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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	29 April 2022
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	[…](2022) XXX draft - D 081047/1
Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction and correcting that Regulation

Delegations will find attached document […](2022) XXX draft - D 081047/1.

Encl.: […](2022) XXX draft - D 081047/1

EUROPEAN
COMMISSION

Brussels, XXX
[…](2022) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction and correcting that Regulation

(Text with EEA relevance)

D081047/01

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction and correcting that Regulation

(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) and Article 15(2), fourth subparagraph, 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 a scientific assessment by the Risk Assessment Committee 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 to be prohibited from use in cosmetic products. A CMR substance may however be used in cosmetic products where the conditions laid down in Article 15(1), second sentence, of Regulation (EC) No 1223/2009 or in Article 15(2), second subparagraph, of that Regulation 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, all CMR substances should be included in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009 and, where relevant, deleted from the lists of restricted or allowed substances in Annexes III to VI to that Regulation. Where the conditions laid down in Article 15(1), second sentence, of Regulation (EC) No 1223/2009 or in Article 15(2), second subparagraph, of that Regulation are fulfilled, the lists of

[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).

restricted or allowed substances in Annexes III to VI to that Regulation should be amended accordingly.

(4) This Regulation covers substances classified as CMR substances of categories 1A, 1B or 2 by Delegated Regulation (EU) 2021/849[3], which will apply from 17 December 2022.

(5) With regard to the substance 'methyl 2-hydroxybenzoate' (CAS No. 119-36-8), with International Nomenclature Cosmetics of Ingredient (INCI) name 'Methyl Salicylate', which has been classified as a CMR substance of category 2 (Toxic for Reproduction), a request for the application of Article 15(1), second sentence, of Regulation (EC) No 1223/2009 was submitted on 25 May 2021 concerning use of that substance as a fragrance ingredient in various cosmetic products.

(6) Methyl Salicylate is used as a fragrance ingredient, flavouring agent and soothing agent in various cosmetic products and is currently not listed in the Annexes to Regulation (EC) No 1223/2009.

(7) In accordance with Article 15(1), second sentence, of Regulation (EC) No 1223/2009, CMR substances of category 2 may be used in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in such products.

(8) The SCCS concluded in its opinion of 26-27 October 2021[4] that Methyl Salicylate can be considered safe as an ingredient in cosmetic products up to the maximum concentrations provided by the applicant. In light of the classification of Methyl Salicylate as a CMR substance of category 2 and the SCCS opinion in its final version, Methyl Salicylate should be added to the list of substances restricted in cosmetic products in Annex III to Regulation (EC) No 1223/2009.

(9) With regard to all substances other than Methyl Salicylate, which were classified as CMR substances pursuant to Regulation (EC) No 1272/2008 by Delegated Regulation (EU) 2021/849, no request for use in cosmetic products by way of exception has been submitted. Consequently, the CMR substances that are not already 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.

(10) The substance Sodium N-(hydroxymethyl)glycinate (CAS No 701-61-44-3) was classified as carcinogenic of category 1B and mutagenic of category 2 by Delegated Regulation (EU) 2020/1182[5]. It follows from notes 8 and 9 to that classification that it is only applicable if it cannot be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 0,1 %. In Commission Regulation (EU) 2021/1902[6], 'Sodium N-

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3 Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 188, 28.5.2021, p. 27).

4 SCCS (Scientific Committee on Consumer Safety), Opinion on methyl salicylate (methyl 2-hydroxybenzoate), preliminary version of 24-25 June, final version of 26-27 October 2021, SCCS/1633/21.

5 Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 261, 11.8.2020, p. 2).

6 Commission Regulation (EU) 2021/1902 of 29 October 2021 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in

(hydroxymethyl)glycinate' was erroneously added as entry 1669 in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009, despite the fact that it was already listed in entry 51 of Annex V to that Regulation under the chemical name/INN 'Sodium hydroxymethylamino acetate' as a preservative allowed in cosmetic products under certain conditions. A substance should not be listed in both Annex II and Annex V to Regulation (EC) No 1223/2009 and entry 1669 should therefore be deleted from Annex II to that Regulation.

(11) The additional condition that was introduced in column h of entry 51 of Annex V to Regulation (EC) No 1223/2009 by Commission Regulation (EU) 2021/1902 concerning the maximum theoretical concentration of formaldehyde was erroneously given a slightly different wording than the condition set out in notes 8 and 9 to the CMR classification of 'Sodium N-(hydroxymethyl)glycinate'. In order to correctly reflect the prohibition of that substance in cosmetic products on the basis of the CMR classification, the wording of the conditions should be the aligned and entry 51 should be adapted accordingly.

(12) Entry 51 of Annex V to Regulation (EC) 1223/2009 also contains an error in column b with regard to the chemical name of the substance. The correct name of the substance is 'Sodium N-(hydroxymethyl)glycinate', as referred to in Delegated Regulation (EU) 2020/1182.

(13) Regulation (EC) 1223/2009 should therefore be amended and corrected accordingly.

(14) The amendments to Regulation (EC) No 1223/2009 that are based on the classifications of the relevant substances as CMR substances by Delegated Regulation (EU) 2021/849 should apply from the same date as those classifications.

(15) 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 and III to Regulation (EC) No 1223/2009 are amended in accordance with Annex I to this Regulation.

Article 2

Annexes II and V to Regulation (EC) No 1223/2009 are corrected in accordance with Annex II to this Regulation.

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 17 December 2022.

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

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cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction (OJ L 387, 3.11.2021, p. 120).

Done at Brussels,

For the Commission
The President
Ursula von der Leyen