



Brussels, **XXX**
[...](2021) **XXX** draft

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

of **XXX**

amending 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 carcinogenic, mutagenic or reproductive toxicant (CMR) substances

(Text with EEA relevance)

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(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/EC¹, 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 and use, for supply to the general public, of substances that are classified as carcinogenic, mutagenic or reproductive toxicant (CMR), categories 1A or 1B, and listed in Appendices 1 to 6 to that Annex and of mixtures containing such substances above specified concentrations.
- (2) Substances classified as CMR are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council².
- (3) Appendices 1 to 6 to Annex XVII to Regulation (EC) No 1907/2006, as last amended by Commission Regulation (EU) 2020/2096³, do not yet reflect the new classifications of substances as CMR under Regulation (EC) No 1272/2008, as amended by Commission Delegated Regulations (EU) 2020/1182⁴ and (EU) 2021/...⁵. It is

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, 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).

³ Commission Regulation (EU) 2020/2096 of 15 December 2020 amending 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 carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, persistent organic pollutants, certain liquid substances or mixtures, nonylphenol and testing methods for azocolourants (OJ L 425, 16.12.2020, p. 3).

⁴ Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of

therefore appropriate to add the newly classified CMR substances of categories 1A or 1B listed in Delegated Regulations (EU) 2020/1182 and (EU) 2021/... to Appendices 2, 4 and 6 to Annex XVII to Regulation (EC) No 1907/2006.

- (4) The classification of substances listed in Delegated Regulation (EU) 2020/1182 will apply from 1 March 2022. The restriction introduced by this Regulation as regards substances classified as CMR category 1A or 1B by Regulation (EU) 2020/1182 should therefore apply from 1 March 2022. The date of application does not prevent operators from applying the restrictions related to the CMR substances category 1A or 1B classified under Regulation (EU) 2020/1182 earlier.
- (5) The classification of substances listed in Delegated Regulation (EU) 2021/... will apply from The restriction introduced by this Regulation as regards substances classified as CMR category 1A or 1B by Regulation (EU) 2021/... should therefore apply from The date of application does not prevent operators from applying the restrictions related to the CMR substances category 1A or 1B classified under Regulation (EU) 2021/... earlier.
- (6) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) 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 to 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*.

Point (1) of the Annex shall apply as follows:

- rows concerning silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1), dibenzo[*def,p*]chrysene; dibenzo[*a,l*]pyrene, *m*-bis(2,3-epoxypropoxy)benzene; resorcinol diglycidyl ether, 2,2-bis(bromomethyl)propane-1,3-diol, sodium *N*-(hydroxymethyl)glycinate; [formaldehyde released from sodium *N*-(hydroxymethyl)glycinate], butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime and *N*-(hydroxymethyl)acrylamide; methylolacrylamide; [NMA] shall apply from 1 March 2022,
- rows concerning tetrafluoroethylene, 1,4-dioxane and 7-oxa-3-oxiranyl bicyclo[4.1.0]heptane; 1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide shall apply from

the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 261, 11.8.2020, p. 2).

⁵ Commission Delegated Regulation (EU) 2021/... of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ ...). [This is the act adopted under number C(2021)1533 final. It appears in the Register of delegated and implementing acts under <https://webgate.ec.europa.eu/regdel/#/delegatedActs/1452.>]

Point (2) of the Annex shall apply from 1 March 2022.

Point (3) of the Annex shall apply as follows:

- rows concerning tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane, dichlorodioctylstannane, dioctyltin dilaurate; [1] stannane, dioctyl-, bis(coco acyloxy) derivs. [2], ipconazole (ISO); (1*RS*,2*SR*,5*RS*;1*RS*,2*SR*,5*SR*)-2-(4-chlorobenzyl)-5-isopropyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol, bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme, 2-(4-*tert*-butylbenzyl)propionaldehyde, diisooctyl phthalate, 2-methoxyethyl acrylate, pyrithione zinc; (*T*-4)-bis[1-(hydroxy- κ .*O*)pyridine-2(1*H*)-thionato- κ .*S*]zinc, flurochloridone (ISO); 3-chloro-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one and bis(α , α -dimethylbenzyl) peroxide shall apply from 1 March 2022,
- rows concerning mancozeb (ISO); manganese ethylenebis(dithiocarbamate) (polymeric) complex with zinc salt, 7-oxa-3-oxiranylbicyclo[4.1.0]heptane; 1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide, 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol; [DBMC], dimethomorph (ISO); (*E*,*Z*)-4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl)morpholine, 1,2,4-triazole and 3-methylpyrazole shall apply from

