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[...](2017) **XXX** draft

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

of **XXX**

amending the Appendices to Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards CMR substances

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Articles 68(2) and 131 thereof,

Whereas:

- (1) Entries 28, 29 and 30 of Annex XVII to Regulation (EC) No 1907/2006 prohibit the placing on the market or use for supply to the general public of substances that are classified as carcinogenic, mutagenic or reproductive toxicant (CMR), categories 1A or 1B, and of mixtures containing such substances in specified concentrations. The substances concerned are listed in Appendices 1 to 6 to that Annex.
- (2) Substances are classified as CMR in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council² and are listed in Part 3 of Annex VI to that Regulation.
- (3) Since Appendices 1 to 6 to Annex XVII to Regulation (EC) No 1907/2006 were last updated to reflect new classifications of substances as CMR under Regulation (EC) No 1272/2008, Part 3 of Annex VI to the latter has been amended by Commission Regulation (EU) 2017/776³.
- (4) Regulation (EU) 2017/776 also makes changes to titles and numbering in Part 3 of Annex VI to Regulation (EC) No 1272/2008, which necessitate modification of the references to that Regulation in column 1 of entries 28 to 30 of Annex XVII to Regulation (EC) No 1907/2006.

¹ OJ L 396, 30.12.2006, p. 1.

² 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 (OJ L 353, 31.12.2008, p.1).

³ Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 116, 5.5.2017, p.1).

- (5) The substance formaldehyde was classified as a carcinogen category 1B by Commission Regulation (EU) No 605/2014⁴; however the Commission chose to omit it from the last updating exercise pending the outcome of an ongoing examination of all its uses by the European Chemicals Agency⁵, with a view to a possible specific restriction. In the meeting of the committee established under Article 133(1) of Regulation (EC) No 1907/2006, held on 16 March 2017, the majority of Member States expressed a preference to include formaldehyde in entry 28 of Annex XVII to REACH notwithstanding any further specific proposal to restrict the substance, and the Commission agreed to do so at the next available opportunity.
- (6) As operators may apply the harmonised classifications set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008 at an earlier date, they should be able to apply the provisions of this Regulation earlier, on a voluntary basis.
- (7) Regulation (EC) No 1907/2006 should be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex.

Article 2

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. It shall apply from 1 December 2018 except that, to the extent that paragraph (2) of the Annex applies to the substance ‘formaldehyde . . . %’, that paragraph shall apply from the date of entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission
The President
Jean-Claude Juncker*

⁴ Commission Regulation (EU) No 605/2014 of 5 June 2014 amending, for the purposes of introducing hazard and precautionary statements in the Croatian language and its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 167, 6.6.2014, p.36).

⁵ https://echa.europa.eu/documents/10162/13641/annex_xv_report_formaldehyde_en.pdf/58be2f0a-7ca7-264d-a594-da5051a1c74b