



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

COMMISSION REGULATION (EU) No .../..

of **XXX**

**amending Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of
the Council on cosmetic products**

(Text with EEA relevance)

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COMMISSION REGULATION (EU) .../..

of **XXX**

amending Annex II 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) 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 on the market and withdraw from 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.
- (4) 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.
- (5) Annex II to Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS/1459/11.

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1223/2009 is 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 withdrawn from 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



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ANNEX 1

ANNEX

to

COMMISSION REGULATION (EU) No .../..

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ANNEX

In Annex II to Regulation (EC) No 1223/2009, in the table, the following three entries are added:

Reference number	Substance identification		
	Chemical name / INN	CAS number	EC number
a	b	c	d
"1380	3- and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde (HICC)*	51414-25-6/ 31906-04-4/	257-187-9/ 250-863-4/
1381	2,6-Dihydroxy-4-methyl-benzaldehyde (atranol)**	526-37-4	-
1382	3-Chloro-2,6-Dyhydroxy-4-methyl-benzaldehyde (chloroatranol)***	57074-21-2	-

* From [date = 2 years after the date of entry into force]. From [date = 4 years after the date of entry into force] all cosmetic products containing that substance shall be withdrawn from the Union market.

** From [date = 2 years after the date of entry into force]. From [date = 4 years after the date of entry into force] all cosmetic products containing that substance shall be withdrawn from the Union market.

*** From [date = 2 years after the date of entry into force]. From [date = 4 years after the date of entry into force] all cosmetic products containing that substance shall be withdrawn from the Union market."