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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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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 of Vitamin A, Alpha-Arbutin and Arbutin and certain substances with potential endocrine disrupting properties in cosmetic products

Delegations will find attached document [...] (2023) XXX draft - D 093281/1.

Encl.: [...] (2023) XXX draft - D 093281/1



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 Vitamin A, Alpha-Arbutin and Arbutin and certain substances
with potential endocrine disrupting properties in cosmetic 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 Vitamin A, Alpha-Arbutin and Arbutin and certain substances with potential endocrine disrupting properties 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 substances ‘(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethylcyclohexen-1-yl)nona-2,4,6,8-tetraen-1-ol’ (CAS No. 11103-57-4/68-26-8), ‘[(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethylcyclohexen-1-yl)nona-2,4,6,8-tetraenyl] acetate’ (CAS No. 127-47-9), and ‘[(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethylcyclohexen-1-yl)nona-2,4,6,8-tetraenyl] hexadecanoate’ (CAS No. 79-81-2), which have been assigned the names ‘Retinol’, ‘Retinyl Acetate’ and ‘Retinyl Palmitate’, respectively, under the International Nomenclature of Cosmetic Ingredients (INCI) and which are collectively known as vitamin A, are not regulated under Regulation (EC) No 1223/2009. Those substances are used in cosmetic products as skin conditioning agents.
- (2) The Scientific Committee for Consumer Safety (SCCS) concluded, in its opinion of 6 October 2016², that the use of vitamin A is safe but recognised that the population’s overall exposure to vitamin A could exceed the upper intake level established by the European Food Safety Authority. On 24-25 October 2022, the SCCS adopted a revised scientific opinion on vitamin A³ concluding that vitamin A is safe in cosmetic products up to concentrations of 0,05 % Retinol Equivalent (RE) in body lotion and 0,3 % RE in other leave-on and rinse-off products. The SCCS added that the contribution of vitamin A from cosmetic products to the overall consumer exposure, although low, may be of concern for consumers with the highest exposure to vitamin A (5 % of the total population) from food and food supplements.
- (3) In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of vitamin A in cosmetic products when its concentration exceeds certain levels. Therefore, the use of Retinol, Retinyl Acetate and Retinyl Palmitate should be restricted to a maximum concentration of 0,05 % RE in body lotion and 0,3 % RE in other leave-on and rinse-off products. In addition, a warning

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS (Scientific Committee on Consumer Safety), Opinion on Vitamin A (Retinol, Retinyl Acetate, Retinyl Palmitate), SCCS/1576/16, 20 April 2016, final version of 6 October 2016, CORRIGENDUM on 23 December 2016, SCCS/1576/16.

³ SCCS (Scientific Committee on Consumer Safety), revision of the scientific Opinion (SCCS/1576/16) on vitamin A (Retinol, Retinyl Acetate, Retinyl Palmitate), preliminary version of 10 December 2021, final version of 24-25 October 2022, SCCS/1639/21SCCS/1639/21.

should be included to inform consumers already exposed to vitamin A from food and food supplements of the possibility of overexposure from the use of such compounds.

- (4) The substances '4-Hydroxyphenyl-alpha-D-glucopyranoside' (CAS No. 84380-01-8) and '4-Hydroxyphenyl-beta-D-glucopyranoside' (CAS No. 497-76-7), which have been assigned the INCI names 'Alpha-Arbutin' and 'Arbutin', respectively, are not regulated under Regulation (EC) No 1223/2009. Those substances are used in cosmetic products as skin bleaching and skin conditioning agents.
- (5) The SCCS concluded in its opinion of 27 May 2015 on Alpha-Arbutin⁴ and in its opinion of 26 March 2015 on Arbutin⁵ that both substances, when used in limited concentrations, were safe for consumers in cosmetic products. However, it stressed that the potential combined use of those substances and other hydroquinone releasing substances in cosmetic products was not evaluated, and that it could be of concern. On 31 January 2023, the SCCS adopted an opinion on the safety of Alpha-Arbutin and Arbutin in cosmetic products⁶ confirming its previous conclusion that Alpha-Arbutin used in face creams up to a maximum concentration of 2 % and in body lotions up to a concentration of 0,5 % is safe and that Arbutin used in face creams up to a maximum concentration of 7 % is safe. The SCCS also concluded that the aggregate exposure of Alpha-Arbutin with Arbutin are considered safe for consumers. The SCCS also stressed that the presence of Hydroquinone (CAS No. 123-31-9) should remain as low as possible in formulations containing Alpha-Arbutin and Arbutin and should not be higher than the unavoidable trace levels.
- (6) In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of Alpha-Arbutin and Arbutin in cosmetic products when the concentration of those substances exceeds certain levels. Therefore, the use of Alpha-Arbutin should be restricted to a maximum concentration of 2 % in face creams and to a maximum concentration of 0,5 % in body lotions, while the use of Arbutin should be restricted to a maximum concentration of 7 % in face creams. The level of Hydroquinone in cosmetic products containing Alpha-Arbutin or Arbutin should not be higher than the unavoidable trace level.
- (7) The substance '3-(4'-methylbenzylidene)-camphor' (CAS No. 36861-47-9/38102-62-4), which has been assigned the INCI name '4-Methylbenzylidene Camphor', is listed under entry 18 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 4 % in ready for use preparations. 4-Methylbenzylidene Camphor has additional reported functions as a 'UV-absorber' and a 'light stabiliser', which are allowed pursuant to Article 14(1), point (e)(ii), of Regulation (EC) No 1223/2009 up to a concentration of 4 %.
- (8) The substances 'Genisteol 4',5,7-Trihydroxyisoflavone' (CAS No. 446-72-0), 'Daidzeol 7,4'- Dihydroxyisoflavone' (CAS No. 486-66-8) and '5-Hydroxy-2-(hydroxymethyl)-4H-pyran-4-one' (CAS No. 501-30-4), which have been assigned the INCI names 'Genistein', 'Daidzein' and 'Kojic Acid', respectively, are not regulated under Regulation (EC) No 1223/2009. Genistein and Daidzein are used in

⁴ SCCS (Scientific Committee on Consumer Safety), Opinion on α -arbutin, 27 May 2015, SCCS/1552/15.

⁵ SCCS (Scientific Committee on Consumer Safety), Opinion on β -arbutin, SCCS/1550/15, 25 March 2015.

⁶ SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of alpha- (CAS No. 84380-018, EC No. 617-561-8) and beta-arbutin (CAS No. 497-76-7, EC No. 207-8503) in cosmetic products, preliminary version of 15-16 March 2022, final version of 31 January 2023, SCCS/1642/22.

cosmetic products as skin conditioning agents, protecting agents and antioxidants, whereas Kojic Acid is used in cosmetic products as a skin lightening agent, a whitening agent, or a depigmenting agent.

