EUROPEAN
COMMISSION

Brussels, 19.5.2020
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**COMMISSION DELEGATED REGULATION (EU) …/...**

**of 19.5.2020**

**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)

# 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 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 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, 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 basis of this delegated act is Article 37(5) of Regulation (EC) No 1272/2008.

[1] OJ L 123 of 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[2], 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[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;

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

[3] 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/-/

– 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;

– 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;

– 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 < 1mm];) and 082-014-00-7 (lead massive; [particle diameter ≥ 1mm];)), 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[4] or those set out in Article 50 of Regulation (EU) No 528/2012 of the European Parliament and of the Council[5].

(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.

[4] 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 (OJ L 396, 30.12.2006, p. 1).

[5] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

*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, before [***Publications Office, please insert specific date of application determined under the second paragraph***] 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.

Done at Brussels, 19.5.2020

*For the Commission*
*The President*
*Ursula VON DER LEYEN*