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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2024) 3992 final
Subject:	Commission Delegated Regulation (EU) …/... of 19.6.2024 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council as regards the harmonised classification and labelling of certain substances

Delegations will find attached document C(2024) 3992 final.

Encl.: C(2024) 3992 final

EUROPEAN
COMMISSION

Brussels, 19.6.2024
C(2024) 3992 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 19.6.2024

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 (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).

COMMISSION DELEGATED REGULATION (EU) …/...

of 19.6.2024

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 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 (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 18 March 2022 concerning multi-walled carbon tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including multi-walled carbon nanotubes, MWC(N)T;

– Opinion of 18 March 2022 concerning α-methyl-1,3-benzodioxole-5-propionaldehyde [1] (*S*)-α-methyl-1,3-benzodioxole-5-propionaldehyde; (2*S*)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [2] (*R*)-α-methyl-1,3-benzodioxole-5-propionaldehyde; (2*R*)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [3];

– Opinion of 18 March 2022 concerning acetone oxime;

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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 18 March 2022 concerning (3*E*)-dec-3-en-2-one;

– Opinion of 18 March 2022 concerning 2,3-epoxypropyl neodecanoate;

– Opinion of 18 March 2022 concerning propyl 3,4,5-trihydroxybenzoate;

– Opinion of 18 March 2022 concerning benthiavalicarb-isopropyl (ISO); isopropyl [(*S*)-1-{[(*R*)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate;

– Opinion of 18 March 2022 concerning hexyl salicylate;

– Opinion of 18 March 2022 concerning sulfur;

– Opinion of 18 March 2022 concerning reaction mass of *N,N′*-ethane-1,2-diylbis(decanamide) and 12-hydroxy-*N*-[2-[(1-oxodecyl)amino]ethyl]octadecanamide and *N,N′*-ethane-1,2-diylbis(12-hydroxyoctadecanamide) [1] reaction mass of *N,N′*-ethane-1,2-diylbis(decanamide) and 12-hydroxy-*N*-[2-[(1-oxodecyl)amino]ethyl]octadecanamide [2];

– Opinion of 18 March 2022 concerning 2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol;

– Opinion of 30 May 2022 concerning glyphosate (ISO); *N*-(phosphonomethyl)glycine;

– Opinion of 2 June 2022 concerning silver massive: [particle diameter ≥ 1 mm];

– Opinion of 2 June 2022 concerning silver powder: [particle diameter > 100 nm < 1 mm];

– Opinion of 2 June 2022 concerning silver nano: [particle diameter > 1 nm ≤ 100 nm];

– Opinion of 2 June 2022 concerning *S*-metolachlor (ISO); 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*S*)-1-methoxypropan-2-yl]acetamide; (R_aS_a)-2-chloro-*N*-(6-ethyl-*o*-tolyl)-*N*-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100% 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*S*)-1-methoxypropan-2-yl]acetamide and 0-20% 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*R*)-1-methoxypropan-2-yl]acetamide];

– Opinion of 2 June 2022 concerning 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one;

– Opinion of 2 June 2022 concerning formaldehyde … %;

– Opinion of 2 June 2022 concerning formic acid ... %;

– Opinion of 2 June 2022 concerning dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid;

– Opinion of 2 June 2022 concerning 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate;

– Opinion of 2 June 2022 concerning peracetic acid … %;

– Opinion of 2 June 2022 concerning tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy) ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate [1] Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen

sulfate, sodium salts [2] disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl) phenyl]diazenyl}naphthalene-2,7-disulfonate [3];

