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[...](2022) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Annexes III and VI to Regulation (EC) No 1223/2009 of the European
Parliament and of the Council**

(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 Butylated Hydroxytoluene, Acid Yellow 3, Homosalate and HAA299 in cosmetic products and correcting that Regulation as regards the use of Resorcinol in cosmetic 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 products¹, and in particular Article 31(1) thereof,

Whereas:

- (1) The substance ‘2,6-Di-Tert-Butyl-4-Methylphenol’ (CAS No 128-37-0), which has been assigned the name Butylated Hydroxytoluene under the International Nomenclature of Cosmetic Ingredients (INCI), is currently not regulated under Regulation (EC) No 1223/2009. Butylated Hydroxytoluene is a synthetic antioxidant that helps maintain the properties and performance of products when exposed to air and is widely used in cosmetics.
- (2) In light of concerns related to potential endocrine disrupting properties of Butylated Hydroxytoluene, the Commission launched a public call for data in 2019. The industry submitted scientific evidence to demonstrate the safety of Butylated Hydroxytoluene when used in cosmetic products. The Commission requested the Scientific Committee for Consumer Safety (SCCS) to carry out a safety assessment of Butylated Hydroxytoluene in view of the information provided.
- (3) The SCCS concluded in its opinion of 2 December 2021² that Butylated Hydroxytoluene is safe as an ingredient up to a maximum concentration of 0,001 % in mouthwash, 0,1 % in toothpaste and 0,8 % in other leave-on and rinse-off products, when those product categories are used individually or together.
- (4) In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of Butylated Hydroxytoluene in mouthwash, toothpaste and other leave-on and rinse off products when the concentration of that substance exceeds certain levels. Therefore, the use of Butylated Hydroxytoluene in those products should be restricted to a maximum concentration of 0,001 %, 0,1 % and 0,8 % respectively.

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS (Scientific Committee on Consumer Safety), scientific opinion on Butylated Hydroxytoluene (BHT), preliminary version of 27 September 2021, final version of 2 December 2021, SCCS/1636/21 https://ec.europa.eu/health/publications/butylated-hydroxytoluene-bht_en

- (5) The substance '1H-Indene-1,3(2H)-dione, 2-(2-quinoliny)-, sulfonated, sodium salts' (CAS No 8004-92-0), which has been assigned the INCI name Acid Yellow 3, is currently listed under entry 82 of Annex IV to Regulation (EC) No 1223/2009 and is therefore allowed for use as a colorant in cosmetic products without any maximum concentration.
- (6) Based on data provided by the industry on the use of Acid Yellow 3 in non-oxidative hair colouring products, the SCCS concluded in its opinion of 23 July 2021³ that Acid Yellow 3 is safe when used in such products at on-head concentrations of up to 0,5 %.
- (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 Acid Yellow 3 in non-oxidative hair colouring products when the concentration of that substance exceeds a certain level. Therefore, the use of Acid Yellow 3 in those products should be restricted to a maximum concentration of 0,5 %.
- (8) The substance 'Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester' (CAS No 118-56-9), which has been assigned the INCI name Homosalate, is listed under entry 3 of Annex VI to Regulation (EC) No 1223/2009 and is therefore allowed for use as a UV filter in cosmetic products with a maximum concentration of 10 % in ready for use preparation.
- (9) In light of concerns related to potential endocrine disrupting properties of Homosalate, the Commission launched a public call for data in 2019. The industry submitted scientific evidence to demonstrate the safety of Homosalate when used in cosmetic products. The Commission requested the SCCS to carry out a safety assessment of Homosalate in view of the information provided.
- (10) The SCCS concluded in its opinion of 24-25 June 2021⁴ that Homosalate is not safe when used as a UV-filter in cosmetic products at concentrations of up to 10 %. The SCCS found that the use of Homosalate as a UV filter in cosmetic products is safe for the consumer only up to a maximum concentration of 0,5 % in the final product.
- (11) On 30 July 2021, to ensure broad availability of UV-filters and consequently adequate sun protection for consumers, industry submitted a re-calculation of the margin of safety based only on the use of Homosalate in face products (face cream and pump-spray products). On the basis of the information provided by industry, and considering the concerns related to potential endocrine disrupting properties of Homosalate, the SCCS issued scientific advice on 2 December 2021⁵, where it concluded that Homosalate is safe as a UV-filter at concentrations up to 7,34% when used in face products in the form of cream and pump spray. Therefore, the use of Homosalate should be restricted to face products (non-spray and pump spray products) only, up to a maximum concentration of 7,34 %. The combined use of Homosalate up to 0,5% in all cosmetic products and up to 7,34% in face products is not considered safe by the SCCS since the margin of safety of such combined use is below 100.

³ SCCS (Scientific Committee on Consumer Safety), Opinion on Acid Yellow 3 – C054 (CAS No. 8004-92-0, EC No 305-897-5), final version of 23 July 2021, SCCS/1631/21 https://ec.europa.eu/health/publications/acid-yellow-3-c054-cas-no-8004-92-0-ec-no-305-897-5-submission-ii_en

⁴ SCCS (Scientific Committee on Consumer Safety), Opinion on Homosalate, (CAS No 118-56-9, EC No 204-260-8), preliminary version of 27-28 October 2020, final version of 24-25 June 2021, SCCS/1622/20, https://ec.europa.eu/health/publications/homosalate_en

⁵ SCCS (Scientific Committee on Consumer Safety), Scientific Advice on the safety of Homosalate (CAS No 118-56-9, EC No 204-260-8) as a UV-filter in cosmetic products, final version of 2 December 2021, SCCS/1638/21, https://ec.europa.eu/health/system/files/2021-12/sccs_o_260.pdf

