EUROPEAN
COMMISSION

Brussels, XXX
[…](2020) 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, 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

(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.

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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

(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[1], and in particular Articles 68(2) and 131 thereof,

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[2]. As that Directive has been repealed, the references to R65 should be deleted from entry 3.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

[1] OJ L 396, 30.12.2006, p. 1.

[2] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

European Parliament and of the Council[3], entries 22, 67 and 68 of Annex XVII to Regulation (EC) No 1907/2006 should be deleted.

(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[4] 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 1272/2008 of the European Parliament and of the Council[5].

(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[6] 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 Regulation (EU) 2018/1480[7] and by Commission Delegated Regulation (EU) 2020/217[8]. 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 6 to Annex XVII to Regulation (EC) No 1907/2006.

(8) Regulation (EU) 2017/745 of the European Parliament and of the Council[9] lays down rules concerning the placing on the market, making available on the market or putting

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3 Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

4 Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (OJ L 164, 26.6.2009, p. 7).

5 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).

6 Commission Regulation (EU) 2018/675 of 2 May 2018 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 (OJ L 114, 4.5.2018, p. 4).

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 correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).

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 correcting that Regulation (OJ L 44, 18.2.2020, p. 1).

9 Regulation (EU) 2017/745 of the European Parliament and of the Council of 7 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

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.

(9) Deletion of entry 68 of Annex XVII to Regulation (EC) No 1907/2006 should apply from the date of application of the relevant provision of Commission Delegated Regulation (EU) …/...[10], including perfluorooctanoic acid and its salts in Annex I to Regulation (EU) 2019/1021.

(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.

(12) Commission Regulation (EU) 2017/776[11] made changes to titles and numbering in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Corresponding modifications to entries 28, 29 and 30 in column 1 of Annex XVII to Regulation (EC) No 1907/2006 were made by Regulation (EU) 2018/675. Similar changes should be made to the titles of Appendices 1 to 6 to Annex XVII to Regulation (EC) No 1907/2006.

(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,

[10] 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 (OJ L …, …., p…).

[11] 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).

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[*b,def*]chrysene; dibenzo[*a,h*]pyrene shall apply from 1 October 2021;

– rows concerning 1,2-dihydroxybenzene; pyrocatechol, acetaldehyde; ethanal 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