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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	21 September 2026
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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, including those classified as carcinogenic, mutagenic or toxic for reproduction

Delegations will find attached document D(2026) 117774.

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EUROPEAN
COMMISSION

Brussels, XXX
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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, including those classified as carcinogenic, mutagenic or toxic for reproduction

(Text with EEA relevance)

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, including those 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 products ([1]), and in particular Article 15(1), third sentence, Article 15(2), fourth subparagraph, 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 a scientific assessment by the Committee for Risk Assessment of the European Chemicals Agency. The substances are classified as CMR substances of category 1A, 1B or 2, depending on the weight of evidence of their CMR properties.

(2) Article 15 of Regulation (EC) No 1223/2009 provides that the use of substances which have been classified as CMR substances of category 1A, 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 are to be prohibited in cosmetic products. Those CMR substances can, however, be used in cosmetic products where the conditions laid down in Article 15(1), second sentence, or Article 15(2), second subparagraph, 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, all CMR substances should be included in the list of prohibited substances set out in Annex II to Regulation (EC) No 1223/2009 and, where relevant, deleted from the lists of restricted or allowed substances set out in Annexes III to VI to that Regulation. However, where the conditions laid down in Article 15(1), second sentence, or Article 15(2), second subparagraph, of Regulation (EC) No 1223/2009 are fulfilled, the lists of restricted or allowed 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, ELI: http://data.europa.eu/eli/reg/2009/1223/oj.

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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

(4) No request for use in cosmetic products by way of exception has been submitted for the substances of categories 1A, 1B or 2 classified as CMR substances by Commission Delegated Regulation (EU) 2025/1222 ([3]). Consequently, where those CMR substances are not listed in Annex II to Regulation (EC) No 1223/2009, they should be added to the list of substances prohibited in cosmetic products.

(5) Furthermore, this Regulation concerns certain cosmetic ingredients that have been recently assessed by the Scientific Committee on Consumer Safety (SCCS), namely 'Benzophenone-1', 'Benzophenone-2', 'Butylated Hydroxyanisole', 'Butylparaben', 'Basic Brown 16', 'Basic Blue 99', 'ethyl tafluprostamide', 'methylamido-dihydro-noralfaprostal', 'isopropyl cloprostenate', 'thiomersal', 'phenylmercuric salts', 'Cannabidiol' and 'Hydroxyapatite (nano)'.

(6) The substance '2,4-dihydroxybenzophenone' (CAS No 131-56-6), which has been assigned the name 'Benzophenone-1' under the International Nomenclature of Cosmetic Ingredients (INCI), is not regulated by Regulation (EC) No 1223/2009. However, it is used as a light stabiliser in cosmetic products since it can absorb and disperse ultraviolet (UV) radiation, protecting the product formulation from the damaging effects of UV radiation.

(7) The substance '2,2',4,4'-tetrahydroxybenzophenone' (CAS No 131-55-5), which has been assigned the INCI name 'Benzophenone-2', is not regulated by Regulation (EC) No 1223/2009. However, it is used in cosmetic products as a UV filter, light stabiliser and fragrance, protecting the products from the deterioration effects caused by light, including UV light and enhancing their smell or perfuming the skin.

(8) The substance '*tert*-butyl-4-methoxyphenol' (CAS No 25013-16-5), which has been assigned the INCI name 'Butylated Hydroxyanisole', is composed of two isomers: 2-*tert*-butyl-4-methoxyanisole and 3-*tert*-butyl-4-hydroxyanisole. Butylated Hydroxyanisole is not regulated by Regulation (EC) No 1223/2009. However, it is used as a fragrance ingredient and an antioxidant in cosmetic products to prolong their shelf life.

(9) The substance 'butyl 4-hydroxybenzoate' (CAS No 94-26-8), which has been assigned the INCI name 'Butylparaben', is listed in entry 12a of Annex V to Regulation (EC) No 1223/2009. It is therefore allowed for use as a preservative, as an acid, in a concentration of up to 0.14 %, when used on its own or for the sum of its combined use with propylparaben and its salts.

(10) Considering concerns related to potential endocrine-disrupting properties of Benzophenone-1, Benzophenone-2, Butylated Hydroxyanisole and Butylparaben, the Commission launched a public call for data in 2019 and 2021. The cosmetics industry submitted scientific evidence to demonstrate the safety of those substances when used in cosmetic products. The Commission requested the SCCS to carry out safety assessments of those substances in light of the information provided by the industry.

