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## COVER NOTE

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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 November 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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No. Cion doc.:	<a href="#">[...]</a> (2023) XXX draft -D 093318/1
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of the nanomaterials Styrene/Acrylates copolymer, Sodium Styrene/Acrylates copolymer, Copper, Colloidal Copper, Hydroxyapatite, Gold, Colloidal Gold, Gold Thioethylamino Hyaluronic Acid, Acetyl heptapeptide-9 Colloidal gold, Platinum, Colloidal Platinum, Acetyl tetrapeptide-17 Colloidal Platinum and Colloidal Silver in cosmetics products

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Delegations will find attached document [\[...\]](#)(2023) XXX draft -D 093318/1.

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Encl.: [\[...\]](#)(2023) XXX draft -D 093318/1



EUROPEAN  
COMMISSION

Brussels, XXX  
[...] (2023) 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 of the nanomaterials Styrene/Acrylates copolymer, Sodium  
Styrene/Acrylates copolymer, Copper, Colloidal Copper, Hydroxyapatite, Gold,  
Colloidal Gold, Gold Thioethylamino Hyaluronic Acid, Acetyl heptapeptide-9 Colloidal  
gold, Platinum, Colloidal Platinum, Acetyl tetrapeptide-17 Colloidal Platinum and  
Colloidal Silver in cosmetics products**

(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 of the nanomaterials Styrene/Acrylates copolymer, Sodium Styrene/Acrylates copolymer, Copper, Colloidal Copper, Hydroxyapatite, Gold, Colloidal Gold, Gold Thioethylamino Hyaluronic Acid, Acetyl heptapeptide-9 Colloidal gold, Platinum, Colloidal Platinum, Acetyl tetrapeptide-17 Colloidal Platinum and Colloidal Silver in cosmetics 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<sup>1</sup>, and in particular Article 16(6) thereof,

Whereas:

- (1) Regulation (EC) No 1223/2009 provides that for every cosmetic product that contains nanomaterials, a high level of protection of human health is to be ensured. That Regulation further provides that, in the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission is to make a request to the Scientific Committee on Consumer Safety (SCCS) for its opinion on the safety of the nanomaterial for use in cosmetic products.
- (2) On 8 January 2021 the SCCS adopted a Scientific advice on the safety of nanomaterials in cosmetics<sup>2</sup> concluding that with a collective consideration of the physicochemical, toxicological and exposure aspects of Styrene/Acrylates Copolymer (nano), Sodium Styrene/Acrylates Copolymer (nano) (CAS No. 9010-92-8) and Colloidal Silver (nano) (CAS No. 7440-22-4) there is a basis for concern that those nanomaterials, as notified through the cosmetic products notification portal (CPNP), can pose a health risk to the consumer when used in cosmetic products.
- (3) On 5 March 2021, the SCCS adopted an Opinion on Copper (nano) and Colloidal Copper (nano)<sup>3</sup> (CAS No. 7440-50-8), concluding that it is not possible to carry out a safety assessment due to the limited or missing essential information. However, the SCCS indicated that based on the available information from scientific literature and in the CPNP, a systemic uptake of Copper nanoparticle (and/or ionic Copper) is possible and could lead to accumulation in certain organs, notably the liver and spleen. In addition, the SCCS found that the potential mutagenic/genotoxic and immunotoxic/nephrotoxic effects of Copper nanomaterials raise concerns that warrants further safety evaluation of copper nanomaterials used as cosmetic ingredients.

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<sup>1</sup> OJ L 342, 22.12.2009, p. 59.

<sup>2</sup> SCCS (Scientific Committee on Consumer Safety), Scientific advice on the safety of nanomaterials in cosmetics, preliminary version of 6 October 2020, final version of 8 January 2021, SCCS/1618/20, Corrigendum of 8 March 2021.

