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 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 in cosmetics products

(Text with EEA relevance)

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(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 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[2] concluding that with a collective consideration of the physicochemical, toxicological and exposure aspects of Styrene/Acrylates copolymer (nano) and Sodium styrene/Acrylates copolymer (nano) (CAS No. 9010-92-8) there is a basis for concern that these nanomaterials as notified through the CPNP can pose a health risk to the consumer.

(3) On 5 March 2021, the SCCS adopted an Opinion on Copper (nano) and Colloidal Copper (nano)[3] (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 may lead to accumulation in certain organs, notably the liver and spleen. In addition, the potential mutagenic/genotoxic and immunotoxic/nephrotoxic effects of Copper nanomaterials raise concerns.

(4) On 30 March 2021, the SCCS adopted an Opinion on Hydroxyapatite (nano)[4] (CAS No. 1306-06-5 / 12167-74-7). The SCCS could not conclude on the safety of

1 OJ L 342, 22.12.2009, p. 59.
2 SCCS/1618/20.
3 SCCS/1621/20.
4 SCCS/1624/20.

Hydroxyapatite (nano) composed of rod-shaped nanoparticles for use in oral-care cosmetic products remarking that the available data/information is not sufficient to exclude concerns over its genotoxic potential.

(5) On 25 June 2021, the SCCS adopted two Opinions, one 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)[5] (CAS No. not reported) and a second one on Platinum (nano), Colloidal Platinum (nano) (CAS No. 7440-06-4) and Acetyl tetrapeptide-17 Colloidal Platinum (nano)[6] (CAS No. not reported). In either case, the SCCS was not able to carry out a safety assessment due to the limited or missing essential information. However, the SCCS concluded that based on the collective consideration of the physicochemical, toxicological and exposure aspects the use of such nanomaterials in cosmetic products raise concerns regarding consumer safety.

(6) To ensure a high level of protection of human health for cosmetic products that contain nanomaterials, even when there is insufficient data, it is necessary to uniformly implement within the internal market the prohibition to use the nanomaterials for which the SCCS has identified a basis of concern in their Opinions and Advice.

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

(8) 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 specific nanomaterials, as well as the number of cosmetic products concerned.

(9) 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

Annex 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.*

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

[5] SCCS/1629/21.
[6] SCCS/1630/21.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen