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Subject: 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

Delegations will find attached document D049872/01.

Encl.: D049872/01



Brussels, **XXX**
[...](2017) **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 products¹, and in particular Article 31(1) thereof,

Whereas:

- (1) Zinc oxide is authorised as a colorant in cosmetic products under entry 144 of Annex IV to Regulation (EC) No 1223/2009.
- (2) In its opinion of 18 September 2012², which was revised in 23 September 2014³, the Scientific Committee on Consumer Safety (SCCS) concluded that the use of zinc oxide is safe when used as colorant, in its uncoated non-nano form, in cosmetics for dermal application. However, the SCCS also considered that in view of the lung inflammation induced by zinc oxide particles after inhalation, the use of zinc oxide in cosmetic products that may result in exposure of the consumer's lungs to zinc oxide by inhalation was of concern.
- (3) In light of the SCCS opinions, the use of zinc oxide as a colorant, in its uncoated non-nano form, in cosmetic products should be restricted to those applications which may not lead to exposure of the end-user's lungs by inhalation.
- (4) Annex IV to Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (5) The industry should be allowed a reasonable period of time to make the necessary adjustments to product formulations in view of their placing on the market and for the withdrawal of non-compliant products from the market.

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS/1489/12 Revision of 11 December 2012,
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_103.pdf

³ SCCS/1539/14 Revision of 25 June 2015,
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_163.pdf

- (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

From (please insert date – six months after entry into force of this Regulation) only cosmetic products which comply with this Regulation shall be placed on the Union market.

From (please insert date – nine months after entry into force of this Regulation) only cosmetic products which comply with this Regulation shall be made available on the Union market.

Article 3

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*