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 (Text with EEA relevance)

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

(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 As that Directive has been repealed, the references to R65 should be deleted from entry 3.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, paragraphs 6 and 7 of entry 3 have become superfluous and should be deleted.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/2096. (See end of Document for details)*

(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 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 into service of medical devices for human use, accessories for such devices and certain groups of products without an intended medical purpose. As Regulation (EU) 2017/745 contains provisions on CMR substances, and to avoid double regulation, 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) 2020/784[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,

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 (6) of the Annex shall apply from 4 July 2020.

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 5 July 2021.

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

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2020/2096. (See end of Document for details)*

— 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 5 July 2021.

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

Done at Brussels, 15 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

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

(1) Column 2 of entry 3 is amended as follows:

(a) paragraph 3 is replaced by the following:

3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:

— can be used as fuel in decorative oil lamps for supply to the general public, and

— present an aspiration hazard and are labelled with H304.;

(b) paragraph 5 is replaced by the following:

5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:

(a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";

(b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';

(c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.;

(c) paragraph 6 is deleted;

(d) paragraph 7 is deleted.

(2) Entry 22 is deleted.

(3) In entries 28-30, the following point (f) is added in paragraph 2 of column 2:

(f) devices covered by Regulation (EU) 2017/745.

(4) In entry 46, the references to CAS number and EC number in paragraph (a) of column 1 are deleted.

(5) Entry 67 is deleted.

(6) Entry 68 is deleted.

(7) The title of Appendix 1 is replaced by the following:

Entry 28 – Carcinogens: Category 1A.