Commission Regulation (EU) 2016/1198 of 22 July 2016 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/1198

of 22 July 2016

amending Annex V 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) Methylisothiazolinone is authorised as a preservative in cosmetic products at concentrations up to 0,01 % weight/weight (100 ppm) through entry 57 of Annex V to Regulation (EC) No 1223/2009.

(2) The Scientific Committee on Consumer Safety (SCCS) adopted an opinion on the safety of methylisothiazolinone (sensitisation only) on 12 December 2013[(2)].

(3) The SCCS concluded that current clinical data indicate that the concentration of 100 ppm of methylisothiazolinone in cosmetic products is not safe for the consumer. For leave-on cosmetic products (including ‘wet wipes’), no safe concentrations of methylisothiazolinone for induction of contact allergy or elicitation have been adequately demonstrated.

(4) In light of the SCCS opinion mentioned above, it is important to address the increased incidence of allergies induced by methylisothiazolinone and this substance should therefore be banned in leave-on products.

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

(6) The application of the above-mentioned ban 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 to withdraw from the market non-compliant products after the entry into force of this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1198. (See end of Document for details)*

Article 1

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

Article 2

From 12 February 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, 22 July 2016.

For the Commission

The President

Jean-Claude JUNCKER