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

date of receipt: 23 February 2022

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

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Delegations will find attached document [...] (2022) XXX draft - D079385/1.

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Encl.: [...] (2022) XXX draft - D079385/1



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

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

**of **XXX****

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

(Text with EEA relevance)

**COMMISSION REGULATION (EU) .../... of XXX**

**amending the preamble of Annex V 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<sup>1</sup>, and in particular Article 31(1) thereof,

Whereas:

- (1) The substance formaldehyde (CAS No. 50-00-0, EC No. 200-001-8) has been classified as a carcinogen (Category 1B) and a skin sensitizer (Category 1) in Part 3 of Annex VI to Regulation (EC) No 1272/2008<sup>2</sup>. According to Article 15 of Regulation (EC) No 1223/2009, substances classified as carcinogenic of category 1B in that Annex are to be prohibited from use in cosmetic products. Therefore, the use of formaldehyde as such has been prohibited in cosmetic products and is currently listed in entry 1577 of Annex II to Regulation (EC) No 1223/2009.
- (2) Annex V to Regulation (EC) No 1223/2009 contains a list of substances allowed for use in cosmetic products as preservatives. Certain of those preservatives are gradually releasing formaldehyde in order to fulfil a preserving function in the final cosmetic product (so called formaldehyde releasers). Formaldehyde releasers are used in both leave-on and rinse-off cosmetic products.
- (3) In order to inform consumers sensitised to formaldehyde about the presence of formaldehyde that may trigger an allergic reaction, it is set out in point 2 of the preamble of Annex V to Regulation (EC) No 1223/2009 that all finished products containing substances which are listed in that Annex and which release formaldehyde are to be labelled with the specific warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0,05 %.
- (4) The Scientific Committee on Consumer Safety (SCCS) concluded, in its scientific advice of 7 May 2021<sup>3</sup>, that the present threshold of 0,05 % (500 ppm) does not sufficiently protect consumers sensitised to formaldehyde. The SCCS further concluded that in order to protect the vast majority of those consumers, the current threshold for the labelling requirement should be reduced to 0,001 % (10 ppm), which

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<sup>1</sup> OJ L 342, 22.12.2009, p. 59.

<sup>2</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p.1).

<sup>3</sup> SCCS (Scientific Committee on Consumer Safety), Scientific advice on the threshold for the warning 'contains formaldehyde' in Annex V, preamble point 2 for formaldehyde-releasing substances, final version of 7 May 2021, SCCS/1632/21.

should apply to the total formaldehyde released irrespective of whether a product contains one or more formaldehyde releaser(s).

- (5) In light of the SCCS opinion, it can be concluded that the potential risk to human health arising from the use of certain substances that release formaldehyde in finished cosmetic products justify a lower threshold regarding the requirement to label such products with the specific warning 'contains formaldehyde' than the one currently applicable. That threshold should be decreased as proposed by the SCCS. Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (6) The industry should be allowed a reasonable period of time to adapt to the new requirements by making the necessary adjustments to labelling, as well as to product formulations that are necessary 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 cosmetic products which do not comply with the new requirements from the market and which were placed on the market before the new labelling provision becomes applicable. Therefore, considering the relatively low risk associated to formaldehyde releasers and the large number of cosmetic products concerned the transition period should be 24 and 48 months, respectively.
- (7) 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*

Point 2 to the Preamble of Annex V to Regulation (EC) No 1223/2009 is replaced by the following:

'2. All finished products containing substances which are listed in this Annex and which release formaldehyde shall be labelled with the warning 'releases formaldehyde' where the total concentration of formaldehyde released in the finished product exceeds 0,001 % (10 ppm), irrespective of whether the finished product contains one or more substances releasing formaldehyde.

However, all finished products containing substances referred to in the first subparagraph which comply with Regulation (EC) No 1223/2009 as applicable on [OP please insert the date = the day before the date of entry into force of this Regulation] may be placed on the Union market until [OP please insert date = 24 months after the date of entry into force of this Regulation] and be made available on the Union market until [OP please insert the date = 48 months after the date of entry into force of 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.

Done at Brussels,

*For the Commission  
The President  
Ursula von der Leyen*