- (9) The substance ‘5-Chloro-2-(2,4-dichlorophenoxy)phenol’ (CAS No. 3380-34-5), which has been assigned the INCI name ‘Triclosan’, is currently listed under entry 25 of Annex V to Regulation (EC) No 1223/2009 and is therefore allowed for use as a preservative in cosmetic products with a maximum concentration of 0,3 % in toothpastes, hand soaps, body soaps/shower gels, deodorants (non-spray), face powders and blemish concealers, and in nail products for cleaning the fingernails and toenails before the application of artificial nail systems, and with a maximum concentration of 0,2 % in mouthwashes.
- (10) The substance ‘1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea’ (CAS No. 101-20-2), which has been assigned the INCI name ‘Triclocarban’, is currently listed under entry 23 of Annex V to Regulation (EC) No 1223/2009 and is therefore allowed for use as a preservative in cosmetic products with a maximum concentration of 0,2 %. In addition, Triclocarban is listed under entry 100 of Annex III to that Regulation and is therefore allowed for purposes other than inhibiting the development of micro-organisms in rinse-off products with a maximum concentration of 1,5 %.
- (11) In light of concerns related to potential endocrine disrupting properties of ‘4-Methylbenzylidene Camphor’, ‘Genistein’, ‘Daidzein’, ‘Kojic Acid’, ‘Triclosan’ and ‘Triclocarban’, the Commission launched a public call for data in 2019. The industry submitted scientific evidence to demonstrate the safety of those substances when used in cosmetic products. The Commission requested the SCCS to carry out a safety assessment of those substances in view of the information provided by the industry.
- (12) In its opinion of 29 April 2022⁷, the SCCS could not conclude on the safety of 4-Methylbenzylidene Camphor because the information provided was insufficient to fully evaluate potential genotoxicity. The SCCS observed, however, that there is sufficient evidence that 4-Methylbenzylidene Camphor may act as an endocrine disruptor and has effects on both the thyroid and estrogen systems and that it is not possible to derive a maximum concentration for safe use of the substance. In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of 4-Methylbenzylidene Camphor as a UV-filter in cosmetic products. The substance should, therefore, no longer be allowed as a UV-filter in cosmetic products. In addition, there is no scientific basis that the conclusions of the SCCS on the safety of 4-Methylbenzylidene Camphor would not apply when that substance is used in cosmetic products with the additional reported functions as ‘UV-absorber’ and ‘light stabiliser’ agent. To ensure that 4-Methylbenzylidene Camphor does not continue to be used in cosmetic products for purposes other than as a UV-filter, which would also present a potential risk to human health as identified in the SCCS opinion, the substance should be prohibited for all use in cosmetic products.
- (13) The SCCS concluded in its opinion of 16 September⁸ that both Genistein and Daidzein are safe for use in cosmetic products up to a maximum concentration of 0,007 % and 0,02 %, respectively. Considering the SCCS opinion, it can be concluded

⁷ SCCS (Scientific Committee on Consumer Safety), scientific opinion on 4-Methylbenzylidene camphor (4-MBC), preliminary version of 22 December, final version of 29 April 2022, SCCS/1640/21.

⁸ SCCS (Scientific Committee on Consumer Safety), Scientific opinion on genistein and daidzein, preliminary version of 12 January 2022, final version of 16 September 2022, corrigendum of 11 October 2022, SCCS/1641/22.

that there is a potential risk to human health arising from the use of Genistein and Daidzein in cosmetic products when the concentration of those substances exceeds certain levels. Therefore, the use of Genistein and Daidzein in cosmetic products should be restricted to a maximum concentration of 0,007 % and 0,02 %, respectively.

- (14) The SCCS concluded in its opinion of 15-16 March 2022⁹ that Kojic Acid is safe when used as a skin lightening agent in cosmetic products up to a maximum concentration of 1 %. Considering the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of Kojic Acid in cosmetic products when its concentration exceeds certain levels. Therefore, Kojic Acid should be restricted to use as a skin lightening agent in face and hand products with a maximum concentration of 1 %.
- (15) The SCCS concluded in a scientific advice on Triclosan adopted on 24-25 October 2022¹⁰ that use of Triclosan as a preservative in dermally applied cosmetic products is safe up to a maximum concentration of 0,3 % for both children (0,5-18 years) and adults, with the exception of body lotion. It also concluded that the use of Triclosan as a preservative in toothpaste at a concentration of 0,3 % is safe for both children (0,5-18 years) and adults but that the use of the substance as a preservative in toothpaste is not safe for children under 3 years of age when used in combination with other cosmetic products containing Triclosan. According to SCCS, the use of Triclosan as a preservative in mouthwash is safe for adults at a maximum concentration of 0,2 % when used individually but not when used in combination with other cosmetic products containing Triclosan, while for children and adolescents, it is not safe at 0,2 % in mouthwash, even when used individually.
- (16) 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 Triclosan in cosmetic products when its concentration exceeds certain levels, when there is a combined use of different cosmetic products containing that substance and when it is used by certain age groups. Therefore, the use of Triclosan as a preservative in cosmetic products should remain restricted to a maximum concentration of 0,3 % for toothpastes, hand soaps, body soaps/shower gels, deodorants (non-spray), face powders and blemish concealers, nail products for cleaning the fingernails and toenails before the application of artificial nail systems. Triclosan should neither be allowed for use in mouthwash, nor in toothpaste intended for children under 3 years of age. Labelling requirements should also be introduced, to further enhance the protection of consumers and facilitate market surveillance activities in Member States.
- (17) The SCCS concluded in a scientific advice on Triclocarban adopted on 24-25 October 2022¹¹ that the use of Triclocarban as a preservative up to a maximum concentration of 0,2 % is safe in dermally applied cosmetic products for both children (0,5-18 years) and adults but is neither safe in mouthwash for adults and children, nor in toothpaste

