EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

The objectives of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) are to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles. These objectives are fulfilled, *inter alia*, by establishing a list of substances with their harmonised classifications and labelling elements at Union level. Article 37(5) of Regulation (EC) No 1272/2008 empowers the Commission to include, without undue delay, substances in Table 3 of Part 3 of Annex VI, where it finds that the harmonisation of the classification and labelling is appropriate (Table 3.1 has been renamed Table 3 since the deletion of Table 3.2).

Based on the opinions issued by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as on the comments received from Member States and stakeholders, it is appropriate to introduce or update the harmonised classification and labelling of certain substances and amend Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 accordingly.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 37(4) of Regulation (EC) No 1272/2008, ECHA has performed a public consultation for each substance to be included in or modified in Table 3 of Part 3 of Annex VI, before the adoption of the respective opinion on the proposals for harmonised classification and labelling by its Committee for Risk Assessment (RAC). The comments provided in the course of the public consultations have been taken into account by RAC and the Commission.

Pursuant to Article 53a(4) of Regulation (EC) No 1272/2008, experts designated by each Member State were consulted in the relevant expert group CARACAL (Competent authorities for REACH and CLP). In accordance with points 10 and 11 of the Annex to the Interinstitutional Agreement on Better Law-Making of 13 April 2016[1] the European Parliament and the Council have been invited to participate in the CARACAL expert group.

Stakeholders were consulted in the CARACAL expert group in accordance with point 6 of the Annex to that Agreement.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal act amends Regulation (EC) No 1272/2008. The legal basis of this delegated act is Article 37(5) of Regulation (EC) No 1272/2008.

[1] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.05.2016, p. 1).

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(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 (the 'Agency') pursuant to Article 37 of Regulation (EC) No 1272/2008. The Committee for Risk Assessment of the Agency (RAC) adopted, after having taken account of the comments received from the parties concerned, the following opinions[2] on those proposals:

– Opinion of 5 December 2019 concerning silanamine, 1,1,1-trimethyl-*N*-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide;

– Opinion of 4 May 2020 concerning cyfluthrin (ISO); *α*-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate;

– Opinion of 4 May 2020 concerning beta-cyfluthrin (ISO); reaction mass of rel-(*R*)-cyano(4-fluoro-3-phenoxyphenyl)methyl (1*S*,3*S*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate and rel-(*R*)-cyano(4-fluoro-3-

[1] OJ L 353, 31.12.2008, p. 1

[2] The opinions are accessible via the following website: https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/name/-/ecNumber/-/casNumber/-/dte_receiptFrom/-/dte_receiptTo/-/prc_public_status/Opinion+Adopted/dte_withdrawnFrom/-/dte_withdrawnTo/-/sbm_expected_submissionFrom/-/sbm_expected_submissionTo/-/dte_finalise_deadlineFrom/-/dte_finalise_deadlineTo/-/haz_addional_hazard/-/lec_submitter/-/dte_assessmentFrom/-/dte_assessmentTo/-/prc_regulatory_programme/-/. – The opinions of 11 June 2020 and of 10 December 2020 concerning a reassessment at the request of the European Commission are accessible via the following website: https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment/opinions-of-the-rac-adopted-under-specific-echa-s-executive-director-requests

phenoxyphenyl)methyl (1*S*,3*R*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate;

– Opinion of 4 May 2020 concerning acetamiprid (ISO); (1*E*)-*N*-[(6-chloropyridin-3-yl)methyl]-*N*'-cyano-*N*-methylethanimidamide; (*E*)-*N*1-[(6-chloro-3-pyridyl)methyl]-*N*2-cyano-*N*1-methylacetamidine;

– Opinion of 11 June 2020 concerning tellurium;

– Opinion of 11 June 2020 concerning tellurium dioxide;

– Opinion of 11 June 2020 concerning 2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol;

– Opinion of 11 June 2020 concerning piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether;

