EUROPEAN
COMMISSION

Brussels, XXX
[…](2023) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Regulation (EC) No 1272/2008 as regards the harmonised classification and labelling of certain substances

(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 taking into account 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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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 he 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 18 March 2021 concerning benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate;
- Opinion of 18 March 2021 concerning benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1);
- Opinion of 18 March 2021 concerning reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and

[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 opinion of 16 September 2021 concerning a reassessment at the request of the Commission is 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.

benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1);

– Opinion of 18 March 2021 concerning reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1);

– Opinion of 18 March 2021 concerning 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF;

– Opinion of 18 March 2021 concerning cinnamaldehyde; 3-phenylprop-2-enal; cinnamic aldehyde; cinnamal [1], (2E)-3-phenylprop-2-enal [2];

– Opinion of 18 March 2021 concerning benfluralin (ISO); *N*-butyl-*N*-ethyl-α,α,α-trifluoro-2,6-dinitro-*p*-toluidine;

– Opinion 18 March 2021 concerning 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate;

– Opinion of 18 March 2021 concerning foramsulfuron (ISO); 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-formamido-*N*,*N*-dimethylbenzamide; 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl)urea;

– Opinion of 18 March 2021 concerning ethyl acrylate;

– Opinion of 18 March 2021 concerning methyl acrylate; methyl propenoate;

– Opinion of 18 March 2021 concerning methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate;

– Opinion of 18 March 2021 concerning transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate;

– Opinion of 18 March 2021 concerning allyl methacrylate; 2-methyl-2-propenoic acid 2-propenyl ester;

– Opinion of 18 March 2021 concerning mepiquat chloride (ISO); 1,1-dimethylpiperidinium chloride;

– Opinion of 10 June 2021 concerning triethylamine;

– Opinion of 10 June 2021 concerning di-*n*-butylamine;

– Opinion of 10 June 2021 concerning 4-nitrosomorpholine;

– Opinion of 10 June 2021 concerning difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether;

– Opinion 10 June 2021 concerning *N*,*N*-dimethyl-p-toluidine;

– Opinion of 10 June 2021 concerning potassium chlorate;

– Opinion of 10 June 2021 concerning sodium chlorate;

– Opinion of 10 June 2021 Concerning reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane;

– Opinion of 10 June 2021 concerning metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4*H*)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one;

– Opinion 16 September 2021 concerning lithium carbonate [1] lithium chloride [2] lithium hydroxide [3];

– Opinion of 16 September 2021 concerning dimethyl propylphosphonate;

– Opinion of 16 September 2021 concerning dibutyltin maleate;

– Opinion of 16 September 2021 concerning dibutyltin oxide;

– Opinion of 16 September 2021 concerning clothianidin (ISO); (*E)*-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine;

– Opinion of 16 September 2021 concerning cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide;

– Opinion of 16 September 2021 concerning nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof];

– Opinion of 16 September 2021 concerning nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof];

– Opinion of 16 September 2021 concerning nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof];

– Opinion of 16 September 2021 concerning 1-phenylethan-1-one (1-phenylethylidene)hydrazone;

– Opinion of 16 September 2021 concerning 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylium chloride; Basic Red 1;

– Opinion of 16 September 2021 concerning picolinafen (ISO); *N*-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4′-fluoro-6-[(α,α,α-trifluoro-m-tolyl)oxy]picolinanilide;

– Opinion of 16 September 2021 concerning diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea;

– Opinion of 16 September 2021 concerning diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide;

– Opinion of 16 September 2021 concerning hydrogen sulphide, hydrogen sulfide;

– Opinion of 16 September 2021 concerning benzyl alcohol;

– Opinion of 16 September 2021 concerning resorcinol; 1,3-benzenediol;

– Opinion of 16 September 2021 concerning 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A;

– Opinion of 16 September 2021 concerning a reassessment at the request of the Commission to review the harmonised classification of lead (environment) - ;

– Opinion of 26 November 2021 concerning 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol;

– Opinion of 26 November 2021 concerning 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol;

– Opinion of 26 November 2021 concerning 1,4-Benzenediamine, *N,N'*-mixed Ph and tolyl derivs.; Reaction mass of *N*-phenyl,*N'*-o-tolyl-phenylene diamine, *N,N'*-diphenyl-p-phenylene diamine and *N,N'*-di-o-tolyl-phenylene diamine;

– Opinion of 26 November 2021 concerning tetramethylene dimethacrylate;

– Opinion of 26 November 2021 concerning 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate;

– Opinion of 26 November 2021 concerning 2,2'-ethylenedioxydiethyl dimethacrylate;

– Opinion of 26 November 2021 concerning bifenox (ISO); methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate;

– Opinion of 26 November 2021 concerning 4-methylimidazole;

– Opinion of 26 November 2021 concerning sulfur dioxide;

– Opinion of 26 November 2021 concerning 1,2-benzisothiazol-3(2*H*)-one; 1,2-benzisothiazolin-3-one;

– Opinion of 26 November 2021 concerning benalaxyl (ISO); methyl *N*-(2,6-dimethylphenyl)-*N*-(phenylacetyl)-DL-alaninate.

(3) The Commission has received additional information from stakeholders contesting the scientific assessment set out in the RAC opinion of 26 November 2021 concerning 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs. and in the RAC opinion of 16 September 2021 concerning dibutyltin oxide. The additional information has been assessed and has not been found sufficient to cast doubts on the scientific analysis contained in the RAC opinions. It is therefore appropriate to introduce the harmonised classification and labelling of the substances concerned on the basis of the assessment made in those opinions.

(4) The RAC opinion of 16 September 2021 concerning the environmental toxicity of lead put forward various possible options to update the harmonised classification of lead for aquatic toxicity. These options give the possibility to either have a single entry for both lead in powder form (‘lead powder’) and in massive form (‘lead massive’) or to keep two separate entries, one for each form. However, as data for lead massive indicates a lower dissolution in water than for lead powder, a calculation in accordance with Part 4 of Annex I to Regulation (EC) No 1272/2008 leads to a less severe classification for lead massive. It is therefore appropriate to amend the existing aquatic toxicity classification for lead powder with regard to the M-factor and to introduce a different aquatic toxicity classification for lead massive.

(5) In light of the RAC opinions, it is therefore appropriate to introduce or update the harmonised classification and labelling of the substances concerned on the basis of the assessment made in those opinions and following the further assessments.

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

(7) As regards the classification of methyl methacrylate as a respiratory sensitiser and the classification of lithium carbonate, lithium chloride and lithium hydroxide as reproductive toxic substances the Commission has received additional information

from stakeholders after obtaining the RAC opinions of 18 March 2021 and of 16 September 2021 respectively concerning those substances. Since that new scientific information requires further assessment by RAC, methyl methacrylate, lithium carbonate, lithium chloride and lithium hydroxide recommended in the RAC opinions should not be subject to harmonised classification and labelling at this stage.

(8) 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

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

Article 2

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 … [OP: please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]

By way of derogation from Regulation (EC) No 1272/2008 as applicable on … [OP: please insert the date = the day before the date of entry into force of this Regulation], substances and mixtures may until … [OP: please insert the date = the last day of the month following 17 months after the date of entry into force of this Regulation] 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,

For the Commission
The President
Ursula VON DER LEYEN