Commission Regulation (EU) 2017/2228 of 4 December 2017 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

COMMISSION REGULATION (EU) 2017/2228

of 4 December 2017

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

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) Several Member States have recently indicated safety problems in relation to the use of peanut oil, its extracts and its derivatives in cosmetic products. Concerns have been raised that sensitisation to peanuts might be induced through skin exposure to peanut oil through the use of cosmetic products.

(2) The Scientific Committee on Consumer Safety ('SCCS') acknowledged those concerns in its revised opinion of 23 September 2014[(2)]. In that opinion, the SCCS concluded that there are insufficient data to define a safe level of skin exposure in the non-sensitised population. It added that, however, in view of the documented safe levels of oral intake of peanut proteins in sensitised individuals and in view of the industry's capability to refine peanut oil to protein levels of 0,5 ppm or below, that value can be accepted as the maximum allowable concentration in (refined) peanut oil, its extracts and its derivatives used in cosmetic products.

(3) Several Member States have also indicated safety problems in relation to cosmetic products containing hydrolysed wheat proteins. A number of cases of contact urticaria provoked by such cosmetic products, followed by anaphylactic shock after the ingestion of food containing wheat proteins, have been reported.

(4) In its revised opinion of 22 October 2014[(3)] the SCCS considered the use of hydrolysed wheat proteins in cosmetic products safe for consumers, provided that the maximum molecular weight average of the peptides in hydrolysates is 3,5 kDa.

(5) In light of the opinions given by the SCCS, the use of cosmetic products containing peanut oil, its extracts and its derivatives and the use of cosmetic products containing hydrolysed wheat proteins present a potential risk to human health. In order to ensure the safety of such cosmetic products for human health, it is appropriate to set a maximum concentration of 0,5 ppm for peanut proteins in peanut oil, its extracts and its derivatives used in cosmetic products and to restrict the molecular weight average of the peptides in hydrolysed wheat proteins used in cosmetic products to a maximum of 3,5 kDa.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/2228. (See end of Document for details)*

(6) The industry should be allowed a reasonable period of time to adapt to the new requirements by making the necessary adjustments to their product formulations to ensure that only products complying with those requirements are placed on the market. The industry should also be allowed a reasonable period of time to withdraw products which do not comply with the new requirements from the market.

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

Article 2

From 25 September 2018 cosmetic products containing one or more of the substances restricted by this Regulation and not complying with the restrictions laid down in this Regulation shall not be placed on the Union market.

From 25 December 2018 cosmetic products containing one or more of the substances restricted by this Regulation and not complying with the restrictions laid down in this Regulation shall 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*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 December 2017.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2017/2228. (See end of Document for details)*

ANNEX

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

Reference number	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*	Peanut oil, extracts and derivatives	Arachis Hypogaea Oil	8002-03-7	232-296-4			Maximum concentration of peanut proteins: 0,5 ppm[a]	
		Arachis Hypogaea Seedcoat Extract	8002-03-7	232-296-4				
		Arachis Hypogaea Flour	8002-03-7	232-296-4				
		Arachis Hypogaea Fruit Extract	8002-03-7	232-296-4				
		Arachis Hypogaea Sprout Extract						
		Hydrogenated Peanut Oil	68425-36-2	270-350-9				
		Peanut Acid	91051-35-2	293-087-1				
		Peanut Glycerides	91744-77-2	294-643-6				
		Peanut Oil PEG-6 Esters	68440-49-3					

a From 25 September 2018 cosmetic products containing peanut oil, extracts and derivatives and not complying with that restriction shall not be placed on the Union market. From 25 December 2018 cosmetic products containing peanut oil, extracts and derivatives and not complying with that restriction shall not be made available on the Union market.

b From 25 September 2018 cosmetic products containing hydrolyzed wheat proteins and not complying with that restriction shall not be placed on the Union market. From 25 December 2018 cosmetic products containing hydrolyzed wheat proteins and not complying with that restriction shall not be made available on the Union market.