(11) The SCCS concluded in its opinion of 27 March 2025 ([4]) that Benzophenone-1 is not safe when used as a light stabiliser in cosmetic products. It can be concluded from the

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[3] Commission Delegated Regulation (EU) 2025/1222 of 2 April 2025 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council as regards the harmonised classification and labelling of certain substances (OJ L , 20.6.2025, ELI: https://eur-lex.europa.eu/eli/reg_del/2025/1222/oj).

[4] SCCS (Scientific Committee on Consumer Safety), Opinion on Benzophenone-1 (CAS No. 131-56-6, EC No. 205-029-4), preliminary version of 25 October 2024, final version of 27 March 2025, SCCS/1672/24.

SCCS opinion that there is a potential risk to human health arising from the use of Benzophenone-1 in cosmetic products. That substance should therefore be added to the list of substances prohibited in cosmetic products set out in Annex II to Regulation (EC) No 1223/2009.

(12) In its corrigendum of 26 March 2026 to its scientific advice of Benzophenone-2 and Benzophenone-5 ([5]), the SCCS could not draw any conclusions on the safety of Benzophenone-2 because its genotoxicity potential could not be excluded. Data on the repeated dose toxicity and reproductive toxicity of Benzophenone-2 are also either limited or not available. The available evidence shows that of Benzophenone-2 is an endocrine-active substance by clearly demonstrating oestrogenic activity both *in vitro* and *in vivo*. That substance should therefore be added to the list of substances prohibited in cosmetic products set out in Annex II to Regulation (EC) No 1223/2009.

(13) The SCCS concluded in its scientific advice of 26 March 2026 ([6]), that Butylated Hydroxyanisole is safe for use in leave-on and rinse-off cosmetic products up to the maximum concentration of 0.07 %. This SCCS scientific advice considered only dermal use and hence is applicable to the use of Butylated Hydroxyanisole only in dermally applied products, and not in oral care products or cosmetic products, which can lead to exposure of the end-user's lungs by inhalation.

(14) It can be concluded from the SCCS scientific advice of 26 March 2026 that there is a potential risk to human health arising from the use of Butylated Hydroxyanisole in cosmetic products when the concentration of that substance exceeds certain levels. The use of Butylated Hydroxyanisole in cosmetic products should therefore be restricted to the maximum concentration proposed by the SCCS.

(15) On 30 April 2025 the SCCS adopted an opinion ([7]) concluding that Butylparaben can be considered safe for children of all age groups and product types included in the assessment, whether used individually or in combination, provided that the concentration of Butylparaben, as acid, does not exceed 0.14 % in rinse-off products, 0.002 %, as acid, in leave-on products and 0.092 %, as acid, in oral care products. The opinion is not applicable to sprayable products, including mouth sprays, that could lead to exposure of the end user's lungs by inhalation.

(16) It can be concluded from the SCCS opinion of 30 April 2025 that there is a potential risk to human health arising from the use of Butylparaben in cosmetic products. The current restrictions on the use of Butylparaben in those products should therefore be revised by creating a separate entry for Butylparaben as entry 12b in Annex V to Regulation (EC) No 1223/2009. At the same time, the existing entry 12a, which currently regulates Butylparaben together with Propylparaben, should be amended in order for it to apply exclusively to Propylparaben.

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5 SCCS (Scientific Committee on Consumer Safety), scientific advice on the safety of Benzophenone-2 (BP-2) (CAS No. 131-55-5, EC No. 205-028-9) and Benzophenone-5 (BP-5) (CAS No. 6628-37-1, EC No. 613-918-7) as substances with potential endocrine disrupting properties in cosmetic products, preliminary version of 27 March 2025, final version of 26 June 2025, Corrigendum of 26 March 2026, SCCS/1679/25

6 SCCS (Scientific Committee on Consumer Safety), scientific advice on the safety of Butylated Hydroxyanisole (BHA) (CAS No. 25013-16-5, EC No. 246-563-8) as a substance with potential endocrine disrupting properties in cosmetic products, preliminary version of 30 October 2025, final version of 26 March 2026, SCCS/1682/25.