- Opinion of 15 September 2022 concerning perboric acid, sodium salt [1] perboric acid, sodium salt, monohydrate [2] perboric acid ($HBO(O_2)$), sodium salt, monohydrate [3] sodium peroxoborate [4]
sodium perborate [5];
- Opinion of 15 September 2022 concerning perboric acid ($H_3BO_2(O_2)$), monosodium salt trihydrate [1] perboric acid, sodium salt, tetrahydrate [2] perboric acid ($HBO(O_2)$), sodium salt, tetrahydrate [3] sodium peroxoborate, hexahydrate [4]
- Opinion of 15 September 2022 concerning sodium peroxometaborate;
- Opinion of 15 September 2022 concerning trimethyl borate;
- Opinion of 15 September 2022 concerning ethanethiol;
ethyl mercaptan;
- Opinion of 15 September 2022 concerning 1*H*-benzotriazole;
- Opinion of 15 September 2022 concerning methyl-1*H*-benzotriazole;
- Opinion of 15 September 2022 concerning *N,N*'-methylenediacrylamide;
- Opinion of 15 September 2022 concerning Sodium 3-(allyloxy)-2-hydroxypropanesulphonate;
- Opinion of 1 December 2022 concerning *tert*-butyl 2-ethylperoxyhexanoate;
- Opinion of 1 December 2022 concerning *n*-hexane;
- Opinion of 1 December 2022 concerning biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl;
- Opinion of 1 December 2022 concerning copper; [specific surface area > 0.67 mm2/mg];
- Opinion of 1 December 2022 concerning reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol;
- Opinion of 1 December 2022 concerning 1,4-dichloro-2-nitrobenzene;
- Opinion of 1 December 2022 concerning 2,4-dimethylcyclohex-3-ene-1-carbaldehyde [1] (1α,2α,5α)-2,5-dimethylcyclohex-3-ene-1-carbaldehyde [2] 2,6-dimethylcyclohex-3-ene-1-carbaldehyde [3] 3,5-dimethylcyclohex-3-ene-1-carbaldehyde [4] 3,6-dimethylcyclohex-3-ene-1-carbaldehyde [5] 4,6-dimethylcyclohex-3-ene-1-carbaldehyde [6] reaction mass of 3,5-dimethylcyclohex-3-ene-1-carbaldehyde and 2,4-dimethylcyclohex-3-ene-1-carbaldehyde [7] dimethylcyclohex-3-ene-1-carbaldehyde [8] Dimethylcyclohex-3-ene-1-carbaldehyde [9] 1,2,4(or 1,3,5)-trimethylcyclohex-3-ene-1-carbaldehyde [10] 1,3,4-trimethylcyclohex-3-ene-1-carbaldehyde [11] 2,2,4-trimethylcyclohex-3-ene-1-carbaldehyde [12] 2,4,6-trimethylcyclohex-3-enecarbaldehyde [13] isocyclocitral [14] 3,5,6-trimethylcyclohex-3-ene-1-carbaldehyde [15] 4,6,6-trimethylcyclohex-3-ene-1-carbaldehyde [16];

– Opinion of 1 December 2022 concerning pyraclostrobin (ISO); methyl *N*-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate;

– Opinion of 1 December 2022 concerning dibenzoyl peroxide; benzoyl peroxide;

– Opinion of 1 December 2022 concerning fenpropidin (ISO); (*R*,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine.

(3) The Commission has received additional information from stakeholders contesting the scientific assessment set out in the RAC opinions of 18 March 2022 concerning benthiavalicarb-isopropyl, 2,3-epoxypropyl neodecanoate, multi-walled carbon tubes, hexyl salicylate, in the RAC opinions of 2 June 2022 concerning silver massive, silver powder and silver nano and in the RAC opinions of 1 December 2022 concerning *n*-hexane and copper. 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) With regard to the substance copper flakes (coated with aliphatic acid) (index number 029-019-01-X[3]), its entry for its classification as hazardous for the aquatic environment should be amended to be in accordance with the more generic entry copper; [specific surface area > 0.67 mm2/mg] (index number 029-026-00-0), inserted in the Annex.

(5) With regard to the substance granulated copper[4] (index number 029-024-00-X), its entry should be deleted as it is covered by the more generic entry copper; [specific surface area > 0.67 mm2/mg] (index number 029-026-00-0), inserted in the Annex.

(6) Acute Toxicity Estimates (ATE) are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. The inclusion of harmonised ATE values in the entries listed in Annex VI to Regulation (EC) No 1272/2008 facilitates the harmonisation of the classification of mixtures and provides support for enforcement authorities. Following further scientific assessment, an ATE value for the inhalation route has been derived for fenpropidin (index number 612-299-00-0), in addition to those proposed in the RAC opinions for other substances. That ATE value should be inserted in the penultimate column of Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008.

(7) The entries corresponding to index numbers 005-017-00-7, 005-017-01-4, 005-018-00-2, 005-018-01-X, 005-019-00-8, 005-019-01-5 have been replaced by the entries for perboric acid, sodium salt [1] perboric acid, sodium salt, monohydrate [2] perboric acid (HBO(O2)), sodium salt, monohydrate [3] sodium peroxoborate [4] sodium perborate [5] (index number ‘005-022-00-4), for perboric acid (H3BO2(O2)), monosodium salt trihydrate [1] perboric acid, sodium salt, tetrahydrate [2] perboric acid (HBO(O2)), sodium salt, tetrahydrate [3] sodium peroxoborate, hexahydrate [4] (index number 005-023-00- X) and for sodium peroxometaborate (index number 005-024-00-5) and should therefore be deleted.

[3] See RAC Opinion Opinion of 1 December 2022 concerning copper; [specific surface area > 0.67 mm2/mg], listed above;

[4] Ibidem

(8) In light of the RAC opinions, it is 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 and following the further assessments.

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

(10) 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, substances and mixtures may be classified, labelled and packaged 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, 19.6.2024

For the Commission
The President
Ursula VON DER LEYEN