– Opinion of 11 June 2020 concerning benzophenone;

Opinion of 11 June 2020 concerning exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate;

– Opinion of 11 June 2020 concerning daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; *N*-dimethylaminosuccinamic acid;

– Opinion of 11 June 2020 concerning clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine;

– Opinion of 11 June 2020 concerning fluopicolide (ISO); 2,6-dichloro-*N*-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide;

– Opinion of 11 June 2020 concerning trichlorosilane;

– Opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts;

– Opinion of 11 June 2020 concerning a reassessment at the request of the European Commission of the developmental toxicity of N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid) (DTPA) and its pentasodium and pentapotassium salts

– Opinion of 17 September 2020 concerning dibutyltin bis(2-ethylhexanoate);

– Opinion of 17 September 2020 concerning dibutyltin di(acetate);

– Opinion of 17 September 2020 concerning barium diboron tetraoxide;

– Opinion of 17 September 2020 concerning quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone;

– Opinion of 17 September 2020 concerning 4,4'-oxydi(benzenesulphonohydrazide);

– Opinion of 17 September 2020 toluene-4-sulphonohydrazide;

– Opinion of 17 September 2020 concerning theophylline; 1,3-dimethyl-3,7-dihydro-1*H*-purine-2,6-dione;

– Opinion of 17 September 2020 concerning 1,3-bis(1-isocyanato-1-methylethyl)benzene; [*m*-TMXDI];

– Opinion of 17 September 2020 concerning Bis(isocyanatomethyl)benzene; [*m*-XDI];

– Opinion of 17 September 2020 concerning 2,4,6-triisopropyl-*m*-phenylene diisocyanate;

– Opinion of 17 September 2020 concerning *N*-(2-nitrophenyl)phosphoric triamide;

– Opinion of 17 September 2020 concerning cumene;

– Opinion of 17 September 2020 concerning 2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate; 2,2-bis(acryloyloxymethyl)butyl acrylate;trimethylolpropane triacrylate;

– Opinion of 17 September 2020 concerning 1,5-naphthylene diisocyanate [containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm];

– Opinion of 17 September 2020 concerning 1,5-naphthylene diisocyanate [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm];

– Opinion of 8 October 2020 concerning ammonium bromide;

– Opinion of 8 October 2020 concerning 2,4,6-tri-tert-butylphenol;

– Opinion of 8 October 2020 concerning pyridalyl (ISO); 2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether;

– Opinion of 8 October 2020 concerning pyridine-2-thiol 1-oxide, sodium salt; pyrithione sodium; sodium pyrithione;

– Opinion of 8 October 2020 concerning *N*-(5-chloro-2-isopropylbenzyl)-*N*-cyclopropyl-3-(difluoromethyl)-5-fluoro-1-methyl-1*H*-pyrazole-4-carboxamide; isoflucypram;

– Opinion of 8 October 2020 concerning 2-(2-methoxyethoxy)ethanol; diethylene glycol monomethyl ether;

– Opinion of 8 October 2020 concerning 4,4'-isopropylidenediphenol; bisphenol A;

– Opinion of 8 October 2020 concerning pendimethalin (ISO); *N*-(1-ethylpropyl)-2,6-dinitro-3,4-xylidene;

– Opinion of 8 October 2020 concerning dimoxystrobin (ISO); (2*E*)-2-{2-[(2,5-dimethylphenoxy)methyl]phenyl}-2-(methoxyimino)-N-methylacetamide; (*E*)-2-(methoxyimino)-*N*-methyl-2-[*α*-(2,5-xylyloxy)-*o*-tolyl]acetamide;

– Opinion of 10 December 2020 concerning 4,4'-sulphonyldiphenol; bisphenol S;

– Opinion of 10 December 2020 2-[*N*-ethyl-4-[(5-nitrothiazol-2-yl)azo]-m-toluidino]ethyl acetate; C.I. Disperse Blue 124;

