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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION REGULATION (EU) …/… of XXX amending and correcting Annex II and amending Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

Delegations will find attached document […](2021) XXX draft - D 071191/01.

Encl.: […](2021) XXX draft - D 071191/01

EUROPEAN
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Brussels, XXX
[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending and correcting Annex II and amending Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Text with EEA relevance)

D071191/01

Commission Regulation (EU) …/…of XXX amending and correcting Annex II and amending Annexes III, IV and 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 15(1), the fourth subparagraph of Article 15(2) and Article 31(1) thereof,

Whereas:

(1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2] provides for a harmonised classification of substances as carcinogenic, mutagenic or toxic for reproduction (CMR) based on an opinion prepared by the Committee for Risk Assessment of the European Chemicals Agency. The substances are classified as CMR substances of category 1A, CMR substances of category 1B or CMR substances of category 2 depending on the level of evidence of their CMR properties.

(2) Article 15 of Regulation (EC) No 1223/2009 provides that substances which have been classified as CMR substances of category 1A, category 1B or category 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CMR substances) are prohibited from use in cosmetic products. A CMR substance may however be used in cosmetic products where the conditions laid down in the second sentence of Article 15(1) or in the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009 are fulfilled.

(3) In order to uniformly implement the prohibition of CMR substances within the internal market, to ensure legal certainty, in particular for economic operators and national competent authorities, and to ensure a high level of protection of human health, CMR substances should be included in the list of prohibited or, as applicable, restricted substances in Annex II or Annex III, respectively, to Regulation (EC) No 1223/2009 and, where relevant, deleted from the lists of restricted or authorised substances in Annexes III to VI to that Regulation. Where the conditions laid down in the second sentence of Article 15(1) or the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009 are fulfilled, the lists of restricted or authorised substances in Annexes III to VI to that Regulation should be amended accordingly.

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1 OJ L 342, 22.12.2009, p. 59.

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(4) By Commission Delegated Regulation (EU) 2020/217[3], which is to apply from 1 October 2021, certain substances have been classified as CMR substances in accordance with Regulation (EC) No 1272/2008. It is therefore necessary to prohibit the use of those CMR substances in cosmetic products from the same date.

(5) In particular, Delegated Regulation (EU) 2020/217 provides for a classification of the substance TiO_2 (INCI name: titanium dioxide) as 'Carcinogen Category 2 (inhalation)', that applies to titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter of ≤ 10 μm.

(6) Titanium dioxide is currently listed in entry 143 of Annex IV to Regulation (EC) No 1223/2009 and allowed for use as colorant in cosmetic products, provided that it complies with the purity criteria as set out in entry E 171 (titanium dioxide) of the Annex to Commission Regulation (EU) No 231/2012[4]. Titanium dioxide is also listed in entries 27 and 27a (nano form) of Annex VI to Regulation (EC) No 1223/2009 as UV filter and only allowed in cosmetic products in concentrations of up to 25%. In addition, titanium dioxide (nano) is allowed in ready for use preparation, except in applications that may lead to exposure of the end user's lungs by inhalation and subject to the other conditions listed in that entry.

(7) Following the classification of titanium dioxide as a CMR substance, a request for its use in cosmetic products by way of exception pursuant to the second sentence of Article 15(1) of Regulation (EC) No 1223/2009 was submitted on 28 January 2020.

(8) On 6 October 2020, the Scientific Committee on Consumer Safety (SCCS) adopted a scientific opinion on titanium dioxide[5] ("the SCCS opinion") for the purpose of the adoption of the necessary measures in accordance with Article 15(1) of Regulation (EC) No 1223/2009. The SCCS opinion, which covered titanium dioxide (inhalable) in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 μm, concluded that, based on the available data, TiO_2 was safe for general consumers when used in face products in loose powder form up to a maximum concentration of 25 % and in hair products in aerosol spray form up to a maximum concentration of 1.4 %. As regards professional use, TiO_2 was considered safe when used in hair products in aerosol spray form up to a maximum concentration of 1.1 %.

(9) Finally, the SCCS concluded that those results were drawn from cosmetic products based on only one type of titanium dioxide material (pigmentary) and that, in the absence of more information, it could not be established whether those conclusions would be also applicable to other cosmetic applications containing other types of titanium dioxide not explicitly covered by the SCCS opinion.

(10) In the light of the SCCS conclusions, titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 μm should not be authorised for use in applications that may give rise to inhalation exposure by the end user and should, therefore, be added to the list of restricted substances in Annex III to

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3 Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that Regulation (OJ L 44, 18.2.2020, p. 1).

4 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

5 SCCS (Scientific Committee on Consumer Safety), Opinion on Titanium dioxide (TiO_2), preliminary version of 7 August 2020, final version of 6 October 2020, SCCS/1617/20.

