Commission Regulation (EU) 2016/314 of 4 March 2016 amending Annex 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) 2016/314

of 4 March 2016

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

Whereas:

(1) The substance Diethylene Glycol Monoethyl Ether (DEGEE) with the INCI name Ethoxydiglycol which is used in cosmetic products is not yet regulated under Regulation (EC) No 1223/2009.

(2) DEGEE was the subject of a risk assessment done by France on the basis of which France decided[(2)] that it is safe for consumers, when used in a concentration up to 1,5 % in all cosmetics products except products for oral hygiene. This decision was notified to the Commission and the Member States in accordance with Article 12 of Council Directive 76/768/EEC[(3)]. As a result, the Commission gave a mandate to the Scientific Committee on Consumer Products (SCCP) to issue an opinion on the safety of each of the glycolethers restricted by the French decision.

(3) The SCCP, subsequently replaced by the Scientific Committee on Consumer Safety (SCCS) pursuant to Commission Decision 2008/721/EC[(4)], adopted scientific opinions on DEGEE, on 19 December 2006[(5)], 16 December 2008[(6)], 21 September 2010[(7)] and 26 February 2013[(8)].

(4) The SCCS concluded that the use of DEGEE in oxidative hair dye formulations at a maximum concentration of 7 % w/w, in non-oxidative hair dye formulations at a maximum concentration of 5 % w/w and in other rinse-off products at a maximum concentration of 10 % w/w does not pose a risk to the health of consumers. The SCCS also concluded that the use of DEGEE does not pose a risk to the health of consumers at a maximum concentration of 2,6 % w/w in other non-spray cosmetic products and in the following spray products: fine fragrances, hair sprays, antiperspirants and deodorants. However, the use of DEGEE in oral hygiene products and eye products has not been assessed by the SCCS and thus cannot be considered safe for consumers.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/314. (See end of Document for details)*

(5) In light of those SCCS opinions, the Commission considers that the non-regulation of DEGEE raises a potential risk to human health.

(6) Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(7) The application of the abovementioned restrictions should be deferred to allow industry to make the necessary adjustments to product formulations. In particular, undertakings should be granted 12 months to place on the market compliant products and to withdraw from the market non-compliant products after the entry into force of this Regulation.

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

Article 2

From 25 March 2017 only cosmetic products which comply with this Regulation shall be placed and 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, 4 March 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2016/314. (See end of Document for details)*

ANNEX

In Annex III to Regulation (EC) No 1223/2009, the following entry is added:

Ref. No	**Substance identification**				**Restrictions**			**Wording of conditions of use and warnings**
	Chemical name/ INN	**Name of Common Ingredients Glossary**	**CAS number**	**EC number**	**Product type, body parts**	**Maximum concentration in ready for use preparation**	**Other**	
a	**b**	**c**	**d**	**e**	**f**	**g**	**h**	**i**
‘*x*	2-(2-ethoxyethoxy)ethanol Diethylene Glycol Monoethyl Ether (DEGEE)	Ethoxydiglycol	111-90-0	203-919-7	(a) hair dye products	(a) Oxidative: 7 %	(a) to (e):	The level of ethylene glycol impurity in Ethoxydiglycol must be ≤ 0,1 %. Not to be used in eye products and oral products.’
					(b) oxidative hair dye products	(b) Non-oxidative: 5 %		
					(c) rinse-off products other than hair dye products	(c) Rinse-off: 10 %		
					(d) non-spray cosmetic products	(d) Other: 2,6 %		
					(e) following spray products: fine fragrances, hair sprays, antiperspirants and deodorants	(e) The: 2,6 %		