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Delegations will find attached document D049972/02.

Encl.: D049972/02



Brussels, **XXX**
[...](2017) **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 Scientific Committee on Consumer Safety (SCCS) concluded in its opinion of 26–27 June 2012² that 3- and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde (HICC), with the INCI name of Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, 2,6-Dihydroxy-4-methyl-benzaldehyde (atranol) and 3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde (chloroatranol) should not be used in cosmetic products as they are the fragrance allergens which caused the highest number of contact allergies cases in past years.
- (2) Consequently, there is a potential risk to human health and those substances should therefore be prohibited in cosmetic products.
- (3) HICC is regulated in entry 79 of Annex III to Regulation (EC) No 1223/2009, where it is provided that its presence must be indicated in the list of ingredients referred to in Article 19(1)(g) of that Regulation when its concentration exceeds 0,001 % in leave-on products and 0,01 % in rinse-off products. Since HICC should be prohibited in cosmetic products, it is necessary to delete that entry.
- (4) The SCCS indicated in its opinion of 26-27 June 2012 that atranol and chloroatranol are natural components of oak tree moss (*Evernia prunastri*) and treemoss (*Evernia furfuracea*) extracts regulated in entry 91 and 92, respectively, of Annex III to Regulation (EC) No 1223/2009.

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS/1459/11.

- (5) It is appropriate to provide for reasonable periods of time in order for the industry to adapt to the new prohibitions and for this reason no longer place or make available on the market products concerned which contain one or more of the prohibited substances. When determining those periods of time, due account should also be taken of the potential risk of those products to human health. The restriction for HICC set out in entry 79 of Annex III to Regulation (EC) No 1223/2009 should continue to apply until the making available of products containing that substance is no longer allowed. The deletion of that entry should therefore be deferred.
- (6) In particular, the exceptionally complex and lengthy procedure for fragrance reformulation and consumers' concerns over the change of the olfactory properties of fragrances should be reflected in longer than usual duration of the deadline given to the industry for adjustments of products. Manifestations of contact allergies to fragrances are normally confined to skin. Consumers with contact allergy to fragrance allergens often are aware that they cannot tolerate scented products on their skin and therefore can avoid them.
- (7) Annex II and III to Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (8) 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 II and III to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

From [date = 2 years after the date of entry into force] cosmetic products containing one or more of the substances prohibited by this Regulation shall not be placed on the Union market.

From [date = 4 years after the date of entry into force] cosmetic products containing one or more of the substances prohibited by this Regulation shall be not 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*.

Point (2) of the Annex shall apply from [date = 4 years after the date of entry into force].

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