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 the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (Text with EEA relevance)

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 the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

(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 Article 37(5) 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[(2)] 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 the harmonised classification and labelling of certain substances. Those RAC opinions are:

— Opinion of 8 June 2018 concerning nitric acid ... %[C ≤ 70 %];

— Opinion of 9 March 2018 concerning silicon carbide fibres (with diameter < 3 μm, length > 5 μm and aspect ratio ≥ 3:1);

— Opinion of 8 June 2018 concerning trimethoxyvinylsilane; trimethoxy(vinyl)silane;

— Opinion of 8 June 2018 concerning tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane;

— Opinion of 8 June 2018 concerning dimethyl disulphide;

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/1182. (See end of Document for details)*

— Opinion of 8 June 2018 concerning granulated copper;

— Opinion of 30 November 2018 concerning bis(*N*-hydroxy-*N*-nitrosocyclohexylaminato-*O,O'*)copper; bis(*N*-cyclohexyl-diazenium-dioxy)-copper; [Cu-HDO];

— Opinion of 14 September 2018 concerning dioctyltin dilaurate; [1] stannane, dioctyl-, bis(coco acyloxy) derivs. [2];

— Opinion of 30 November 2018 concerning dibenzo[*def,p*]chrysene; dibenzo[*a,l*]pyrene;

— Opinion of 9 March 2018 concerning 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;

— Opinion of 8 June 2018 concerning bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme;

— Opinion of 8 June 2018 concerning paclobutrazol (ISO); (2*RS*,3*RS*)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1*H*-1,2,4-triazol-1-yl)pentan-3-ol;

— Opinion of 8 June 2018 concerning 2,2-bis(bromomethyl)propane-1,3-diol;

— Opinion of 14 September 2018 concerning geraniol; (2*E*)-3,7-dimethylocta-2,6-dien-1-ol;

— Opinion of 28 January 2019 concerning 2-(4-*tert*-butylbenzyl)propionaldehyde;

— Opinion of 9 March 2018 concerning MCPA-thioethyl (ISO); *S*-ethyl (4-chloro-2-methylphenoxy)ethanethioate; *S*-ethyl 4-chloro-*o*-tolyloxythioacetate;

— Opinion of 9 March 2018 concerning diisooctyl phthalate;

— Opinion of 14 September 2018 concerning 4-{[(6-chloropyridin-3-yl)methyl](2,2-difluoroethyl) amino}furan-2(5*H*)-one; flupyradifurone;

— Opinion of 30 November 2018 concerning thiencarbazone-methyl (ISO); methyl 4- [(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate;

— Opinion of 9 March 2018 concerning L-(+)-lactic acid; (2*S*)-2-hydroxypropanoic acid;

— Opinion of 9 March 2018 concerning 2-methoxyethyl acrylate;

— Opinion of 8 June 2018 concerning glyoxylic acid …%;

— Opinion of 14 September 2018 concerning sodium *N*-(hydroxymethyl)glycinate; [formaldehyde released from sodium *N*-(hydroxymethyl)glycinate];

— Opinion of 30 November 2018 concerning potassium (oxido-*NNO*-azoxy)cyclohexane; cyclohexylhydroxydiazene 1-oxide, potassium salt; [K-HDO];

— Opinion of 14 September 2018 concerning mecetronium etilsulfate; *N*-ethyl-*N,N*-dimethylhexadecan-1-aminium ethyl sulfate; mecetronium ethyl sulphate [MES];

— Opinion of 9 March 2018 concerning (2*RS*)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1*H*-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole;

— Opinion of 30 November 2018 concerning oxathiapiprolin (ISO); 1-(4-{4-[5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1*H*-pyrazol-1-yl]ethanone;

— Opinion of 14 September 2018 concerning pyrithione zinc; (*T*-4)-bis[1-(hydroxy-.kappa.*O*) pyridine-2(1*H*)-thionato-.kappa.*S*]zinc;

— Opinion of 30 November 2018 concerning 3-chloro-4-(chloromethyl)-1-[3-trifluoromethyl)phenyl]pyrrolidin-2-one; flurochloridone (ISO);

— Opinion of 30 November 2018 concerning 4,5-dichloro-2-octyl-2*H*-isothiazol-3-one; [DCOIT];

— Opinion of 8 June 2018 concerning 2-methyl-1,2-benzothiazol-3(2*H*)-one; [MBIT];

— Opinion of 30 November 2018 concerning 3-(difluoromethyl)-1-methyl-*N*-(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide; fluxapyroxad;

— Opinion of 8 June 2018 concerning *N*-(hydroxymethyl)acrylamide; methylolacrylamide; [NMA];

— Opinion of 15 October 2018 concerning 5-fluoro-1,3-dimethyl-*N*-[2-(4-methylpentan-2-yl)phenyl]-1*H*-pyrazole-4-carboxamide; 2'-[(*RS*)-1,3-dimethylbutyl]-5-fluoro-1,3-dimethylpyrazole-4-carboxanilide; penflufen;

— Opinion of 30 November 2018 concerning iprovalicarb(ISO); isopropyl [(2*S*)-3-methyl-1-{[1-(4-methylphenyl)ethyl]amino}-1-oxobutan-2-yl]carbamate;

— Opinion of 30 November 2018 concerning silthiofam (ISO); *N*-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide;