7 SCCS (Scientific Committee on Consumer Safety), Opinion on Butylparaben (CAS No. 94-26-8, EC No. 202-318-7) – children exposure, preliminary version of 10 January 2025, final version of 30 April 2025, SCCS/1674/25.

(17) The substance '8-[(4-aminophenyl)diazenyl]-7-hydroxy-N,N,N-trimethylnaphthalen-2-aminium chloride' (CAS No 26381-41-9), which has been assigned the INCI name 'Basic Brown 16', is not regulated by Regulation (EC) No 1223/2009. However, it is used as a hair dye ingredient in non-oxidative hair dye formulations.

(18) The SCCS concluded in its scientific advice of 2 February 2026 ([8]) that it does not consider the use of Basic Brown 16 to be safe when used as an ingredient in non-oxidative hair dye formulations because the weight of evidence indicates its potential for mutagenicity. Therefore, it can be concluded that there is a potential risk to human health arising from the use of Basic Brown 16 in cosmetic products. That substance should therefore be added to the list of substances prohibited in cosmetic products set out in Annex II to Regulation (EC) No 1223/2009.

(19) The substance '3-[(4-amino-6-bromo-5,8-dihydro-1-hydroxy-8-imino-5-oxo-2-naphtyl)amino]-N,N,N-trimethylanilinium chloride' (CAS No 68123-13-7), which has been assigned the INCI name 'Basic Blue 99', is not regulated by Regulation (EC) No 1223/2009. However, it is used as a hair dye ingredient in non-oxidative hair dye formulations.

(20) The SCCS concluded in its scientific advice of 2 February 2026 ([9]) that it does not consider the use of Basic Blue 99 safe when used as an ingredient in non-oxidative hair dye formulations because the collective evidence indicates a potential for genotoxicity. Therefore, it can be concluded that there is a potential risk to human health arising from the use of Basic Blue 99 in cosmetic products. That substance should therefore be added to the list of substances prohibited in cosmetic products set out in Annex II to Regulation (EC) No 1223/2009.

(21) Prostaglandins and their analogues, used in cosmetic products to promote the growth of eyelashes, are not regulated by Regulation (EC) No 1223/2009. Moreover, their use is currently not restricted in cosmetic products. Therefore, considering the concerns related to potential undesirable health effects caused by cosmetic products for eyelash growth containing prostaglandins, and their analogues, the Commission launched a public call for data in 2020. The cosmetics industry submitted scientific evidence on the safety of prostaglandins and two dossiers on the safety of the analogues 'ethyl tafluprostamide' (CAS No 1185851-52-8) and 'isopropyl cloprostenate' (CAS No 157283-66-4). In 2021 the Commission requested the SCCS to carry out a safety assessment on the safety of prostaglandins and their analogues in cosmetic products in view of the information provided.

(22) The SCCS was not able in its opinion of 3 February 2022 ([10]) to draw any conclusions on the safety of 'ethyl tafluprostamide' and 'isopropyl cloprostenate' in cosmetic products in view of the limited data provided and the information available in the published literature. Nevertheless, the SCCS noted concerns about the safety of prostaglandin analogues in cosmetic products intended for use in the proximity of the eye.

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8 SCCS (Scientific Committee on Consumer Safety), Scientific Advice on hair dye 'Basic Brown 16' (C009) (CAS No. 26381-41-9, EC No. 247-640-9) – submission V ter., preliminary version of 30 October 2025, final version of 2 February 2026, SCCS/1684/25.

9 SCCS (Scientific Committee on Consumer Safety), Scientific Advice on hair dye 'Basic blue 99' (C059) (CAS No. 68123-13-7, EC No. 268-544-3) – submission IV & V, preliminary version of 30 October 2025, final version of 2 February 2026, SCCS/1683/25

10 SCCS (Scientific Committee on Consumer Safety), Opinion on Prostaglandins and prostaglandin-analogues used in cosmetic products, preliminary version of 27 September 2021, final version of 3 February 2022, SCCS/1635/21.

(23) By January 2024 the cosmetics industry submitted additional evidence to support the safe use of 'ethyl tafluprostamide', 'methylamido-dihydro-noralfaprostal' and 'isopropyl cloprostenate' in eyelash and eyebrow products. The Commission requested the SCCS to carry out a safety assessment on those three substances in view of the new information provided.

