



Brussels, **XXX**  
[...] (2016) **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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**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)

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/EC<sup>1</sup>, and in particular Article 68(2) 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 Council<sup>2</sup> 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) No 605/2014<sup>3</sup>, Commission Regulation (EU) 2015/1221<sup>4</sup> and Commission Regulation (EU) 2016/1179<sup>5</sup>

<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<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 (OJ L 353, 31.12.2008, p.1).

<sup>3</sup> 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).

<sup>4</sup> Commission Regulation (EU) No 2015/1221 of 24 July 2015 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, for the purposes of its adaptation to technical and scientific progress (OJ L 197, 25.7.2015, p.10)

<sup>5</sup> Commission Regulation (EU) No 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European

- (4) The substance formaldehyde was included in the Community Rolling Action Plan (CoRAP) for evaluation of its emission/exposure to consumers, which led to a decision by the Agency requiring registrants to provide data. In the light of the data provided, the Commission asked the Agency to make a general assessment of formaldehyde, including its industrial and professional uses, to enable the Commission to decide whether to request the Agency to prepare an Annex XV dossier for restriction. Therefore formaldehyde should not be included in the scope of entry 29 of Annex XVII to Regulation (EC) No 1907/2006.
- (5) 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.
- (6) Regulation (EC) No 1907/2006 should be amended accordingly.
- (7) 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 the date of entry into force, with the exception of

- paragraphs (1), (2) and (3) of the Annex, which shall apply on 1 March 2018, and

- paragraph (4)(a) of the Annex which shall apply on 1 March 2018 to the extent that it relates to the following substances:

bisphenol A; [phenol, dodecyl-, branched]; [phenol, 2-dodecyl-, branched]; [phenol, 3-dodecyl-, branched]; [phenol, 4-dodecyl-, branched]; [phenol, (tetrapropenyl) derivatives]; chlorophacinone (ISO); coumatetralyl (ISO); difenacoum (ISO); flocoumafen (ISO); disodium octaborate anhydrous; disodium octaborate tetrahydrate; bromadiolone (ISO); difethialone; [perfluorononan-1-oic acid, and its sodium and ammonium salts]; dicyclohexyl phthalate and triflumizole (ISO).

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*

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Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 195, 29.7.2016, p.11).



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ANNEX 1

**ANNEX**

*to*

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

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## ANNEX

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

(1) In Appendix 2, the following entries are inserted in the table in order of the index numbers set out therein:

'1,2-dichloropropane; propylene dichloride	602-020-00-0	201-152-2	78-87-5	
e-glass microfibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO <sub>2</sub> 50.0-56.0 %, Al <sub>2</sub> O <sub>3</sub> 13.0-16.0 %, B <sub>2</sub> O <sub>3</sub> 5.8-10.0 %, Na <sub>2</sub> O <0.6 %, K <sub>2</sub> O <0.4 %, CaO 15.0-24.0 %, MgO <5.5 %, Fe <sub>2</sub> O <sub>3</sub> <0.5 %, F <sub>2</sub> <1.0 %. Process: typically produced by flame attenuation and rotary process. (Additional individual elements may be present at low levels; the process list does not preclude innovation).]	014-046-00-4	-	-	

(2) In Appendix 4, the following entry is inserted in the table in order of the index number set out therein:

'3,7-dimethylocta-2,6-dienenitrile	608-067-00-3	225-918-0	5146-66-7'	
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(3) In Appendix 5,

(a) the following entries are inserted in the table in order of the index numbers set out therein:

'brodifacoum (ISO); 4-hydroxy-3-(3-(4'-bromo-4-biphenyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	607-172-00-1	259-980-5	56073-10-0	
lead powder; [particle diameter < 1 mm]	082-013-00-1	231-100-4	7439-92-1	
lead massive; [particle diameter ≥ 1 mm]	082-014-00-7	231-100-4	7439-92-1'	

(b) the entry relating to warfarin; 4-hydroxy-3-(3-oxo-1- phenylbutyl)-coumarin is replaced by the following entry:

'warfarin (ISO); 4-hydroxy-3-(3-oxo-1- phenylbutyl)-2H-chromen-2-one; [1] (S)-4-hydroxy-3-(3-oxo- 1-phenylbutyl)-2-benzopyrone; [2] (R)-4-hydroxy-3-(3-oxo- 1-phenylbutyl)-2-benzopyrone [3]	607-056-00-0	201-377-6 [1] 226-907-3 [2] 226-908-9 [3]	81-81-2 [1] 5543-57-7 [2] 5543-58-8 [3]'	
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(4) In Appendix 6,

(a) the following entries are inserted in the table in order of the index numbers set out therein:

'tetrahydro-2-furyl-methanol; tetrahydrofurfuryl	603-061-00-7	202-625-6	97-99-4	
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alcohol				
gallium arsenide	031-001-00-4	215-114-8	1303-00-0	
Tributyltin compounds, with the exception of those specified elsewhere in this Annex	050-008-00-3	-	-	
1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear	607-710-00-5	271-093-5	68515-50-4	
imidazole	613-319-00-0	206-019-2	288-32-4	
bisphenol A; 4,4'-isopropylidenediphenol	604-030-00-0	201-245-8	80-05-7	
phenol, dodecyl-, branched; [1] phenol, 2-dodecyl-, branched; [2] phenol, 3-dodecyl-, branched; [3] phenol, 4-dodecyl-, branched; [4] phenol, (tetrapropenyl) derivatives [5]	604-092-00-9	310-154-3 [1] - [2] - [3] - [4] - [5]	121158-58-5 [1] - [2] - [3] 210555-94-5 [4] 74499-35-7 [5]	
chlorophacinone (ISO); 2-[(4-chlorophenyl)(phenyl)acetyl]-1H-indene-1,3(2H)-dione	606-014-00-9	223-003-0	3691-35-8	
coumatetralyl (ISO); 4-hydroxy-3-(1,2,3,4-tetrahydro-1-naphthyl)coumarin	607-059-00-7	227-424-0	5836-29-3	
difenacoum (ISO); 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	607-157-00-X	259-978-4	56073-07-5	
flocoumafen (ISO); reaction mass of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin and trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin	607-375-00-5	421-960-0	90035-08-8	
disodium octaborate anhydrous; [1] disodium octaborate tetrahydrate [2]	005-020-00-3	234-541-0 [1] 234-541-0 [2]	12008-41-2 [1] 12280-03-4 [2]	
bromadiolone (ISO); 3-[3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-chromen-2-one	607-716-00-8	249-205-9	28772-56-7	
difethialone (ISO); 3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydronaphthalen-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one	607-717-00-3	-	104653-34-1	
perfluorononan-1-oic acid [1] and its sodium [2] and ammonium [3] salts	607-718-00-9	206-801-3 [1] - [2] - [3]	375-95-1 [1] 21049-39-8 [2] 4149-60-4 [3]	
dicyclohexyl phthalate	607-719-00-4	201-545-9	84-61-7	
triflumizole (ISO); (1E)-N-[4-chloro-2-(trifluoromethyl)phenyl]-1-(1H-imidazol-1-yl)-2-propoxyethanimine	612-289-00-6	-	68694-11-1'	

(b) the entry relating to flumioxazin (ISO); N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl)—2,2H 1,4-benzoxazin-6-yl) cyclohex-1-ene-1,2dicarboxamide is replaced by the following entry:

'flumioxazin (ISO); 2-[7-fluoro-3-oxo-4- (prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3 (2H)-dione	613-166-00-X	-	103361-09-7'	
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