Commission Regulation (EU) 2016/621 of 21 April 2016 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/621

of 21 April 2016

amending Annex VI 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(2) thereof,

Whereas:

(1) The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, subsequently replaced by the Scientific Committee on Consumer Products ('SCCP'), pursuant to Commission Decision 2004/210/EC[(2)], subsequently replaced by the Scientific Committee on Consumer Safety ('SCCS'), pursuant to Commission Decision 2008/721/EC[(3)], delivered an opinion on 25 June 2003[(4)], in which it stated that, in general, zinc oxide may be considered as a non-toxic substance, including when used in cosmetic products. However, the potential for absorption by inhalation was not considered and the SCCP expressed concern on the safety of micronised zinc oxide, due to the lack of a reliable safety dossier on that substance. Following requests for clarification by the Commission, the SCCP[(5)] confirmed that the use of the non-nano zinc oxide in cosmetic products was safe up to a maximum concentration of 25 % and that adequate data should be submitted for the risk assessment of zinc oxide in nano form.

(2) The SCCS was requested to perform a safety assessment of zinc oxide in nano form and delivered an opinion on 18 September 2012[(6)], followed by an addendum of 23 July 2013[(7)]. The SCCS concluded, on the basis of available evidence, that the use of zinc oxide nanoparticles with the characteristics as indicated, at a concentration up to 25 % as a UV filter in sunscreens, can be considered not to pose a risk of adverse effects in humans after dermal application. In addition, the SCCS indicated that there is no evidence for the absorption of zinc oxide nanoparticles through skin and via the oral route. In the Margin of Safety calculation, the calculation of the exposure to zinc oxide nanoparticles results in acceptable Margin of Safety for both the oral and dermal routes. The SCCS later confirmed that zinc oxide nano may be used in cosmetic products other than sunscreens, intended for dermal application.

(3) The characteristics indicated by the SCCS in its opinion concern the physico-chemical properties of the material (such as purity, structure and physical appearance, particle number size distribution and water solubility) and whether it is uncoated or coated with specific chemicals. Other cosmetic ingredients can be used as coatings as long as they are demonstrated to the SCCS to be safe and do not affect the particle properties related to behaviour and/or toxicological effects, compared to the nanomaterials covered in the relevant SCCS opinion. Therefore, the Commission considers that these physico-chemical properties and requirements regarding coatings should be reflected in Regulation (EC) No 1223/2009.

(4) The SCCS also considered that, on the basis of available information, the use of zinc oxide nanoparticles in spray products cannot be considered safe. In addition, the SCCS indicated, in a further opinion of 23 September 2014 for clarification of the meaning of the term 'sprayable applications/products' for the nano forms of carbon black CI 77266, titanium dioxide and zinc oxide[8], that its concern is limited to spray products that could lead to exposure of the consumer's lungs to nano zinc oxide by inhalation. The SCCS also indicated that non-nano zinc oxide has similar toxic effects to nano zinc oxide, as far as lung toxicity after inhalation is concerned.

(5) In light of the SCCS opinions mentioned above, the Commission considers that zinc oxide in non-nano form should be authorised for use as a UV filter in cosmetic products; zinc oxide in nano form (according to the SCCS's specifications) should be authorised for use as a UV filter in cosmetic products. Both forms of the substance should be authorised at a maximum concentration of 25 %, except in applications that may lead to exposure of the end-user's lungs by inhalation.

(6) The Commission considers that Annex VI to Regulation (EC) No 1223/2009 should be amended for the purpose of adapting it to technical and scientific progress.

(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:

Article 1 U.K.

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

Article 2 U.K.

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, 21 April 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX U.K.

The following entries are added to Annex VI to Regulation (EC) No 1223/2009 as reference numbers 30 and 30a:

Reference number	Substance identification				Conditions			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
‘30	Zinc oxide	Zinc Oxide	1314-13-2	215-222-5		25 %[a]	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.	
30a	Zinc oxide	Zinc Oxide (nano)	1314-13-2	215-222-5		25 %[a]	Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: — purity ≥ 96 %, with wurtzite	

a In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit given in column g.’

							—	crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, with impurities consisting only of carbon dioxide and water, whilst any other impurities are less than 1 % in total, median diameter of the particle number size distribution D50 (50 % of the number below

a In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit given in column g.’

								this diameter) > 30 nm and D1 (1 % below this size) > 20 nm,
							—	water solubility < 50 mg/L
							—	uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetrietho cross-polymer, or octyl triethoxy silane.

a In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit given in column g.’

(**1**) OJ L 342, 22.12.2009, p. 59.

(**2**) OJ L 66, 4.3.2004, p. 45.

(**3**) OJ L 241, 10.9.2008, p. 21.

(**4**) SCCNFP/0649/03, http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out222_en.pdf

(**5**) SCCP/0932/05, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_00m.pdf SCCP/1147/07, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf and SCCP/1215/09, http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_167.pdf

(**6**) SCCS/1489/2012 Revision of 11 December 2012, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_103.pdf

(**7**) SCCS/1518/13 Revision of 22 April 2014, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_137.pdf

(**8**) SCCS/1539/14 Revision of 25 June 2015, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_163.pdf

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2016/621.