Commission Regulation (EU) 2018/978 of 9 July 2018 amending Annexes II and 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) 2018/978

of 9 July 2018

amending Annexes II and 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) Tagetes erecta, Tagetes minuta and Tagetes patula extracts and oils are widely used fragrance ingredients of many fragrance compounds used in perfumery. The Scientific Committee on Consumer Products (SCCP), subsequently replaced by the Scientific Committee on Consumer Safety (SCCS), concluded in its opinion of 21 June 2005[(2)] that Tagetes erecta, Tagetes minuta and Tagetes patula extracts and oils should not be used in cosmetic products as no safe limits had been demonstrated.

(2) Following the submission in August 2013 of an update dossier on the safety assessment of Tagetes minuta and Tagetes patula extracts and oils, the SCCS adopted a revised opinion on 25 March 2015[(3)]. In that opinion, as corrected on 13 December 2017[(4)], the SCCS concluded that for Tagetes minuta and Tagetes patula extracts and oils in leave-on products (except sunscreen products and products marketed for exposure to natural/artificial UV light), a maximum concentration in ready to use preparation of 0,01 % is safe, provided that the alpha terthienyl (terthiophene) content of those extracts and oils does not exceed 0,35 %. The SCCS thus concluded that Tagetes minuta and Tagetes patula extracts and oils should not be used as ingredients in sunscreen products and in products marketed for exposure to natural/artificial UV light.

(3) In a comment of 6 October 2016[(5)] to its opinion of 25 March 2015, the SCCS indicated that for Tagetes minuta and Tagetes patula extracts and oils in rinse-off products, a maximum concentration in ready to use preparation of 0,1 % should be set.

(4) In light of the opinion of the SCCP of 21 June 2005 there is a potential risk to human health arising from the use of Tagetes erecta flower extract and Tagetes erecta flower oil in cosmetic products. Those substances should therefore be prohibited in cosmetic products and added in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/978. (See end of Document for details)*

(5) In light of the opinion of the SCCP of 21 June 2005, the revised opinion of the SCCS of 25 March 2015, as corrected on 13 December 2017, and the comment of the SCCS of 6 October 2016, there is a potential risk to human health arising from the use of Tagetes minuta and Tagetes patula flower extracts and flower oils in cosmetic products in a concentration exceeding 0,01 % in leave-on products and 0,1 % in rinse-off products and from the use of those extracts and oils in a leave-on or rinse-off product where the content of alpha terthienyl (terthiophene) in the extracts or oils exceeds 0,35 %. There is also a potential risk to human health arising from the use of Tagetes minuta and Tagetes patula flower extracts and flower oils in any concentration in sunscreen products and products marketed for exposure to natural/artificial UV light. Those substances should therefore be added in the list of restricted substances in Annex III to Regulation (EC) No 1223/2009.

(6) It is appropriate to provide for reasonable periods of time in order for the industry to adapt to the new prohibitions and restrictions. The complex and lengthy procedure for fragrance reformulation should be reflected in a longer than usual duration of the time periods given to the industry for adjustments of products.

(7) Annexes II and III to Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(8) The measure 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 II and III to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

From 1 May 2019 cosmetic products containing one or more of the substances prohibited by this Regulation and 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 1 August 2019 cosmetic products containing one or more of the substances prohibited by this Regulation and 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2018/978. (See end of Document for details)*

Done at Brussels, 9 July 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/978. (See end of Document for details)*

ANNEX

Annexes II and III are amended as follows:

(1) in Annex II, in the table, the following entry is added:

Ref No.	Substance identification		
	Chemical name/ INN	CAS number	EC number
a	b	c	d
‘x	Tagetes erecta flower extract[a]	90131-43-4	290-353-9
	Tagetes erecta flower oil[b]	90131-43-4	290-353-9/-

a From 1 May 2019 cosmetic products containing that substance shall not be placed on the Union market. From 1 August 2019 cosmetic products containing that substance shall not be made available on the Union market.

b From 1 May 2019 cosmetic products containing that substance shall not be placed on the Union market. From 1 August 2019 cosmetic products containing that substance shall not be made available on the Union market.’

(2) in Annex III, in the table, the following 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	Tagetes minuta flower extract[a] Tagetes minuta flower oil[b]	Tagetes minuta flower extract Tagetes minuta flower oil	91770-75-7; 91770-75-7/8016-84-0	294-862-7; 294-862-7/-	(a) leave-on products	(a) leave-%	For (a) and (b): Alpha terthienyl (terthiophen) content in the extract/ oil ≤ 0,35 %. For (a): Not to be used in sunscreen	0,01
					(b) rinse-off products	(b) rinse-%		0,1