(24) In its final opinion of 2 February 2026 ([11]), the SCCS considered that prostaglandins and certain prostaglandin analogues used in cosmetic products raise safety concerns in view of their pharmacological activity, even at very low concentrations, and the potential for serious undesirable effects, particularly affecting ocular health. In addition, the SCCS highlighted the absence of sufficient evidence to rule out potential adverse effects related to reproductive and developmental toxicity. That lack of evidence is of particular importance given that users of the cosmetic products containing prostaglandins and prostaglandin analogues will most likely be women of child-bearing age.

(25) Following its assessment of the scientific information submitted by the cosmetics industry in the context of the SCCS safety evaluation of prostaglandins and their analogues used in cosmetic products, the SCCS was not able to establish, on the basis of the scientific information assessed, conditions of use under which those substances could be considered safe in cosmetic products. To ensure a high level of protection of human health, the use of prostaglandins and their analogues in cosmetic products should be prohibited and therefore, they should be added to Annex II to Regulation (EC) No 1223/2009.

(26) Council Directive 76/768/EEC ([12]) has prohibited the use of mercury and its compounds. Mercury and its compounds are still prohibited pursuant to entry 221 of Annex II to Regulation (EC) No 1223/2009.

(27) The substances 'thiomersal' and 'phenylmercuric salts (including borate)' are mercury-containing compounds listed in entries 16 and 17 of Annex V to Regulation (EC) No 1223/2009. They are therefore allowed for use as preservatives in cosmetic products under specific conditions. In addition, cosmetic products that contain such compounds must include in their labelling the warning 'Contains Thiomersal' or 'Contains Phenylmercuric compounds'. Apart from 'thiomersal', which is a single substance, 'phenylmercuric salts' covers all salts composed of the phenylmercury cation ($C_6H_5Hg^+$) paired with an anion, such as acetate, benzoate, borate, bromide, chloride, oleate, etc.

(28) In light of the severe health risks associated with mercury, the Commission requested the SCCS to provide scientific advice on the safety of preservatives containing mercury and its compounds. The SCCS concluded in its scientific advice of 2 February 2026 ([13]) that, considering that the margin of safety (MoS), based on renal toxicity as the most sensitive endpoint, is below 100, and given that genotoxicity

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11 SCCS (Scientific Committee on Consumer Safety), Opinion on prostaglandin analogues used in cosmetic products, preliminary version of 28 May 2025, final version of 2 February 2026, SCCS/1680/25.

12 Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, pp. 169, ELI: http://data.europa.eu/eli/dir/1976/768/oj).

13 SCCS (Scientific Committee on Consumer Safety), scientific advice on the safety of Thiomersal (CAS No. 54-64-8, EC No. 200-210-4) and Phenylmercuric salts as preservatives in cosmetic products, preliminary version of 30 October 2025, final version of 2 February 2026, SCCS/1686/25.

evidence is unclear, the preservatives that contain mercury and its compounds are not considered safe at the concentration levels currently permitted in cosmetic products.

(29) It can be concluded from the SCCS scientific advice of 2 February 2026 that there is a potential risk to human health arising from the use of mercury compounds in cosmetic products. Therefore, entries 16 and 17 of Annex V to Regulation (EC) No 1223/2009 should be deleted and the generic entry 221 for mercury and its compounds in Annex II to Regulation (EC) No 1223/2009 should be amended by deleting the exception from the ban for the special cases included in Annex V to that Regulation.

(30) The substance '2-[(6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol' (CAS No 13956-29-1), which has been assigned the INCI name 'Cannabidiol' (CBD), is used in cosmetic products for functions such as skin conditioning and protecting, antioxidant and anti-sebum. Cannabidiol is not regulated by Regulation (EC) No 1223/2009. However, entry 306 of Annex II to that Regulation prohibits the use of 'Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on narcotic drugs signed in New York on 30 March 1961' in cosmetic products.

