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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	24 March 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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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

Delegations will find attached document [...](2022) XXX draft - D 088783/1.

Encl.: [...](2022) XXX draft - D 088783/1



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**

(Text with EEA relevance)

D0088783/01

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**

(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 products¹, 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 Council² 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

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).

Article 15(2), second subparagraph of that Regulation are fulfilled, the lists of 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 by Delegated Regulation (EU) 2022/692³ ('the relevant substances'). Delegated Regulation (EU) 2022/692 will apply from 1 December 2023.
- (5) No request for use in cosmetic products by way of exception has been submitted for the relevant substances.
- (6) The relevant substances are currently neither restricted in Annex III to Regulation (EC) No 1223/2009, nor allowed in Annexes IV, V or VI to that Regulation.
- (7) The substance 2-ethylhexanoic acid (CAS No. 149-57-5) is currently listed in entry 1024 of Annex II to Regulation (EC) No 1223/2009. However, the salts of that substance, which have been classified as CMR substances [of category 1B] by Delegated Regulation (EU) 2022/692, are not included in that entry. None of the other relevant substances are currently listed in Annex II to Regulation (EC) No 1223/2009. Therefore, those substances should be added to the list of substances prohibited in cosmetic products in Annex II to Regulation (EC) No 1223/2009 and the salts of the substance 2-ethylhexanoic acid should be added in entry 1024 of that Annex.
- (8) Regulation (EC) 1223/2009 should therefore be amended accordingly.
- (9) The amendments to Regulation (EC) No 1223/2009 are based on the classifications of the relevant substances as CMR substances and should therefore apply from the same date as those classifications.
- (10) 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 to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 December 2023.

³ Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 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 129, 3.5.2022, p.1–17).

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