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

(Text with EEA relevance)

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 are 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 the parties concerned, it is appropriate to introduce, update, delete or leave unchanged the harmonised classification and labelling of certain substances and amend Table 3 of Annex VI to Regulation (EC) No 1272/2008 accordingly. Moreover, it is appropriate to amend certain Notes in Part I of Annex VI related to the entries in Table 3 of Part 3 of Annex VI for reasons of legal clarity and certainty.

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, modified or deleted 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.

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 point 10 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 bases of this delegated act are Articles 37(5) and 53(1) of Regulation (EC) No 1272/2008.

[1] OJ L 123 of 12.05 2016, p. 1.

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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

(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[2], 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[3] 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-(2methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6silaundecane
- Opinion of 8 June 2018 concerning Dimethyl disulphide

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

[3] 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/-/

- Opinion of 8 June 2018 concerning Granulated copper
- Opinion of 30 November 2018 concerning bis(N-hydroxy-N-nitrosocyclohexylaminatoO,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
- Opinion of 9 March 2018 concerning ipconazole (ISO); (1RS,2SR,5RS;1RS,2SR,5SR)-2(4-chlorobenzyl)-5-isopropyl-1-(1H-1,2,4-triazol1-ylmethyl)cyclopentanol
- Opinion of 8 June 2018 concerning Bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme
- Opinion of 8 June 2018 concerning paclobutrazol (ISO); (2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2- (1H-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; (2E)-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-2methylphenoxy)ethanethioate; S-ethyl 4-chloroo-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(5H)-one; flupyradifurone
- Opinion of 30 November 2018 concerning thiencarbazone-methyl (ISO); methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H1,2,4-triazol-1-yl)carbonylsulfamoyl]-5methylthiophene-3-carboxylate
- Opinion of 9 March 2018 concerning L-(+)-lactic acid; (2S)-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,Ndimethylhexadecan-1-aminium ethyl sulfate; Mecetronium ethyl sulphate [MES]
- Opinion of 9 March 2018 concerning (2RS)-2-[4-(4-chlorophenoxy)-2(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1yl)propan-2-ol; mefentrifluconazole
- Opinion of 30 November 2018 concerning oxathiapiprolin (ISO); 1-(4-{4-[5-(2,6difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3(trifluoromethyl)-1H-pyrazol-1-yl]ethanone
- Opinion of 14 September 2018 concerning pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O) pyridine-2(1H)-thionato-.kappa.S]zinc
- Opinion of 30 November 2018 concerning 3-chloro-4-(chloromethyl)-1-[3(trifluoromethyl)phenyl]pyrrolidin-2-one
- Opinion of 30 November 2018 concerning 4,5-dichloro-2-octyl-2H-isothiazol-3-one; [DCOIT]
- Opinion of 8 June 2018 concerning 2-methyl-1,2-benzothiazol-3(2H)-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 3-(difluoromethyl)-1-methyl-N-(3',4',5'trifluorobiphenyl-2-yl)pyrazole-4-carboxamide; fluxapyroxad
- Opinion of 15 October 2018 concerning 5-fluoro-1,3-dimethyl-N-[2-(4-methylpentan-2yl)phenyl]-1H-pyrazole-4-carboxamide; 2'-[(RS)1,3-dimethylbutyl]-5-fluoro-1,3dimethylpyrazole-4-carboxanilide; penflufen
- Opinion of 30 November 2018 concerning 5-fluoro-1,3-dimethyl-N-[2-(4-methylpentan-2yl)phenyl]-1H-pyrazole-4-carboxamide; 2'-[(RS)1,3-dimethylbutyl]-5-fluoro-1,3dimethylpyrazole-4-carboxanilide; penflufen
- 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 supercritical 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)-6methylpyrimidin-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-oxa3,5-dithia-4-stannatetradecanoate; [DOTE]
- Opinion of 30 November 2018 concerning lead powder; [particle diameter < 1mm]
- Opinion of 30 November 2018 concerning lead massive; [particle diameter ≥ 1mm]
- Opinion of 14 September 2018 concerning 2-butoxyethanol; ethylene glycol monobutyl ether
- Opinion of 30 November 2018 concerning m-bis(2,3-epoxypropoxy)benzene; resorcinol diglycidyl ether
- Opinion of 14 September 2018 concerning citral; 3,7-dimethylocta-2,6-dienal
- Opinion of 14 September 2018 concerning tribenuron-methyl (ISO); methyl 2- [N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-Nmethylcarbamoylsulfamoyl]benzoate
- Opinion of 8 June 2018 concerning azoxystrobin (ISO); methyl (E)-2-{2-[6-(2cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3methoxyacrylate
- Opinion of 9 March 2018 concerning ethofumesate (ISO); (RS)-2-ethoxy-2,3-dihydro3,3-dimethylbenzofuran-5-yl methanesulfonate
- Opinion of 30 November 2018 concerning 2,4-dinitrophenol
- Opinion of 14 September 2018 concerning mesotrione (ISO) 2-[4-(methylsulfonyl)-2nitrobenzoyl]-1,3-cyclohexanedione
- Opinion of 30 November 2018 concerning octhilinone (ISO); 2-octyl-2H-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)-Ncyclohexyl-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(2H)-one
- Opinion of 9 March 2018 concerning imiprothrin (ISO); reaction mass of: [2,4-dioxo(2-propyn-1-yl)imidazolidin-3-yl]methyl(1R)-cischrysanthemate; [2,4-dioxo-(2-propyn-1yl)imidazolidin-3-yl]methyl(1R)-transchrysanthemate
- 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) It is appropriate and scientifically justified to follow the RAC opinions regarding the hazard classes proposed for the harmonised classification and labelling of certain substances.

(4) It is appropriate to update specific Notes in Part I of Annex VI relating to the identification, classification and labelling of substances, for reasons of legal clarity and certainty.

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

(6) To ensure that suppliers of substances and mixtures have time to adapt to the new harmonised classification and labelling provisions in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008, a transitional period of 18 months should be provided during which suppliers may choose whether or not to apply those provisions..

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*.

Until 18 months from the date of entry into force of this Regulation, substances and mixtures are not required to be classified, labelled and packaged in accordance with this Regulation.

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

Done at Brussels,

For the Commission
The President
[…]