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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 4 March 2021

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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

Delegations will find attached document [...] (2021) XXX draft - D071732/01.

Encl.: [...] (2021) XXX draft - D071732/01



Brussels, **XXX**
[...](2021) **XXX** draft

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

of **XXX**

**amending Annexes II and III 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 Annexes II and III 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) The substance 4-[(tetrahydro-2H-pyran-2-yl)oxy]phenol (common name: deoxyarbutin, INCI name: Tetrahydropyranloxy Phenol), currently not regulated in Regulation (EC) No 1223/2009, results in the release of 1,4-Dihydroxybenzene (INCI name: Hydroquinone). Hydroquinone is included among the substances prohibited for use in cosmetic products, listed under entry 1339 of Annex II to Regulation (EC) No 1223/2009, with the exception of entry 14 of Annex III to that Regulation.
- (2) The use of deoxyarbutin in cosmetic products was assessed by the Scientific Committee on Consumer Safety (SCCS). In its opinion adopted on 25 June 2015², the SCCS concluded that due to safety concerns raised with regard to the life-cycle of products containing that substance, the use of deoxyarbutin up to 3% in face creams cannot be considered as safe³.
- (3) Based on that opinion, deoxyarbutin should be prohibited for use in cosmetic products and added to the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009.
- (4) The substance 1,3-Dihydroxy-2-propanone (INCI name: Dihydroxyacetone) is a cosmetic ingredient with the reported functions of skin conditioning and tanning. Dihydroxyacetone is currently not regulated under Regulation (EC) No 1223/2009.
- (5) In its opinion adopted on 3-4 March 2020⁴, the SCCS considered Dihydroxyacetone safe when used as a hair colouring ingredient in leave-on applications (non-oxidative) up to a maximum concentration of 6.25%. Furthermore, the SCCS concluded in that opinion that the use of Dihydroxyacetone as a hair colouring ingredient in leave-on applications (non-oxidative) up to a maximum concentration of 6.25% together with the use of self-tanning lotion and face cream containing up to a maximum concentration of 10% Dihydroxyacetone is also considered safe.
- (6) Based on those conclusions, it is necessary to add a new entry in Annex III to Regulation (EC) No 1223/2009 that will allow for a restricted use of

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS (Scientific Committee on Consumer Safety), Opinion on deoxyarbutin - Tetrahydropyranloxy Phenol, 25 June 2015, SCCS/1554/15.

³ See point 4 of the opinion.

⁴ SCCS (Scientific Committee on Consumer Safety), Opinion on Dihydroxyacetone - DHA, 3-4 March 2020, SCCS/1612/19.

Dihydroxyacetone in non-oxidative hair dye products and in self-tanning products only, in a maximum concentration of up to 6.25% and 10% respectively.

- (7) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (8) It is appropriate to provide for reasonable periods of time in order for the industry to adapt to the new requirements on the use of Dihydroxyacetone in cosmetic products and to phase out the placing and making available on the market of cosmetic products which do not comply with those requirements.
- (9) 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

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
Ursula von der Leyen