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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	15 July 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

Delegations will find attached document […](2020) XXX draft - D067419/01.

Encl.: […](2020) XXX draft - D067419/01

EUROPEAN
COMMISSION

Brussels, XXX
[…](2020) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Text with EEA relevance)

D067419/01

Commission Regulation (EU) …/…of XXX amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on 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 products[1], and in particular Article 31(1) thereof,

Whereas:

(1) The substances 2-hydroxyethyl methacrylate (HEMA) and 11,14-Dioxa-2,9-diazaheptadec-16-enoic Acid, 4,4,6,16-tetramethyl-10,15-dioxo, 2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl ester (Di-HEMA Trimethylhexyl Dicarbamate or Di-HEMA TMHDC) are currently not subject to prohibition or restriction pursuant to Regulation (EC) No 1223/2009.

(2) On 2 July 2014, the Swedish Medical Products Agency, which is the Swedish competent authority for the purposes of Regulation (EC) No 1223/2009, adopted and communicated a decision under Article 27 of Regulation (EC) No 1223/2009 introducing provisional restrictive measures on a nail cosmetic product that had caused a high number of undesirable effects. The substances identified as likely to cause those undesirable effects were HEMA and Di-HEMA TMHDC.

(3) According to Article 27(2) of Regulation (EC) No 1223/2009, the Swedish Medical Products Agency communicated immediately to the Commission and the competent authorities of the other Member States the measures taken and any supporting data.

(4) The Scientific Committee on Consumer Safety (SCCS) concluded in its opinion of 21-22 June 2018[2] that 'HEMA and di-HEMA-TMHDC, when applied appropriately to the nail plate (…) as part of an artificial nail modelling system, are not likely to pose a risk of sensitisation, provided that their use is restricted to the nail plate only and contact with the adjacent skin is avoided'. The SCCS further concluded that '[b]oth HEMA and di-HEMA-TMHDC are weak to moderate sensitisers and pose a risk of sensitisation from misuse of the products or from inappropriately carried out application or from unintentional contamination of the skin adjacent to the nails under normal and reasonably foreseeable conditions of use'.

(5) According to Article 3 of Regulation (EC) No 1223/2009, cosmetic products made available on the market must be safe for human health when used under normal or reasonably foreseeable conditions of use.

(6) When assessing 'normal or reasonably foreseeable conditions of use', account has to be taken of possible misuse, inappropriate or unintentional use. In the case of products

[1] OJ L 342, 22.12.2009, p. 59.

[2] SCCS/1592/17; https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_214.pdf

requiring high level of precision, it is necessary to take into account situations of insufficient precision in their application.

(7) Cases of sensitisation to nail products containing HEMA and Di-HEMA TMHDC reported in some Member States lead the Commission to the conclusion that there is a risk that such products may be applied with insufficient precision, causing contact with the skin adjacent to the nail plate.

(8) A distinction should be made between professional and consumer use of cosmetic products. Higher safety standards are expected from professionals. In particular, a professional is expected to have more skills, experience and knowledge on the use of a cosmetic product compared to the consumer.

(9) Possible health and safety risks for professionals are regulated by certain Union Directives laying down minimum requirements, in particular Council Directives 89/391/EEC[3] and 98/24/EC[4]. Additional professional safety rules may apply.

(10) As regards consumers, since the SCCS opinion considers the substances HEMA and Di-HEMA TMHDC safe in nail products only when applied on the nail plate and since 'normal or reasonably foreseeable conditions of use' should take into account the possibility of application on the skin adjacent to the nail plate, there is a potential risk to human health from the use of HEMA and Di-HEMA TMHDC in nail products.

(11) As the use of nail products containing HEMA and Di-HEMA TMHDC by professionals is expected to be safer for the consumer, such products should be used only by professionals and therefore the warning 'for professional use only' should be added on the package of such products.

(12) To draw attention of both professionals and consumers to the potential health risk, the warning 'can cause an allergic reaction' should be added on the package of nail products containing HEMA and Di-HEMA TMHDC.

(13) Therefore, the safeguard measure taken by Sweden should be considered as justified. Consequently, it is necessary to impose a restriction on the use of HEMA and Di-HEMA TMHDC in nail products.

(14) Annex III to Regulation (EC) No 1223/2009 should therefore be amended accordingly.

(15) It is appropriate to provide for a reasonable period of time in order for the industry to adapt to the new requirements.

(16) 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.

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[3] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

[4] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

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