<sup>3</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on Copper (nano) and Colloidal Copper (nano), preliminary version of 27-28 October 2020, final version of 5 March 2021, SCCS/1621/2020

- (4) On 25 June 2021, the SCCS adopted an Opinion<sup>4</sup> on Gold (nano), Colloidal Gold (nano) (CAS No. 7440-57-5), Gold Thioethylamino Hyaluronic Acid (nano) (CAS No. 1360157-34-1) and Acetyl heptapeptide-9 Colloidal gold (nano) (CAS No. not reported) and an Opinion<sup>5</sup> on Platinum (nano), Colloidal Platinum (nano) (CAS No. 7440-06-4) and Acetyl tetrapeptide-17 Colloidal Platinum (nano) (CAS No. not reported). In both opinions, the SCCS concluded that it is not possible to carry out a safety assessment due to the limited or missing essential information. However, based on the collective consideration of the physicochemical, toxicological and exposure aspects, it also concluded that the use of such nanomaterials in cosmetic products can pose a health risk to the consumer.
- (5) In light of the Opinions and the Advice of the SCCS, it can be concluded that there is insufficient data to assess the safety of Styrene/Acrylates copolymer (nano), Sodium Styrene/Acrylates copolymer (nano), Copper (nano), Colloidal Copper, Colloidal Silver (nano), Gold (nano), Colloidal Gold (nano), Gold Thioethylamino Hyaluronic Acid (nano), Acetyl heptapeptide-9 Colloidal gold (nano), Platinum (nano), Colloidal Platinum (nano) and Acetyl tetrapeptide-17 Colloidal Platinum (nano) in cosmetic products and, therefore, a potential risk to human health arising from the use of those substances in such products.
- (6) On 22 March 2023, the SCCS adopted an Opinion on Hydroxyapatite (nano)<sup>6</sup> (CAS No. 1306-06-5/12167-74-7). The SCCS concluded that Hydroxyapatite (nano) is safe when used at concentrations up to 10 % in toothpaste, and up to 0,465 % in mouthwash. The SCCS also stressed that their conclusions apply only to Hydroxyapatite (nano) composed of rod-shaped particles, that are not coated or surface modified, of which at least 95,8 % (in particle number) have an aspect ratio less than 3, and the remaining 4,2 % have an aspect ratio not exceeding 4,9. In addition, no data was provided to allow an assessment of consumer safety from inhalation exposure and, therefore, the SCCS stressed that their conclusions are not applicable to sprayable products that might lead to exposure of the consumer's lungs to nanoparticles by inhalation.
- (7) In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of Hydroxyapatite (nano) in cosmetic products when the concentration of that substance exceeds certain levels or when it is used in sprayable products that might lead to exposure of the consumer's lungs to nanoparticles by inhalation. Therefore, the use of Hydroxyapatite (nano) in cosmetic products should be restricted to a maximum concentration of 10 % in toothpaste and of 0,465 % in mouthwash with the respective characteristics, while the use of Hydroxyapatite (nano) in applications that may lead to exposure of the end user's lungs by inhalation should not be allowed.
- (8) Regulation (EC) No 1223/2009 should therefore be amended accordingly.

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<sup>4</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on Gold (nano), Colloidal Gold (nano), Gold Thioethylamino Hyaluronic Acid (nano) and Acetyl heptapeptide-9 Colloidal gold (nano), final version of 24-25 June 2021, SCCS/1629/2021.

<sup>5</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on Platinum (nano), Colloidal Platinum (nano) and Acetyl tetrapeptide-17 Colloidal Platinum (nano), final version of 24-25 June 2021, SCCS/1630/21

<sup>6</sup> SCCS (Scientific Committee on Consumer Safety), Opinion on Hydroxyapatite (nano), preliminary version 4 January 2023, final version 21-22 March 2023, SCCS/1648/22

- (9) The industry should be allowed a reasonable period of time to adapt to the new requirements, including by making the necessary adjustments to product formulations and to labelling in order to ensure that only cosmetic products complying with the new requirements are placed on the market. Economic operators should also be allowed a reasonable period of time to withdraw from the market those cosmetic products that do not comply with the new requirements and which were placed on the market before the new requirements become applicable. The length of those periods should be determined considering the SCCS concerns and the potential risk to human health associated to the nanomaterials concerned, as well as the number of cosmetic products concerned.
- (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 and III 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*.

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*