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[...] (2022) XXX draft

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</p> <p>CAS No 50-00-0</p> <p>EC No 200-001-8</p> <p>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>] where formaldehyde or formaldehyde releasing substances have been intentionally added during their production, 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 wood-based articles and furniture;</p> <p>(b) 0,08 mg/m³ for articles other than wood-based articles and furniture.</p> <p>The first subparagraph shall not apply to:</p> <p>(a) articles that are only for outdoor use under reasonably foreseeable conditions;</p> <p>(b) 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>(c) articles within the scope of entry 72 of this Annex;</p> <p>(d) articles that are biocidal products within the scope of Regulation (EU) 528/2012 of the European Parliament and of the Council*;</p> <p>(e) devices within the scope of Regulation (EU) 2017/745;</p> <p>(f) personal protective equipment within the scope of Regulation (EU) 2016/425;</p> <p>(g) articles intended to come into contact directly or indirectly with food within the scope of Regulation (EC) No 1935/2004;</p> <p>(h) second-hand articles.</p> <p>2. Shall not be placed on the market in road</p>
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	<p>vehicles after [<i>OP, please insert the date: 48 months after the date of entry into force of this amending Regulation</i>] where formaldehyde or formaldehyde releasing substances have been intentionally added during their production, 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]

1.1 Reference conditions

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 reference conditions:

- (a) the temperature in the test chamber shall be $(23 \pm 0,5)$ °C;
- (b) the relative humidity in the test chamber shall be (45 ± 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 $(1 \pm 0,02) \text{ m}^2/\text{m}^3$; in cases where such a loading factor is clearly not realistic under reasonably 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, to measure 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].

Formaldehyde released from articles referred to in paragraph 1, first subparagraph, of entry xx] may also be measured in the air of a test chamber under the reference conditions that are more stringent than the ones listed in the first paragraph of this point; higher temperature and/or higher relative humidity and/or higher loading factor and/or lower air exchange rate shall be considered to be more stringent conditions.

1.2. Non-reference conditions

If data from a test method using the reference conditions specified in Section 1.1 are not available, data obtained from a test method using non-reference conditions may be used, where there is a correlation between the results of the test method used and the reference conditions specified in Section 1.1.

Suppliers of articles may, where applicable, apply existing correlations to the specific articles and test methods considered, to calculate the formaldehyde releases under the reference conditions specified in Section 1.1 in order to demonstrate compliance with paragraph 1, first subparagraph, of entry [xx].

If relevant correlation data are not available, they may be generated on a case-by-case basis. Correlation data may be generated, by performing measurements of formaldehyde released from articles or samples of articles using a method with non-reference conditions and, in parallel, to measure the formaldehyde released from samples of the same articles under the

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

reference conditions specified in Section 1.1. Sufficient repeat testing shall be conducted to ensure the reliability of such derived correlation.

Where a correlation is evident, it shall only be necessary to undertake the testing to verify the compliance with the limit value of formaldehyde using the method with non-reference conditions. Parallel measurements shall only need to be repeated in case of variations in the characteristics of the article, such as material, size, and production process, that may foreseeably affect the release of formaldehyde.

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 accordance with the conditions specified in ISO 12219-1², ISO 12219-10³ or an equivalent method, 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].’

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.