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



Brussels, **XXX**
[...](2021) **XXX** draft

ANNEX

ANNEX

to the

COMMISSION REGULATION

**amending 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 carcinogenic, mutagenic or reproductive
toxicant (CMR) substances**

ANNEX

Annex XVII is amended as follows:

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

Substances	Index No	EC No	CAS No	Notes
“silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1)	014-048-00-5	206-991-8	409-21-2 308076-74-6”	
“dibenzo[<i>def,p</i>]chrysene; dibenzo[<i>a,l</i>]pyrene	601-092-00-0	205-886-4	191-30-0”	
“tetrafluoroethylene	602-110-00-X	204-126-9	116-14-3”	
“1,4-dioxane	603-024-00-5	204-661-8	123-91-1”	
“ <i>m</i> -bis(2,3-epoxypropoxy)benzene; resorcinol diglycidyl ether	603-065-00-9	202-987-5	101-90-6”	
“7-oxa-3-oxiranyl bicyclo[4.1.0]heptane; 1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	603-066-00-4	203-437-7	106-87-6”	
“2,2-bis(bromomethyl)propane-1,3-diol	603-240-00-X	221-967-7	3296-90-0”	
“sodium <i>N</i> -(hydroxymethyl)glycinate; [formaldehyde released from sodium <i>N</i> -(hydroxymethyl)glycinate]	607-746-00-1	274-357-8	70161-44-3”	
“butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime	616-014-00-0	202-496-6	96-29-7”	
“ <i>N</i> -(hydroxymethyl)acrylamide; methylolacrylamide; [NMA]	616-230-00-5	213-103-2	924-42-5”;	

- (2) In Appendix 4, the following entries are inserted in the table in the order of the index numbers set out therein:

Substances	Index No	EC No	CAS No	Notes
“2,2-bis(bromomethyl)propane-1,3-diol	603-240-00-X	221-967-7	3296-90-0”	
“ <i>N</i> -(hydroxymethyl)acrylamide; methylolacrylamide; [NMA]	616-230-00-5	213-103-2	924-42-5”;	

- (3) In Appendix 6, the following entries are inserted in the table in the order of the index numbers set out therein:

Substances	Index No	EC No	CAS No	Notes
“mancozeb (ISO); manganese ethylenebis(dithiocarbamate) (polymeric) complex with zinc salt	006-076-00-1	-	8018-01-7”	
“tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-	014-050-00-6	213-934-0	1067-53-4”	

silaundecane				
“dichlorodioctylstannane	050-021-00-4	222-583-2	3542-36-7”	
“dioctyltin dilaurate; [1] stannane, dioctyl-, bis(coco acyloxy) derivs. [2]	050-031-00-9	222-883-3 [1] 293-901-5 [2]	3648-18-8 [1] 91648-39-4 [2]”	
“7-oxa-3-oxiranyl bicyclo[4.1.0]heptane; 1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide	603-066-00-4	203-437-7	106-87-6”	
“ipconazole (ISO); (1 <i>RS</i> ,2 <i>SR</i> ,5 <i>RS</i> ;1 <i>RS</i> ,2 <i>SR</i> ,5 <i>SR</i>)-2-(4-chlorobenzyl)-5-isopropyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol	603-237-00-3	-	125225-28-7 115850-69-6 115937-89-8”	
“bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme	603-238-00-9	205-594-7	143-24-8”	
“6,6'-di- <i>tert</i> -butyl-2,2'-methylenedi- <i>p</i> -cresol; [DBMC]	604-095-00-5	204-327-1	119-47-1”	
“2-(4- <i>tert</i> -butylbenzyl)propionaldehyde	605-041-00-3	201-289-8	80-54-6”	
“diisooctyl phthalate	607-740-00-9	248-523-5	27554-26-3”	
“2-methoxyethyl acrylate	607-744-00-0	221-499-3	3121-61-7”	
“dimethomorph (ISO); (<i>E,Z</i>)-4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl)morpholine	613-102-00-0	404-200-2	110488-70-5”	
“1,2,4-triazole	613-111-00-X	206-022-9	288-88-0”	
“pyrithione zinc; (<i>T</i> -4)-bis[1-(hydroxy- κ . <i>O</i>)pyridine-2(1 <i>H</i>)-thionato- κ . <i>S</i>]zinc	613-333-00-7	236-671-3	13463-41-7”	
“flurochloridone (ISO); 3-chloro-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one	613-334-00-2	262-661-3	61213-25-0”	
“3-methylpyrazole	613-339-00-X	215-925-7	1453-58-3”	
“bis(α,α -dimethylbenzyl) peroxide	617-006-00-X	201-279-3	80-43-3”	