Council of the
European Union

Brussels, 12 March 2021
(OR. en)

7007/21

COMPET 176
MI 165
ENT 50
ENV 154
CHIMIE 34
SAN 143
CONSOM 64
DELACT 54

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	11 March 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 1533 final - C(2021) 1533 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 11.3.2021 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

Delegations will find attached document C(2021) 1533 final - C(2021) 1533 final.

Encl.: C(2021) 1533 final - C(2021) 1533 final

EUROPEAN
COMMISSION

Brussels, 11.3.2021
C(2021) 1533 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 11.3.2021

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 taking into account comments received from Member States and stakeholders, it is appropriate to introduce, update or delete 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, modified or deleted from 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 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] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123 of 12.05.2016, p. 1).

Commission Delegated Regulation (EU) …/... of 11.3.2021 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)

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. The Committee for Risk Assessment of the Agency (RAC) adopted opinions[3] on those proposals, after having taken account of the comments received from the parties concerned. Those RAC opinions are:

– Opinion of 15 March 2019 concerning 1,2,4-triazole;
– Opinion of 15 March 2019 concerning 1,4-dioxane;
– Opinion of 15 March 2019 concerning benzyl salicylate;
– Opinion of 15 March 2019 concerning flumioxazin (ISO);
– Opinion of 15 March 2019 concerning mancozeb (ISO);
– Opinion of 15 March 2019 concerning M-factors for long-term aquatic hazard for the copper substances listed in Commission Regulation (EU) 2016/1179;

[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 15 March 2019 concerning N-{2-[[1,1'-bi(cyclopropyl)]-2-yl]phenyl}-3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxamide; sedaxane;

– Opinion of 15 March 2019 concerning N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)-ethyl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide; pydiflumetofen;

– Opinion of 15 March 2019 concerning p-cymene; 1-isopropyl-4-methylbenzene;

– Opinion of 15 March 2019 concerning p-mentha-1,3-diene; alpha-terpinene; 1-isopropyl-4-methylcyclohexa-1,3-diene;

– Opinion of 15 March 2019 concerning prothioconazole;

– Opinion of 15 March 2019 concerning (R)-p-mentha-1,8-diene;d-limonene;

– Opinion of 15 March 2019 concerning thiophanate-methyl;

– Opinion of 15 March 2019 concerning tolclofos-methyl (ISO); O-(2,6-dichloro-p-tolyl) O,O-dimethyl thiophosphate;

– Opinion of 15 March 2019 concerning tolpyralate;

– Opinion of 15 March 2019 concerning trinickel disulphide;

– Opinion of 13 June 2019 concerning azamethiphos;

– Opinion of 13 June 2019 concerning 2-phenoxyethanol;

– Opinion of 13 June 2019 concerning 2,2-dibromo-2-cyanoacetamide;

– Opinion of 13 June 2019 concerning 3-aminomethyl-3,5,5-trimethylcyclohexylamine;

– Opinion of 13 June 2019 concerning 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol;

– Opinion of 13 June 2019 concerning diflufenican (ISO) *N*-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide;

– Opinion of 13 June 2019 concerning imidacloprid (ISO); 1-(6-chloropyridin-3-ylmethyl)-*N*-nitroimidazolidin-2-ylidenamine;

– Opinion of 13 June 2019 concerning pyriofenone;

– Opinion of 13 June 2019 concerning *S*-abscisic acid;

– Opinion of 13 June 2019 concerning tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate.

– Opinion of 20 September 2019 concerning 1,2-epoxy-4-epoxyethylcyclohexane;

– Opinion of 20 September 2019 concerning 4-methylpentan-2-one;

– Opinion of 20 September 2019 concerning boric acid; diboron trioxide; tetraboron disodium heptaoxide hydrate; disodium tetraborate anhydrous; orthoboric acid sodium salt; disodium tetraborate decahydrate; disodium tetraborate pentahydrate;

– Opinion of 20 September 2019 concerning citric acid;

– Opinion of 20 September 2019 concerning clomazone;

– Opinion of 20 September 2019 concerning desmedipham;

– Opinion of 20 September 2019 concerning dimethomorph;

– Opinion of 20 September 2019 concerning emamectin benzoate;

– Opinion of 20 September 2019 concerning esfenvalerate (ISO) (*S*)-α-cyano-3-phenoxybenzyl (*S*)-2-(4-chlorophenyl)-3-methylbutyrate;

– Opinion of 20 September 2019 concerning ethametsulfuron-methyl (ISO);

– Opinion of 20 September 2019 concerning mecoprop-*P* (ISO); (*R*)-2-(4-chloro-2-methylphenoxy)propionic acid and its salts;

– Opinion of 20 September 2019 concerning methyl salicylate;

– Opinion of 20 September 2019 concerning phenmedipham (ISO);

– Opinion of 20 September 2019 concerning trifloxystrobin (ISO);

– Opinion of 20 September 2019 concerning triticonazole;

– Opinion of 5 December 2019 concerning 1,4-dimethylnaphthalene;

– Opinion of 5 December 2019 concerning (3a*S*,5*S*,6*R*,7a*R*,7b*S*,9a*S*,10*R*,12a*S*,12b*S*)-10-[(2*S*,3*R*,4*R*,5*R*)-3,4-dihydroxy-5,6-dimethylheptan-2-yl]-5,6-dihydroxy-7a,9a-dimethylhexadecahydro-3*H*-benzo[c]indeno[5,4-e]oxepin-3-one; 24-epibrassinolide;

– Opinion of 5 December 2019 concerning 3-methylpyrazole;

– Opinion of 5 December 2019 concerning carbendazim (ISO); methyl benzimidazol-2-ylcarbamate;

– Opinion of 5 December 2019 concerning cypermethrin cis/trans +/- 40/ 60; (*RS*)-α-cyano-3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate;

– Opinion of 5 December 2019 concerning imazamox (ISO); (*RS*)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methoxymethylnicotinic acid;

– Opinion of 5 December 2019 concerning tetrafluoroethylene;

– Opinion of 5 December 2019 concerning thiamethoxam (ISO); 3-(2-chloro-thiazol-5-ylmethyl)-5-methyl[1,3,5]oxadiazinan-4-ylidene-*N*-nitroamine;

– Opinion of 5 December 2019 concerning trinexapac-ethyl (ISO); ethyl 4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate;

(3) 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 assessmentsof some substances, ATE values have been derived by the Agency for dicopper oxide, dicopper chloride trihydroxide, tetracopper hexahydroxide sulphate and tetracopper hexahydroxide sulphate hydrate, copper flakes (coated with aliphatic acid), copper(II) carbonate--copper(II) hydroxide (1:1), copper dihydroxide; copper(II)

hydroxide, bordeaux mixture; reaction products of copper sulphate with calcium dihydroxide and copper sulphate pentahydrate, in addition to those proposed in the RAC opinions for other substances. Those ATE values should be inserted in the penultimate column of Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008.

(4) Additional information was received by the Commission contesting the scientific assessment set out in the RAC opinions of 15 March 2019 concerning mancozeb, of 20 September 2019 concerning 4-methylpentan-2-one, and of 20 September 2019 concerning dimethomorph. That information was assessed by the Commission and was not found sufficient to cast doubts on the scientific analysis contained in the RAC opinions.

(5) The Commission therefore considers appropriate to introduce, update or delete the harmonised classification and labelling of certain substances.

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

(7) 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]. 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 and as of the date of entry into force 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

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 be classified, labelled and packaged in accordance with this Regulation from its date of entry into force.

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

Done at Brussels, 11.3.2021

For the Commission
The President
Ursula VON DER LEYEN