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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:	ANNEX to the COMMISSION REGULATION (EU) .../... of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers

Delegations will find attached document D 084710/3 - [...] (2023) XXX draft ANNEX.

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ANNEX

ANNEX

to the

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

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament
and of the Council as regards formaldehyde and formaldehyde releasers**

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

<p>‘xx. Formaldehyde CAS No 50-00-0 EC No 200-001-8 and formaldehyde-releasing substances</p>	<p>1. Shall not be placed on the market in articles, after [<i>OP, please insert the date: 36 months after the date of entry into force of this amending Regulation</i>], if, under the test conditions specified in Appendix [X], the concentration of formaldehyde released from those articles exceeds:</p> <p>(a) 0,062 mg/m³ for furniture and wood-based articles;</p> <p>(b) 0,080 mg/m³ for articles other than furniture and wood-based articles.</p> <p>The first subparagraph shall not apply to:</p> <p>(a) articles in which formaldehyde or formaldehyde releasing substances are exclusively naturally present in the materials from which the articles are produced;</p> <p>(b) articles that are exclusively for outdoor use under foreseeable conditions;</p> <p>(c) articles in constructions, that are exclusively used outside the building shell and vapour barrier and that do not emit formaldehyde into indoor air;</p> <p>(d) articles exclusively for industrial or professional use unless formaldehyde released from them leads to exposure of the general public under foreseeable conditions of use;</p> <p>(e) articles for which the restriction laid down in entry 72 applies;</p> <p>(f) articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council*;</p> <p>(g) devices within the scope of Regulation (EU) 2017/745;</p> <p>(h) personal protective equipment within the</p>
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	<p>scope of Regulation (EU) 2016/425;</p> <p>(i) articles intended to come into contact directly or indirectly with food within the scope of Regulation (EC) No 1935/2004;</p> <p>(j) second-hand articles.</p> <p>2. Shall not be placed on the market in road vehicles after [OP, please insert the date: 48 months after the date of entry into force of this amending Regulation] if, under the test conditions specified in Appendix [X], the concentration of formaldehyde in the interior of those vehicles exceeds 0,062 mg/m³.</p> <p>The first subparagraph shall not apply to:</p> <p>(a) road vehicles exclusively for industrial or professional use unless the concentration of formaldehyde in the interior of those vehicles leads to exposure of the general public under foreseeable conditions of use;</p> <p>(b) second-hand vehicles.</p>
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* Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).’;

(2) the following Appendix [X] is added:

‘Appendix [X]

1. Measurement of formaldehyde released to indoor air from articles referred to in paragraph 1, first subparagraph, of entry [xx]

The formaldehyde released from articles referred to in paragraph 1, first subparagraph of entry [xx] shall be measured in the air of a test chamber under the following cumulative reference conditions:

(a) the temperature in the test chamber shall be $(23 \pm 0,5)^\circ \text{C}$;

- (b) the relative humidity in the test chamber shall be $(45 \pm 3) \%$;
- (c) the loading factor, expressed as the ratio of the total surface area of the test piece to the volume of the test chamber, shall be $(1 \pm 0,02) \text{ m}^2/\text{m}^3$. This loading factor corresponds to the testing of wood-based panels; for other material or products, if such a loading factor is clearly not realistic under foreseeable conditions of use, loading factors in accordance with Section 4.2.2 of EN 16516¹ may be used;
- (d) the air exchange rate in the test chamber shall be $(1 \pm 0,05) \text{ h}^{-1}$;
- (e) an appropriate analytical procedure for measuring the formaldehyde concentration in the test chamber shall be used;
- (f) an appropriate method for sampling of the test pieces shall be used;
- (g) the formaldehyde concentration in the air of the test chamber shall be measured at least twice per day throughout the test with a time interval between two consecutive samplings of 3 hours at a minimum; the measurement shall be repeated until sufficient data are available to determine the steady state concentration;
- (h) the duration of the test shall be sufficiently long to allow the determination of the steady state concentration and shall not exceed 28 days;
- (i) the steady state concentration of formaldehyde measured in the test chamber shall be used to verify the compliance with the limit value of formaldehyde released from articles referred to in paragraph 1, first subparagraph, of entry [xx].

If data from a test method using the reference conditions specified above are not available or suitable for the measurement of the formaldehyde released from a specific article, data obtained from a test method using non-reference conditions may be used, where there is a scientifically valid correlation between the results of the test method used and the reference conditions.

2. Measurement of formaldehyde concentration in the interior of vehicles referred to in paragraph 2, first subparagraph, of entry [xx]

For road vehicles, including trucks and buses, the formaldehyde concentration shall be measured in ambient mode in accordance with the conditions specified in ISO 12219-1² or ISO 12219-10³, and the concentration measured shall be used to verify the compliance with the limit value referred to in paragraph 2, first subparagraph, of entry [xx].⁷

¹ EN 16516: Construction products – Assessment of release of dangerous substances – Determination of emissions into indoor air.

² ISO 12219-1: Interior air of road vehicles – Part 1: Whole vehicle test chamber – Specification and method for the determination of volatile organic compounds in cabin interiors.

³ ISO 12219-10: Interior air of road vehicles — Part 10: Whole vehicle test chamber — Specification and methods for the determination of volatile organic compounds in cabin interiors — Trucks and buses.