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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 Methyl-N-methylantranilate in cosmetic products

Delegations will find attached document D074549/01.

Encl: D074549/01



Brussels, **XXX**
[...] (2021) **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 Methyl-N-methylantranilate in cosmetic products**

(Text with EEA relevance)

D074549/01

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

of **XXX**

amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Methyl-N-methylantranilate 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 Methyl-N-methylantranilate (M-N-MA) (CAS No. 85-91-6) is a fragrance ingredient used in various cosmetics, including fine fragrances, shampoos, soaps and other toiletries. M-N-MA is currently not subject to any prohibition or restriction pursuant to Regulation (EC) No 1223/2009.
- (2) The Scientific Committee on Consumer Safety (SCCS) concluded in an opinion adopted at its plenary meeting of 13-14 December 2011² that there were no safety concerns for use of M-N-MA in a concentration of up to 0,2 % in rinse-off products. It further noted that M-N-MA is phototoxic, which was the toxicological endpoint of concern in that opinion. Whilst up to 0,1 % M-N-MA may be safe for use in many leave-on cosmetic products, the SCCS found that a risk cannot be excluded for the use of that substance in sunscreen or sun care products or products (including fragrances) intended for use on areas exposed to light. Moreover, the SCCS concluded that since M-N-MA is prone to nitrosation, it should not be used in combination with nitrosating agents and the nitrosamine content should be below 50 µg/kg.
- (3) At the plenary meeting of 27 March 2012, the SCCS adopted an opinion on nitrosamines and secondary amines³. In that opinion, the SCCS concluded that the purity specification of 50 µg nitrosamine/ kg should apply to raw materials and to all nitrosamines potentially formed, and not to finished products. It further concluded that the secondary amines should not be in contact with adventitious nitrosating agents such as nitrite treated raw material containers. That opinion applies also to M-N-MA, which is a secondary amine.

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS (Scientific Committee on Consumer Safety, Opinion on methyl-N-methylantranilate, 13-14 December 2011 (SCCS/1455/11).

³ SCCS (Scientific Committee on Consumer Safety) Opinion on Nitrosamines and Secondary Amines in Cosmetic Products, 27 March 2012 (SCCS/1458/11).

- (4) Subsequently, SCCS has concluded, in a scientific advice of 16 October 2020 on the SCCS opinion on M-N-MA⁴, that M-N-MA should not be used in sunscreen products and products marketed for exposure to natural or artificial UV light. For other cosmetic products, SCCS considered the use of M-N-MA safe in a concentration of up to 0,1 % for leave-on products and 0,2 % for rinse-off products.
- (5) In light of the SCCS opinions and scientific advice, there is a potential risk to human health arising from the use of M-N-MA in sunscreen products and products marketed for exposure to natural or artificial UV light and in other cosmetic products where the concentration of the substance is more than 0,1 % for leave-on products and 0,2 % for rinse-off products. Therefore, such use of M-N-MA should be prohibited.
- (6) In light of the SCCS opinions and scientific advice, there is also a potential risk to human health arising from the use of M-N-MA with nitrosating agents. Therefore, such use of M-N-MA should be prohibited, a maximum nitrosamine content of 50 µg/kg should be set and a requirement to keep cosmetic products containing M-N-MA in nitrite-free containers should be introduced.
- (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 by making the adjustments to product formulations and containers that are necessary 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 the new requirements from the market.
- (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 III 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.

⁴ Scientific advice on the SCCS Opinion on methyl N-methylantranilate (MNM) (SCCS/1455/11), 16 October 2020 (SCCS/1616/20).

Done at Brussels,

*For the Commission
The President
Ursula von der Leyen*