Regulation (EC) No 1223/2009 and its use should be allowed only in face products in loose powder form and in hair aerosol spray products as indicated in those conclusions. In addition to the inclusion of titanium dioxide in Annex III to Regulation (EC) No 1223/2009, it should be provided that the use of titanium dioxide as colorant in accordance with entry 143 of Annex IV to that Regulation, as well as the use of titanium dioxide as UV filter in accordance with entry 27 of Annex VI to that Regulation should be allowed without prejudice to its restricted use under Annex III to that Regulation. To this aim, a reference to the restricted use of titanium dioxide under Annex III to Regulation (EC) No 1223/2009 should be added in the relevant entries in Annex IV and Annex VI to that Regulation. As regards the use of titanium dioxide (nano) as UV filter in accordance with entry 27a of Annex VI to Regulation (EC) No 1223/2009, no additional measures are required, as entry 27a already provides that titanium dioxide (nano) is not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.

(11) With regard to substances other than titanium dioxide, which were classified as CMR substances pursuant to Regulation (EC) No 1272/2008 by Delegated Regulation (EU) 2020/217, no request for use in cosmetic products by way of exception has been submitted. This concerns cobalt, metaldehyde (ISO), methylmercuric chloride, benzo[rst]pentaphene, dibenzo[b,def]chrysene; dibenzo[a,h]pyrene, ethanol, 2,2'-iminobis-,N-(C13-15-branched and linear alkyl) derivs, cyflumetofen (ISO), diisohexyl phthalate, halosulfuron-methyl (ISO), 2-methylimidazole, metaflumizone (ISO), dibutylbis(pentane-2,4-dionato-O,O')tin, nickel bis(sulfamidate), 2-Benzyl-2-dimethylamino-4′- morpholinobutyrophenone and ethylene oxide. Those substances are currently neither subject to the restrictions laid down in Annex III nor authorised in accordance with Annexes IV, V or VI to Regulation (EC) No 1223/2009. Three of those substances, namely nickel bis(sulfamidate), ethylene oxide and 2-Benzyl-2-dimethylamino-4′- morpholinobutyrophenone, are currently listed in Annex II to that Regulation. The substances that are not yet listed in Annex II to Regulation (EC) No 1223/2009 should be added to the list of substances prohibited in cosmetic products in that Annex.

(12) Commission Regulation (EU) 2019/1966[6], that was adopted to uniformly implement the prohibition of substances classified as CMR, pursuant to Regulation (EC) No 1272/2008, by Commission Regulation (EU) 2018/1480[7], introduced changes to entry 98 of Annex III to Regulation (EC) No 1223/2009 with regard to the substance benzoic acid, 2-hydroxy- (INCI name: salicylic acid). In order to fully align those changes with the conclusion of the original SCCS opinion[8], it is appropriate to authorise the use of that substance, for purposes other than preservative function, in body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant in a concentration of up to 0,5 %. Entry 98 of Annex III to Regulation (EC) No 1223/2009 should therefore be amended accordingly.

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6 Commission Regulation (EU) 2019/1966 of 27 November 2019 amending and correcting Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 307, 28.11.2019, p. 15).

7 Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018).

8 SCCS (Scientific Committee on Consumer Safety), Opinion on salicylic acid, Corrigendum of 20-21 June 2019, SCCS/1601/18.

(13) Additionally, the substance nickel bis(tetrafluoroborate) (CAS number: 14708-14-6) has been introduced twice by error in Annex II to Regulation (EC) No 1223/2009 (entries 1401 and 1427) by Commission Regulation (EU) 2019/831[9], that was adopted to uniformly implement the prohibition of substances classified as CMR, pursuant to Regulation (EC) No 1272/2008, by Commission Regulation (EU) 2017/776[10]. The second of those entries is therefore redundant and should be removed.

(14) Regulation (EC) No 1223/2009 should therefore be amended and corrected accordingly.

(15) The amendments to Regulation (EC) No 1223/2009 provided for in this Regulation that are based on the classifications of the relevant substances as CMR substances by Delegated Regulation (EU) 2020/217 should apply from the same date as that Delegated Regulation.

(16) 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

Annexes II, III, IV and VI to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

In Annex II to Regulation (EC) No 1223/2009, the entry 1427, corresponding to the substance nickel bis(tetrafluoroborate) (CAS number: 14708-14-6), is deleted.

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*.

Article 1 shall apply from 1 October 2021 with respect to points (1), (2) (b), (3) and (4) of the Annex.

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

Done at Brussels,

For the Commission
The President
Ursula von der Leyen

[9] Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 137, 23.5.2019, p. 29).

[10] Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 116, 5.5.2017, p. 1).