commission Directive 2008/128/EC laying down specific purity criteria

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<sup>1</sup> OJ L 342, 22.12.2009, p. 59.

<sup>2</sup> SCCS/1515/13 Revision of 15 December 2015, [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_144.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_144.pdf).

<sup>3</sup> SCCS/1539/14 Revision of 25 June 2015, [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_163.pdf](http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_163.pdf).

<sup>4</sup> OJ L 226, 22.9.1995, p. 1.

concerning colours for use in foodstuffs<sup>5</sup>. Those criteria should be replaced by the criteria applicable to Carbon Black (nano).

- (4) In light of the SCCS opinions mentioned above, the Commission considers that Carbon Black (nano) (according to the SCCS's specifications) should be authorized for use as a colorant in cosmetic products at a maximum concentration of 10 % w/w, except in applications that may lead to exposure of the end user's lungs by inhalation.
- (5) The Commission considers that Annex IV to Regulation (EC) No 1223/2009 should be amended for the purpose of adapting it to technical and scientific progress.
- (6) 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 IV 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*.

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*

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<sup>5</sup>

OJ L 6, 10.1.2009, p. 20.