— Opinion of 9 March 2018 concerning Margosa, ext. [cold-pressed oil of *Azadirachta indica* seeds without shells extracted with super-critical carbon dioxide];

— Opinion of 8 June 2018 concerning nitric acid …%[C> 70 %];

— Opinion of 9 March 2018 concerning octamethylcyclotetrasiloxane; [D4];

— Opinion of 30 November 2018 concerning pirimiphos-methyl (ISO); *O*-[2-(diethylamino)-6-methylpyrimidin-4-yl] *O,O*-dimethyl phosphorothioate;

— Opinion of 30 November 2018 concerning phosphine;

— Opinion of 14 September 2018 concerning dichlorodioctylstannane;

— Opinion of 30 November 2018 concerning 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate; [DOTE];

— Opinion of 30 November 2018 concerning lead;

— Opinion of 14 September 2018 concerning 2-butoxyethanol; ethylene glycol monobutyl ether;

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2020/1182. (See end of Document for details)*

— Opinion of 30 November 2018 concerning *m*-bis(2,3-epoxypropoxy)benzene; resorcinol diglycidyl ether;

— Opinion of 14 September 2018 concerning tribenuron-methyl (ISO); methyl 2- [*N*-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-*N*-methylcarbamoylsulfamoyl]benzoate;

— Opinion of 8 June 2018 concerning azoxystrobin (ISO); methyl (*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate;

— Opinion of 9 March 2018 concerning ethofumesate (ISO); (*RS*)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate;

— Opinion of 30 November 2018 concerning 2,4-dinitrophenol;

— Opinion of 14 September 2018 concerning mesotrione (ISO); 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione;

— Opinion of 30 November 2018 concerning octhilinone (ISO); 2-octyl-2*H*-isothiazol-3-one; [OIT];

— Opinion of 14 September 2018 concerning hymexazol (ISO); 3-hydroxy-5-methylisoxazole;

— Opinion of 30 November 2018 concerning hexythiazox (ISO); *trans*-5-(4-chlorophenyl)-*N*-cyclohexyl-4-methyl-2-oxo-3-thiazolidine-carboxamide;

— Opinion of 9 March 2018 concerning pymetrozine (ISO); (*E*)-4,5-dihydro-6-methyl-4-(3-pyridylmethylene amino)-1,2,4-triazin-3(2*H*)-one;

— Opinion of 9 March 2018 concerning imiprothrin (ISO); reaction mass of: [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1*R*)-*cis*-chrysanthemate; [2,4-dioxo-(2-propyn-1-yl)imidazolidin-3-yl]methyl(1*R*)-*trans*-chrysanthemate;

— Opinion of 14 September 2018 concerning butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime;

— Opinion of 8 June 2018 concerning bis(α,α-dimethylbenzyl) peroxide;

— Opinion of 9 March 2018 concerning branched hexatriacontane;

— Opinion of 30 November 2018 concerning hexyl 2-(1-(diethylaminohydroxyphenyl) methanoyl)benzoate; hexyl 2-[4-(diethylamino)-2-hydroxybenzoyl]benzoate.

(3) With regard to the substance lead (CAS number 7439-92-1 and index numbers 082-013-00-1 (lead powder; [particle diameter < 1 mm];) and 082-014-00-7 (lead massive; [particle diameter ≥ 1 mm];)), RAC proposed in its opinion of 30 November 2018 to apply the same environmental classification to the massive and the powder form. However, in view of the lower dissolution rate of the massive form, the malleable structure of lead, the specific intentional production of the powder and the different environmental classification between massive and powder forms for existing entries in Annex VI for other metals, further assessment needs to be done by RAC on whether to apply the same environmental classification to the massive as to the powder form of lead. In addition, new scientific data has been made available suggesting that the environmental classification for the massive form as recommended in the RAC opinion might not be appropriate Therefore, the environmental classification for the massive

form will not be included in Annex VI to Regulation (EC) No 1272/2008 until RAC has had the opportunity to deliver a revised opinion.

(4) With regard to the substance 2-butoxyethanol; ethylene glycol monobutyl ether; (CAS number 111-76-2), new scientific data has been made available for the hazard class 'acute toxicity (inhalation)' which suggests that the classification for this hazard class as recommended in the RAC opinion, which is based on older data, might not be appropriate. Therefore, this hazard class should not be modified in Annex VI to Regulation (EC) No 1272/2008 until RAC has had the opportunity to deliver a revised opinion based on the new information, while all other hazard classes covered by the RAC opinion should be included.

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

(6) Compliance with the new or updated harmonised classifications should not be required immediately as a certain period of time is necessary to allow suppliers to adapt the labelling and packaging of substances and mixtures to the new or revised classifications and to sell existing stocks subject to the pre-existing regulatory requirements. That period of time is also necessary to allow suppliers sufficient time to take the actions required to ensure continuing compliance with other legal requirements following the changes made under this Regulation. Such requirements may include those set out in point (f) of Article 22(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(3)] or those set out in Article 50 of Regulation (EU) No 528/2012 of the European Parliament and of the Council[(4)].

(7) Suppliers should, however, have the possibility to apply the new classification, labelling and packaging provisions on a voluntary basis before the date of application of this Regulation. This is consistent with the approach taken under Article 61(2) of Regulation (EC) No 1272/2008,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended as set out in the Annex to this Regulation.

Article 2

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 March 2022.