⁹ SCCS (Scientific Committee on Consumer Safety), scientific opinion on Kojic acid, preliminary version of 26-27 October 2021, final version of 15-16 March 2022, Corrigendum of 10 June 2022, SCCS/1637/2.

¹⁰ SCCS (Scientific Committee on Consumer Safety), Request for a scientific advice on the safety of triclocarban (CAS No. 101-20-2, EC No. 202-924-1) and triclosan (CAS No. 3380-34-5, EC No. 222-182-2) as substances with potential endocrine disrupting properties used in cosmetic products, preliminary version of 15-16 March 2022, final version of 24-25 October 2022, SCCS/1643/22.

¹¹ SCCS (Scientific Committee on Consumer Safety), Request for a scientific advice on the safety of triclocarban (CAS No. 101-20-2, EC No. 202-924-1) and triclosan (CAS No. 3380-34-5, EC No. 222-182-2) as substances with potential endocrine disrupting properties used in cosmetic products, preliminary version of 15-16 March 2022, final version of 24-25 October 2022, SCCS/1643/22.

for children under 6 years of age. The SCCS also concluded that Triclocarban used for purposes other than inhibiting the development of micro-organisms is safe up to a maximum concentration of 1,5 % in rinse-off products for both children (0,5-18 years) and adults.

- (18) 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 Triclocarban in cosmetic products when its concentration exceeds certain levels in some cosmetic products and when it is used for certain age groups. Therefore, the use of Triclocarban as a preservative in cosmetic products should remain restricted to a maximum concentration of 0,2 %, while it should not be allowed for use in mouthwash. The use of Triclocarban in cosmetic products for other purposes should remain restricted to a maximum concentration of 1,5 % in rinse-off products. In addition, it should not be allowed in toothpaste for children under 6 years of age. Labelling requirements should also be introduced, to further enhance the protection of consumers and facilitate market surveillance activities in Member States.
- (19) Regulation (EC) 1223/2009 should therefore be amended 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 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. In particular for the prohibition of 4-Methylbenzylidene Camphor, the reformulation of products containing that UV-filter is technically challenging in view of the shrinking palette of available UV-filters, while 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 4-Methylbenzylidene Camphor. In addition, longer transition periods to ensure compliance of cosmetic products that contain Retinol, Retinyl Acetate and Retinyl Palmitate should be allowed, since there are no immediate health concerns for those substances, since their use concentrations in cosmetic products currently available on the market do not exceed the concentrations that the SCCS considers safe and since shorter deadlines would lead to withdrawals and destruction of cosmetic products with disproportionate financial and environmental costs.
- (21) 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, III, V and VI 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*.

Point (4) of the Annex shall apply from ... [OP please insert the date = first day of the month following 12 months after the date of entry into force of this Regulation]

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*