(31) In light of the judgment of the Court of Justice in Case C-663/18 ([14]), Cannabidiol extracted from cannabis plant varieties containing no more than 0.2 % delta-9-tetrahydrocannabinol (THC), and from 1 January 2023 no more than 0.3 % THC, is not considered to fall within the scope of entry 306 of Annex II to Regulation (EC) No 1223/2009. Consequently, Cannabidiol is not regarded as a prohibited substance under Regulation (EC) No 1223/2009. Cannabidiol therefore can be used in cosmetic products, provided that the product complies with Article 3 of Regulation (EC) No 1223/2009 and is safe for human health under normal or reasonably foreseeable conditions of use. The exception does not extend to the possible presence of THC in cosmetic products containing Cannabidiol.

(32) Considering the very limited information available on the safety of Cannabidiol in cosmetic products, the Commission requested the SCCS to carry out a safety assessment of that ingredient on the basis of the information provided by the cosmetics industry following a call for data from June 2023 to October 2024. The SCCS was requested to assess the maximum concentration of Cannabidiol that is considered safe for use in cosmetic products and to identify the maximum safe level of THC present as a contaminant in Cannabidiol preparations.

(33) The SCCS considered in its opinion of 26 March 2026 ([15]) that Cannabidiol is safe when used at concentrations of up to 0.19 % in dermal cosmetic products and oral cosmetic products, whether used alone or together. In addition, the SCCS considered the presence of THC impurities as safe at concentrations of up to 0.00025 % (2.5 ppm) in dermal and oral cosmetic products, whether used alone or together.

(34) It can be concluded from the SCCS opinion of 26 March 2026 that there is a potential risk to human health arising from the use of Cannabidiol in cosmetic products, when the concentration of that ingredient exceeds certain levels. The use of that ingredient should therefore be restricted in Annex III to Regulation (EC) No 1223/2009.

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14 EUR-Lex - 62018CJ0663 - EN - EUR-Lex.

15 SCCS (Scientific Committee on Consumer Safety), Scientific Advice on Cannabidiol (CBD) (CAS/EC No. 13956-29- 1/ 689-176-3) used in cosmetic products, preliminary version of 30 October 2025, final version of 26 March 2026, SCCS/1685/25.

(35) The substance Hydroxyapatite (CAS No 1306-06-5 and 12167-74-7) in nano form is listed in entry 372 of Annex III to Regulation (EC) No 1223/2009. It is used in cosmetic products as an abrasive, bulking, oral care and skin conditioning agent. In view of potential concerns of that substance related to human safety, the Commission requested the SCCS to carry out a safety assessment on Hydroxyapatite (nano) on the basis of the information provided by the industry.

(36) The SCCS considered in its opinion of 26 June 2025 ([16]) that Hydroxyapatite (nano) is safe when used at concentrations of up to 29.5 % in toothpaste, and up to 10 % in mouthwash. Such safety evaluation applies only to the Hydroxyapatite (nano) composed of rod-shaped particles of which at least 87 % (in particle number) have aspect ratios equal to or less than 3, and the remaining 13 % have aspect ratios not exceeding 9. In addition, the Hydroxyapatite (nano) particles are not coated or surface-modified. The SCCS opinion relates to Hydroxyapatite particles having a maximum length of the Hydroxyapatite nanoparticles that is to say 122 ± 43 nm.

(37) In light of the SCCS opinion of 26 June 2025, the existing entry 372 of Hydroxyapatite (nano) in Annex III to Regulation (EC) No 1223/2009 should be amended.

(38) Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(39) The amendments to Regulation (EC) No 1223/2009, that are based on the classifications of the relevant substances as CMR substances pursuant to Delegated Regulation (EU) 2025/1222, should apply from the same date as those classifications, which is 1 February 2027.

(40) The cosmetics industry should be granted reasonable transitional periods to adapt to the new requirements of Regulation (EC) No 1223/2009 that are not linked to the classification of the relevant substances as CMR substances pursuant to Delegated Regulation (EU) 2025/1222. In particular the transitional periods should allow the cosmetics industry to carry out the necessary reformulation of cosmetic products in order to ensure that only compliant products are placed on the Union market. In addition, economic operators should be allowed a reasonable period of time to withdraw cosmetic products that do not comply with the new requirements from the market.

(41) The measures provided for in this Regulation are in accordance with the opinions of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III and V to Regulation (EC) No 1223/2009 are 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*.

[16] SCCS (Scientific Committee on Consumer Safety), Preliminary Opinion on Hydroxyapatite (nano), submission IV version of 27 March 2025, SCCS/1677/25, final version of 26 June 2025.

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