EUROPEAN
COMMISSION

Brussels, XXX
[…](2024) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council 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.

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).

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

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

(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) Part 3, Table 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 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 (RAC) of the Agency adopted, after having taken account of the comments received from the parties concerned, the following opinions[2] on those proposals:

- Opinion of 16 March 2023 concerning 2-ethylhexanoic acid, monoester with propane-1,2-diol;
- Opinion of 16 March 2023 concerning Aqueous extract from the germinated seeds of sweet Lupinus albus;
- Opinion of 16 March 2023 concerning *N*-1-naphthylaniline; *N*-phenylnaphthalen-1-amine;
- Opinion of 16 March 2023 concerning propyl 4-hydroxybenzoate;
- Opinion of 16 March 2023 concerning α,α'-propylenedinitrilodi-*o*-cresol;
- Opinion of 16 March 2023 concerning ozone;

[1] OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj.

[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/-/.

– Opinion of 16 March 2023 concerning dinitrogen oxide;

– Opinion of 16 March 2023 concerning tetrairon tris(pyrophosphate); ferric pyrophosphate;

– Opinion of 16 March 2023 concerning 2-phenylpropene; α-methylstyrene;

– Opinion of 16 March 2023 concerning tetraphosphorus trisulphide; phosphorus sesquisulphide;

– Opinion of 16 March 2023 concerning pethoxamid (ISO); 2-chloro-*N*-(2-ethoxyethyl)-*N*-(2-methyl-1-phenylprop-1-enyl)acetamide;

– Opinion of 8 June 2023 concerning 1,1-dichloroethylene; vinylidene chloride;

– Opinion of 8 June 2023 concerning bixlozone (ISO); 2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one;

– Opinion of 8 June 2023 concerning 9-octadecenoic acid (Z)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt [3];

– Opinion of 8 June 2023 concerning barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1;

– Opinion of 8 June 2023 concerning barium chromate;

– Opinion of 8 June 2023 concerning *chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents;

– Opinion of 8 June 2023 concerning *chrysanthemum cinerariaefolium* extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO_2;

– Opinion of 8 June 2023 concerning fluoroethylene;

– Opinion of 8 June 2023 concerning tetrahydrofurfuryl methacrylate;

– Opinion of 8 June 2023 concerning 2,3-epoxypropyl isopropyl ether;

– Opinion of 8 June 2023 concerning trimethyl phosphate;

– Opinion of 8 June 2023 concerning 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate;

– Opinion of 8 June 2023 concerning 2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB];

– Opinion of 8 June 2023 concerning folpet (ISO); *N*-(trichloromethylthio)phthalimide;

– Opinion of 14 September 2023 concerning 2-bromo-3,3,3-trifluoroprop-1-ene;

– Opinion of 14 September 2023 concerning clopyralid (ISO); 3,6-dichloropyridine-2- carboxylic acid;

– Opinion of 14 September 2023 concerning 3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate;

– Opinion of 14 September 2023 concerning captan (ISO); 1,2,3,6-tetrahydro-*N*-(trichloromethylthio)phthalimide;

– Opinion of 14 September 2023 concerning dinotefuran (ISO); (*RS*)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine;

– Opinion of 14 September 2023 concerning methyl oct-2-ynoate;

– Opinion of 14 September 2023 concerning proquinazid (ISO); 6-iodo-2-propoxy-3- propylquinazolin-4(3*H*)-one;

– Opinion of 14 September 2023 concerning 2,3-epoxypropyl o-tolyl ether;

– Opinion of 14 September 2023 concerning 2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride.

(3) The Commission has received additional information from stakeholders contesting the scientific assessment set out in the RAC opinion of 16 March 2023 concerning dinitrogen oxide. The additional information has been assessed by the Commission and has not been found sufficient to cast doubts on the scientific analysis contained in the RAC opinions.

(4) In light of the RAC opinions, it is 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 assessment by the Commission.

(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 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].

However, suppliers may classify, label and package substances and mixtures in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation from the date of entry into force of 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