- (12) In light of the SCCS scientific advice, it can be concluded that there is a potential risk to human health arising from the use of Homosalate as a UV filter in cosmetic products in the concentration currently allowed. Therefore, the use of Homosalate should be restricted to face products (non-spray and pump spray products) only up to a maximum concentration of 7,34 %.
- (13) The substance ‘1,1’-(1,4-piperazinediyl)bis[1-[2-[4-(diethylamino)-2-hydroxybenzoyl]phenyl]-methanone’, which has been assigned the INCI name Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (HAA299), is a cosmetic ingredient with the reported functions of a UV-filter. HAA299 is currently not regulated under Regulation (EC) No 1223/2009.
- (14) In 2009, the Commission received a dossier from the industry to support the safe use of HAA299 (micronised and non-micronised) in cosmetic products, which was further substantiated with additional information in 2012. SCCS concluded in an opinion of 23 September 2014⁶ that the use of HAA299 in non-nano form (micronised or non-micronised, with median particle size distribution around 134 nm or larger) at a concentration up to 10 % as a UV-filter in cosmetic products does not pose a risk of systemic toxicity in humans. In addition, the SCCS stated that its opinion did not cover the safety evaluation of HAA299 which is composed of nano particles.
- (15) In view of that opinion on the non-nano form of HAA299, the industry submitted in September 2020 additional data and requested an assessment of the safety of HAA299 in nano form intended to be used as a UV-filter up to a maximum concentration of 10 %.
- (16) The SCCS concluded in its opinion of 26 and 27 October 2021⁷ that HAA299 in nano form, as covered within the provided characteristics (minimum purity equal to or above 97 %, median particle size in terms of particle number equal to or above 50 nm), is safe when used as a UV-filter in dermally applied cosmetic products up to a maximum concentration of 10 %. Considering the inflammatory effects on the lung after acute inhalation exposure to products containing HAA299 (nano), the SCCS did not recommend the use of HAA299 (nano) in applications that could lead to exposure of the consumer’s lungs via inhalation.
- (17) The SCCS finally concluded that it had not been provided with any data that would merit a revision of its previous opinion and that HAA299 therefore can be considered safe both in its non-nano and in its nano form, when used as a UV-filter in cosmetic products up to a maximum concentration of 10 %. The SCCS also considers that the combined maximum concentration of non-nano and nano forms of HAA299 should not exceed 10 % in a cosmetic product.
- (18) In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of HAA299 as a UV-filter in cosmetic products when the concentration of that substance exceeds a certain level. Therefore, the use of HAA299 in those products should be restricted to a maximum concentration of 10 %. With

⁶ SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of 2-(4-(2-(4-Diethylamino-2-hydroxy-benzoyl)-benzoyl)-piperazine-1-carbonyl)-phenyl)-(4-diethylamino-2-hydroxyphenyl)-methanone, HAA299 as UV filter in sunscreen products, 18 June 2014, SCCS/1533/14, revision of 23 September 2014,

⁷ SCCS (Scientific Committee on Consumer Safety), Opinion on HAA299 (nano), preliminary opinion 22 July 2021, final opinion of 26-27 October 2021, SCCS/1634/2021, https://ec.europa.eu/health/publications/haa299-nano_en

regard to HAA 299 (nano), a condition should be introduced regarding its use in applications that may lead to exposure of the lungs.

- (19) Regulation (EC) No 1223/2009 should therefore be amended and corrected accordingly.
- (20) The industry should be allowed reasonable periods of time to adapt to the new requirements, including by making the necessary adjustments to product formulations in order to ensure that only cosmetic products complying with the new requirements are placed on the market. The industry should also be allowed a reasonable period of time to withdraw cosmetic products which do not comply with those requirements. As regards the new restrictions for Homosalate, the reformulation of products containing that UV filter is technically challenging and it is necessary to measure the efficacy of the sun protection factor of the reformulated products. Therefore, longer transition periods should be allowed for the industry to ensure compliance of products containing Homosalate with the new restrictions.
- (21) The substance '1,3-benzenediol' (CAS No 108-46-3), which has been assigned the INCI name Resorcinol, is currently listed under entry 22 of Annex III to Regulation (EC) No 1223/2009 as allowed for use in oxidative hair dye products, products intended for colouring eyelashes and hair lotions and shampoos with certain restrictions. With regard to oxidative hair dye products, the label is to contain the following warning: 'Do not use to dye eyelashes or eyebrows'.
- (22) According to the definition of the term 'hair product' in Regulation (EC) No 1223/2009, which became applicable on 11 July 2013, a hair product means a cosmetic product that is intended to be applied on the hair of head or face, except eye lashes. The exclusion of eyelashes was motivated by the fact that the level of risk is different when cosmetic products are applied on the hair on the head and on eyelashes respectively.
- (23) Entry 22 in Annex III to Regulation (EC) No 1223/2009 was amended by Commission Regulation (EU) No 1197/2013⁸ to allow professional use of Resorcinol in products intended for colouring eyelashes. At that time, the warning concerning the use for eyebrows should have been deleted, since the use of Resorcinol in products intended for colouring eyebrows, considering the new definition, was allowed as included in the product type 'oxidative hair dye products'. That error should be corrected.
- (24) 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

Amendments

Annexes III and VI to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

⁸ Commission Regulation (EU) No 1197/2013 of 25 November 2013 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 315, 26.11.2013, p. 34).

Correction

In Annex III to Regulation (EC) No 1223/2009, in the row for entry 22, column i, point (a), the last sentence is replaced by the following:

‘Do not use to dye eyelashes.’.

Article 3

Entry into force

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