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 (Text with EEA relevance)

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

(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 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[(1)], and in particular Articles 37(5) and 53(1) thereof,

Whereas:

(1) Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 contains the list of harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to that Regulation.

(2) Proposals to introduce harmonised classification and labelling of certain substances and to update or delete the harmonised classification and labelling of certain other substances have been submitted to the European Chemicals Agency ('Agency') pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on the opinions on those proposals issued by the Committee for Risk Assessment of the Agency (RAC), as well as on the comments received from the parties concerned, it is appropriate to introduce, update or delete harmonised classification and labelling of certain substances. Those RAC opinions[(2)] are:

— Opinion of 9 June 2017 concerning 4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol

— Opinion of 22 September 2017 concerning disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene- 2,7-disulfonate

— Opinion of 9 June 2017 concerning Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide;

— Opinion of 22 September 2017 concerning cobalt;

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/217. (See end of Document for details)*

- Opinion of 22 September 2017 concerning nickel bis(sulfamidate); nickel sulfamate;
- Opinion of 22 September 2017 concerning ethylene oxide; oxirane;
- Opinion of 22 September 2017 concerning 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane; metaldehyde;
- Opinion of 15 March 2017 concerning 2-benzyl-2-dimethylamino-4'morpholinobutyrophenone;
- Opinion of 5 December 2017 concerning pyridate (ISO); O-(6-chloro-3-phenylpyridazin-4-yl) S-octyl thiocarbonate;
- Opinion of 22 September 2017 concerning dodecyl methacrylate;
- Opinion of 5 December 2017 concerning 2-phenylhexanenitrile;
- Opinion of 15 March 2017 concerning thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole;
- Opinion of 9 June 2017 concerning N,N-diethyl-m-toluamide; deet;
- Opinion of 14 September 2017 concerning Titanium dioxide;
- Opinion of 15 March 2017 concerning Methylmercuric chloride;
- Opinion of 9 June 2017 concerning benzo[*rst*]pentaphene;
- Opinion of 9 June 2017 concerning Dibenzo[*b,def*]chrysene; Dibenzo[a,h]pyrene;
- Opinion of 22 September 2017 concerning Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs;
- Opinion of 5 December 2017 concerning cyflumetofen (ISO); 2-methoxyethyl (RS) -2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-o-tolyl)propionate;
- Opinion of 9 June 2017 concerning Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate;
- Opinion of 9 June 2017 concerning N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid);
- Opinion of 9 June 2017 concerning pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo) tetraacetate;
- Opinion of 9 June 2017 concerning diisohexyl phthalate;
- Opinion of 9 June 2017 concerning fludioxonil (ISO); 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile;
- Opinion of 22 September 2017 concerning halosulfuron-methyl (ISO); methyl 3-chloro-5{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole4-carboxylate;
- Opinion of 5 December 2017 concerning 2-methylimidazole;
- Opinion of 15 March 2017 concerning (RS)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-o-tolyl]acetamide; mandestrobin;
- Opinion of 5 December 2017 concerning carboxin (ISO); 2-methyl-N-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide;

— Opinion of 5 December 2017 concerning metaflumizone (ISO); (*EZ*)-2'-[2-(4-cyanophenyl)-1-(α,α,α -trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [*E*-isomer ≥ 90 %, *Z*-isomer≤ 10 % relative content] [1] (*E*)-2'-[2-(4-cyanophenyl)-1-(α,α,α -trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [2];

— Opinion of 5 December 2017 concerning Dibutylbis(pentane-2,4-dionato-O,O')tin.

(3) Acute Toxicity Estimates (ATE) are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. The inclusion of harmonised ATE values in the entries listed in Annex VI to Regulation (EC) No 1272/2008 facilitates the harmonisation of the classification of mixtures and provides support for enforcement authorities. Following further scientific assessments of some substances, ATE values have been calculated for methylmercuric chloride, pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), ethylene oxide, oxirane and metaldehyde (ISO), 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane, in addition to those proposed in the RAC opinions. Those ATE values should be inserted in the penultimate column of Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008.

