EUROPEAN
COMMISSION

Brussels, XXX
[…](2013) XXX draft

COMMISSION REGULATION (EU) No …/..

of XXX

amending Annex V 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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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 products[1], and in particular Article 31(1) thereof,

Whereas:

(1) Entry 25 of Annex V to Regulation (EC) No 1223/2009 specifies a maximum concentration of 0,3% in relation to the use of triclosan as a preservative in cosmetic products.

(2) The Scientific Committee on Consumer Products ("SCCP"), subsequently replaced by the Scientific Committee on Consumer Safety ("SCCS") pursuant to Commission Decision 2008/721/EC[2], adopted an opinion on the safety of triclosan for human health in January 2009[3], followed by an addendum of March 2011[4].

(3) The SCCP considered that the continued use of triclosan as a preservative at the current maximum concentration limit of 0,3% in all cosmetic products is not safe for the consumer because of the magnitude of the aggregate exposure, and the SCCS confirmed this position. However, the SCCP considered that its use at a maximum concentration of 0,3% in toothpastes, hand soaps, body soaps/shower gels and deodorant sticks, face powders and blemish concealers is safe. In addition, the SCCS considered that other uses of triclosan in nail products where the intended use is to clean the fingernails and toenails, with a maximum frequency of every two weeks, at a maximum concentration of 0,3 % and in mouthwashes at a maximum concentration of 0,2 % are safe for the consumer.

(4) In light of the SCCS opinions mentioned above, the Commission considers that maintaining the restriction on the use of triclosan at its current level would raise a potential risk to human health. The additional restrictions suggested by the SCCP and the SCCS should therefore be implemented in Annex V to Regulation (EC) No 1223/2009.

(5) Entry 12 of Annex V to Regulation (EC) No 1223/2009 specifies a maximum concentration of 0,4 % for single ester and 0,8 % for mixtures of esters in relation to

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1 OJ L 342, 22.12.2009, p. 59.

2 Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC (OJ L 241, 10.9.2008, p. 21).

3 SCCP/1192/08, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf.

4 SCCS/1414/11,http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_054.pdf.

the use of parabens as preservatives in cosmetic products, under the denomination 4-hydroxybenzoic acid and its salts and esters.

(6) The SCCS adopted an opinion on parabens in December 2010[5], followed by a clarification of October 2011[6] in response to a unilateral decision by Denmark to ban propylparaben and butylparaben, their isoforms and their salts in cosmetic products for children under three years of age based on their potential endocrine activity, taken in accordance with Article 12 of Council Directive 76/768/EEC[7].

(7) The SCCS confirmed that methylparaben and ethylparaben are safe at the maximum authorized concentrations. In addition, the SCCS noted that limited or no information was submitted by industry for the safety evaluation of isopropylparaben, isobutylparaben, phenylparaben, benzylparaben and pentylparaben. As a result, for these compounds, the human risk cannot be evaluated. Therefore, those substances should no longer be listed in Annex V and, given that their only function is that of preservatives, they should not be used in cosmetic products.

(8) The conclusions the SCCS drew in the same opinions on propylparaben and butylparaben were challenged by a study carried out by the French authorities[8], therefore a further risk assessment of those two substances was adopted by the SCCS in May 2013[9]. Measures on propylparaben and butylparaben are under preparation, as a second step in the risk management of parabens.

(9) No concerns were raised on the safety of 4-Hydroxybenzoic acid and its salts (calcium paraben, sodium paraben, potassium paraben).

(10) The relevant annex to Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(11) The application of the above-mentioned restrictions should be deferred to allow the industry to make the necessary adjustments to product formulations. In particular, undertakings should be granted six months to place on the market compliant products, and fifteen months to stop making available on the market non-compliant products after the entry into force of this Regulation, in order to allow existing stocks to be exhausted.

(12) 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

Annexes V to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

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5 SCCS/1348/10 Revision 22 March 2011.

6 SCCS/1446/11.

7 OJ L 262, 27.9.1976, p. 169.

8 Gazin V., Marsden E., Briffaux J-P (2012), Propylparaben: 8-week postweaning juvenile toxicity study with 26-week treatment free period in male Wistar rat by the oral route (gavage) Poster SOT Annual Meeting San Francisco USA - Abstract ID 2359*327.

9 SCCS/1514/13.

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 – fifteen 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
José Manuel BARROSO

ANNEX

Annex V is amended as follows:

(a) entry 12 is replaced by the following:

	Substance Identification				Conditions			
Reference number	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	Wording of conditions of use and warnings
a	b	c	d	e	f	g	h	i
"12	4-Hydroxybenzoic acid and its salts and esters, other than the esters of isopropyl, isobutyl, phenyl, benzyl and pentyl	4-Hydroxybenzoic acid methylparaben butylparaben potassium ethylparaben potassium paraben propylparaben sodium	99-96-7 99-76-3 94-26-8 36457-19-9 16782-08-4 94-13-3	202-804-9 202-785-7 202-318-7 253-048-1 240-830-2 202-307-7		0,4 % (as acid) for single ester, 0,8 % (as acid) for mixtures of esters"		

[10] For translators: please do not translate these names!

		methylparaben	5026-62-0	225-714-1				
		sodium ethylparaben	35285-68-8	252-487-6				
		sodium propylparaben	35285-69-9	252-488-1				
		sodium butylparaben	36457-20-2	253-049-7				
		ethylparaben	120-47-8	204-399-4				
		sodium paraben	114-63-6	204-051-1				
		potassium methylparaben	26112-07-2	247-464-2				
		potassium butylparaben	38566-94-8	254-009-1				
		potassium propylparaben	84930-16-5	284-597-5				
		sodium propylparaben	35285-69-9	252-488-1				
		calcium paraben[10]	69959-44-0	274-235-4				

(b) entry 25 is replaced by the following:

	Substance Identification				Conditions			
Reference number	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	Wording of conditions of use and warnings
a	b	c	d	e	f	g	h	i
"25	5-Chloro-2- (2,4-dichlorophenoxy) phenol	Triclosan[11]	3380-34-5	222-182-2	(a) Toothpastes Hand soaps Body soaps/Shower gels Deodorants (non-spray) Face powders and blemish concealers Nail products for cleaning the fingernails and toenails (b) Mouthwashes	(a) 0,3 % (b) 0,2 %"	For the nail products for cleaning the fingernails and toenails, the maximum frequency of use should be every two weeks.	

[11] For translators: please do not translate this name!