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

Delegations will find attached document D043810/02.

Encl.: D043810/02



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

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

of **XXX**

**amending Annex VI 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 VI 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(2) thereof,

Whereas:

- (1) Titanium dioxide is authorized both as a colorant under entry 143 of Annex IV to Regulation (EC) No 1223/2009 and as a UV-filter under entry 27 of Annex VI to that Regulation. In accordance with point (3) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009, the substances listed in Annexes III to VI to that Regulation do not cover nanomaterials, except where specifically mentioned. Titanium dioxide (nano) is currently not regulated.
- (2) According to the opinion of the Scientific Committee on Consumer Safety ("SCCS") of 22 July 2013, which was revised on 22 April 2014², the use of titanium dioxide (nano) as a UV-filter in sunscreens, with the characteristics as indicated in the opinion, and at a concentration up to 25 % w/w, can be considered to not pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin. In addition, considering the absence of a systemic exposure, the SCCS considers that the use of titanium dioxide (nano) in dermally applied cosmetic products should not pose any significant risk to the consumer.
- (3) The characteristics indicated by the SCCS in its opinion concern the physico-chemical properties of the material (such as purity, structure and physical appearance, particle number size distribution, aspect ratio, volume specific surface area and photocatalytic activity) and whether it is uncoated or coated with specific chemicals. Therefore, these physico-chemical properties and requirements regarding coatings should be reflected in Regulation (EC) No 1223/2009.

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS/1516/13 Revision of 22 April 2014, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf.

- (4) The SCCS also considered that, on the basis of available information, the use of titanium dioxide (nano) in spray products cannot be considered safe. In addition, 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 oxide³, that its concern is limited to spray applications that might lead to exposure of the consumer's lungs to titanium dioxide (nano) by inhalation.
- (5) In light of the SCCS opinions mentioned above, titanium dioxide (nano), according to the SCCS's specifications, should be authorized for use as a UV-filter in cosmetic products at a maximum concentration of 25 % w/w, except in applications that may lead to exposure of the end user's lungs by inhalation.
- (6) Annex VI to Regulation (EC) No 1223/2009 should be amended for the purpose of adapting it to technical and scientific progress.
- (7) 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 VI 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

³ SCCS/1539/14 23 September 2014 Revision of 25 June 2015
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_163.pdf.