COMMISSION REGULATION (EU) …/…


(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.
COMMISSION REGULATION (EU) .../…

of XXX


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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


Whereas:

(1) Entry 3 of Annex XVII to Regulation (EC) No 1907/2006 contains several references to labelling with R65, which is one of the standard “R-phrases”, indicating special risks arising from the dangers associated with using the substance that were set out in Council Directive 67/548/EEC. As that Directive has been repealed, the references to R65 should be deleted from entry 3.

(2) Pursuant to paragraph 6 of entry 3 of Annex XVII to Regulation (EC) No 1907/2006, on 8 July 2015 the European Chemicals Agency prepared a dossier in accordance with Article 69 of that Regulation and concluded that there is no need to propose an amendment of the restriction set out in that entry. Accordingly, paragraph 6 of entry 3 has become superfluous and should be deleted.

(3) Entries 22, 67 and 68 of Annex XVII to Regulation (EC) No 1907/2006 lay down restrictions as regards pentachlorophenol and its salts and esters, bis(pentabromophenyl)ether and perfluorooctanoic acid and its salts. As more severe restrictions are laid down for those substances in Regulation (EU) 2019/1021 of the

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European Parliament and of the Council, amending and repealing Directives on, Authorisation and
government of.

(4) Entry 46 of Annex XVII to Regulation (EC) No 1907/2006, as first included in
Regulation (EC) No 1907/2006, contained no CAS or EC numbers for nonylphenol.
Commission Regulation (EC) No 552/2009 added a CAS number and an EC number to
that entry, with the intention of clarifying it and allowing operators and enforcement
authorities to apply it correctly. That addition however had the unintended effect that
not all isomers of nonylphenol are now covered by entry 46. The intention of the
legislator at the time of adoption of the restriction should therefore be reflected by
deleting those numbers.

(5) 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.

(6) Substances classified as CMR are listed in Part 3 of Annex VI to Regulation (EC) No

(7) After the last amendment to Appendices 1 to 6 to Annex XVII to Regulation (EC) No
1907/2006 by Commission Regulation (EU) 2018/675 to take into account new
classifications of substances as CMR under Regulation (EC) No 1272/2008, Part 3 of
Annex VI to Regulation (EC) No 1272/2008 has been amended by Commission
2020/217. It is appropriate to add the newly classified CMR substances of categories
1A or 1B listed in Regulations (EU) 2018/1480 and (EU) 2020/217 to Appendices 1 to

rules concerning the placing on the market, making available on the market or putting

of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and
classification, labelling and packaging of substances and mixtures, amending and repealing Directives
6 Commission Regulation (EU) 2018/675 of 2 May 2018 amending the Appendices to Annex XVII to
Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards CMR
7 Commission Regulation (EU) 2018/1480 of 4 October 2018 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 and
8 Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 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 and
into service of medical devices for human use, accessories for such devices and certain groups of products without an intended medical purpose. As the level of protection of human health provided by Regulation (EU) 2017/745 is comparable with that afforded by Regulation (EC) No 1907/2006, devices within the scope of Regulation (EU) 2017/745 should be exempted from the restrictions laid down in entries 28-30 of Annex XVII to Regulation (EC) No 1907/2006.


(10) The classifications of substances introduced by Regulation (EU) 2018/1480 apply from 1 May 2020. Stakeholders should be allowed sufficient time to take appropriate measures to comply with the restriction introduced by this Regulation as regards substances classified as CMR category 1A or 1B by Regulation (EU) 2018/1480. Six months period should be sufficient. 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) 2018/1480 earlier.

(11) Delegated Regulation (EU) 2020/217 will apply from 1 October 2021. The restriction introduced by this Regulation as regards substances classified as CMR category 1A or 1B by Regulation (EU) 2020/217 should therefore apply from 1 October 2021. 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) 2020/217 earlier.


(13) Appendix 10 to Annex XVII to Regulation (EC) No 1907/2006 lists testing methods for azocolourants for the purposes of entry 43 of that Annex. Several of the listed testing methods are outdated and have been replaced by the European Committee for Standardization with more up-to-date testing methods. Appendix 10 should therefore be amended to reflect those changes.

(14) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(15) 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,

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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**

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. Point (6) of the Annex shall apply from [placeholder: same date as the date on which Commission Delegated Regulation (EU) …/… of 8 April 2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds starts applying].

Point (8)(b) of the Annex shall apply as follows:

- rows concerning cobalt, benzo[rst]pentaphene and dibenzo[def,chrysene; dibenzo[a,h]pyrene shall apply from 1 October 2021;

- rows concerning 1,2-dihydroxybenzene; pyrocatechol, acetaldehyde; ethanol and spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4,5]dec-3-en-4-yl 2,2-dimethylbutyrate shall apply from … [six months following the entry into force of this amending Regulation].

Point 11(b) of the Annex shall apply from 1 October 2021.

Point (12)(b) of the Annex shall apply as follows:

- rows concerning cobalt, ethylene oxide; oxirane, ethanol, 2,2'-iminobis-, N-(C13-15 branched and linear alkyl) derivs., diisohexyl phthalate, halosulfuron-methyl (ISO); methyl 3-chloro-5-{[(4,6dimethoxypyrimidin-2yl)carbamoyl]sulfamoyl}1-methyl1H-pyrazole-4-carboxylate, 2-methylimidazole and dibutylbis(pentane-2,4-dionato-O,O')tin shall apply from 1 October 2021;

- rows concerning 2-benzyl-2-dimethylamino-4’-morpholinobutyrophenone, propiconazole (ISO); (2RS,4RS;2RS,4SR)-1-[(2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl)methyl]-1H-1,2,4-triazole and 1-vinylimidazole shall apply from … [six months following the entry into force of this amending Regulation].

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*