(4) In its scientific opinion of 22 September 2017 on the substance cobalt, RAC proposed to classify that substance as carcinogen category 1B with a specific concentration limit of ≥ 0,01 %. However, the methodology used to determine a specific concentration limit required further assessment, in particular of its applicability to metal compounds. It is therefore appropriate not to introduce, for the time being, any specific concentration limit in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 for cobalt, in which case the general concentration limit of ≥ 0,1 % applies, in accordance with Table 3.6.2 of Annex I to that Regulation.

(5) In its scientific opinion of 14 September 2017 on the substance titanium dioxide, RAC proposed to classify that substance as carcinogen category 2 by inhalation. As titanium dioxide-induced lung carcinogenicity is associated with inhalation of respirable titanium dioxide particles, retention and poor solubility of the particles in the lung, it is appropriate to define respirable titanium dioxide particles in the titanium dioxide entry. The deposited particles, but not solutes of titanium dioxide, are assumed to be responsible for the observed toxicity in the lung and subsequent tumour development. In order to avoid unjustified classification of non-hazardous forms of the substance, specific notes should be laid down for the classification and labelling of the substance and mixtures containing it. In addition, as some hazardous dust or droplets could be formed during the use of mixtures containing titanium dioxide, it is necessary to inform the users of the precautionary measures that need to be taken to minimise the hazard for human health.

(6) With regard to the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)

and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), the classification as acute toxicant category 4 and specific target organ toxicant - repeated exposure (category 2) recommended in the RAC opinions of 9 June 2017 should be included in Annex VI to Regulation (EC) No 1272/2008, since sufficient scientific evidence is available justifying those new classifications. With regard to the substances pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate and N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), the classification as eye irritant category 2, recommended in the RAC opinions of 9 June 2017, should be included in Annex VI to Regulation (EC) No 1272/2008, since sufficient scientific evidence is available justifying those new classifications. However, the classification of the substances pentapotassium 2,2',2'',2''',2'''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA), as toxic for reproduction category 1B should not be included, since it requires further assessment by RAC in view of new scientific data on toxicity for reproduction presented by the industry after the RAC opinions were forwarded to the Commission.

(7) Regulation (EC) No 1272/2008 should therefore be amended accordingly.

(8) Regulation (EC) No 1272/2008 contains the harmonised classification, labelling and packaging for the substance pitch, coal tar, high temp. The Commission amended the harmonised classification, labelling and packaging of that substance by Commission Regulation (EU) No 944/2013[(3)] with effect from 1 April 2016. Commission Regulation (EU) 2018/669[(4)] further amended Regulation (EC) No 1272/2008. However, due to an administrative oversight, certain amendments – the validity of which was not affected by the judgment of the General Court in Case T-689/13[(5)] as upheld by the judgment of the Court of Justice in Case C-691/15 P[(6)] – introduced by Regulation (EU) No 944/2013 were not reflected in Regulation (EU) 2018/669. That Regulation will become applicable as of 1 December 2019. Regulation (EC) No 1272/2008 should therefore be corrected, with effect from the same date.

(9) To ensure that suppliers of substances and mixtures have time to adapt to the new classification and labelling provisions, the application of this Regulation should be deferred.

(10) In order to be consistent with the approach underpinning Article 61(2) of Regulation (EC) No 1272/2008, suppliers should have the possibility of applying the classification, labelling and packaging provisions introduced by this Regulation on a voluntary basis before its date of application,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

Regulation (EC) No 1272/2008 is amended as follows:

(1) Annex II is amended as set out in Annex I to this Regulation;

(2) Annex III is amended as set out in Annex II to this Regulation;

(3) Annex VI is amended as set out in Annex III to this Regulation.

Article 2

Correction to Regulation (EC) No 1272/2008

Annex VI to Regulation (EC) No 1272/2008 is corrected as set out in Annex IV to this Regulation.

[X1 Article 3

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 October 2021.

However, Article 2 shall apply from 1 December 2019.

Substances and mixtures may, before 1 October 2021, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.**]**

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

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union of L 44 of 18 February 2020).