– Opinion of 10 December 2020 concerning perfluoroheptanoic acid; tridecafluoroheptanoic acid;

– Opinion of 10 December 2020 concerning methyl *N*-(isopropoxycarbonyl)-*L*-valyl-(3*RS*)-3-(4-chlorophenyl)-*β*-alaninate; valifenalate;

– Opinion of 10 December 2020 concerning 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts;

– Opinion of 10 December 2020 concerning 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid;

– Opinion of 10 December 2020 concerning 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid;

– Opinion of 10 December 2020 concerning 1,3,5-triazine-2,4,6-triamine; Melamine;

– Opinion of 10 December 2020 concerning reaction mass of 3-(difluoromethyl)-1-methyl-*N*-[(1*RS*,4*SR*,9*RS*)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide and 3-(difluoromethyl)-1-methyl-*N*-[(1*RS*,4*SR*,9*SR*)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide [>78% syn isomers <15% anti isomers relative content]; isopyrazam;

– Opinion of 10 December 2020 concerning Margosa, ext. [from the kernels of Azadirachta indica extracted with water and further processed with organic solvents];

– Opinion of 10 December 2020 concerning divanadium pentaoxide; vanadium pentoxide;

– Opinion of 10 December 2020 concerning bentazone (ISO); 3-isopropyl-2,1,3-benzothiadiazine-4-one-2,2-dioxide;

– Opinion of 10 December 2020 concerning a reassessment at the request of the European Commission of the new information on acute inhalation toxicity of 2-butoxyethanol; ethylene glycol monobutyl ether (EGBE)

(3) Additional information was received contesting the scientific assessment set out in the RAC opinions ~~of 5 December 2019 concerning silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide;~~ of 11 June 2020 concerning 2-ethylhexanoic acid and its salts; of 11 June 2020 concerning a reassessment at the request of the European Commission of the developmental toxicity of N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid) (DTPA) and its pentasodium and pentapotassium salts; of 8 October 2020 concerning ammonium bromide; of 10 December 2020 concerning divanadium pentaoxide; of 10 December 2020 concerning a reassessment at the request of the European Commission of the new information on acute inhalation toxicity of 2-butoxyethanol; ethylene glycol monobutyl ether (EGBE); and of 10 December 2020 concerning melamine.

(4) This~~e~~ additional information was assessed by the Commission and was not found sufficient to cast doubts on the scientific analysis contained in the RAC opinions. It is therefore appropriate to introduce, update or delete the harmonised classification and labelling of the substances concerned on the basis of the assessment made in those opinions.

(5) Additional information pertaining to the acute inhalation toxicity of silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide was received after the RAC opinion was forwarded to the Commission. The classification of silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide as acute toxic by inhalation Cat. 2, recommended in the

RAC opinion of 5 December 2019, should not be included in Annex VI to Regulation (EC) No 1272/2008, as the new scientific information was assessed by the Commission and was found to require further assessment by RAC. However, the classification of this substance as STOT RE 2, recommended in the RAC opinion of 5 December 2019, should be included in Annex VI to Regulation (EC) No 1272/2008, since no new information has been received that would require further assessment for that~~is~~ classification.

~~(5)~~(6) Regulation (EC) No 1272/2008 should therefore be amended accordingly.

~~(6)~~(7) 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 updated 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. Suppliers should, however, have the possibility to apply the new or updated harmonised classifications, and to adapt the labelling and packaging accordingly, on a voluntary basis before the date of application of this Regulation, to ensure a high level of protection of human health and of the environment and to provide sufficient flexibility to suppliers,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

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 … [***Publications Office, please insert a date corresponding to 18 months after the entry into force of this Regulation. The date should be the first day of the following month***]

By way of derogation from the second paragraph of this Article, substances and mixtures may be classified, labelled and packaged in accordance with this Regulation from its date of entry into force.

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

Done at Brussels,

For the Commission
The President