Council of the European Union

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ENT 95
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COMPET 412
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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	2 May 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2023) 2674 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 2.5.2023 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards the modification of entries in Part 3 of Annex VI for 2-ethylhexanoic acid and its salts, boric acid, diboron trioxide, tetraboron disodium heptaoxide hydrate, disodium tetraborate anhydrous, orthoboric acid sodium salt, disodium tetraborate decahydrate, and disodium tetraborate pentahydrate

Delegations will find attached document C(2023) 2674 final.

Encl.: C(2023) 2674 final

EUROPEAN
COMMISSION

Brussels, 2.5.2023
C(2023) 2674 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 2.5.2023

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards the modification of entries in Part 3 of Annex VI for 2-ethylhexanoic acid and its salts, boric acid, diboron trioxide, tetraboron disodium heptaoxide hydrate, disodium tetraborate anhydrous, orthoboric acid sodium salt, disodium tetraborate decahydrate, and disodium tetraborate pentahydrate

(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 State experts in the CARACAL expert group (Competent Authorities for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging (CLP)), it is appropriate to update the harmonised classification and labelling of certain substances by assigning to them the notes that have been recently added to Part 1 of Annex VI to Regulation (EC) No 1272/2008 and to 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) …/...

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amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards the modification of entries in Part 3 of Annex VI for 2-ethylhexanoic acid and its salts, boric acid, diboron trioxide, tetraboron disodium heptaoxide hydrate, disodium tetraborate anhydrous, orthoboric acid sodium salt, disodium tetraborate decahydrate, and disodium tetraborate pentahydrate

(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 a 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 of the Agency (the 'RAC') adopted opinions on those proposals, after having taken account of the comments received from the parties concerned.

(3) The RAC's opinion of 20 September 2019 concerning boric acid, diboron trioxide, tetraboron disodium heptaoxide hydrate, disodium tetraborate anhydrous, orthoboric acid sodium salt, disodium tetraborate decahydrate and disodium tetraborate pentahydrate[2], as well as the RAC's opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts[3], described scientific evidence indicating that the reproductive toxicity of each of those substance groups is due to a molecular entity common to all members of a substance group. Member State experts consulted in the Commission expert group CARACAL (Competent Authorities for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging (CLP)) therefore requested the addition of notes to the entries

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

[2] https://echa.europa.eu/documents/10162/584263da-199c-f86f-9b73-422a4f22f1c3

[3] https://echa.europa.eu/documents/10162/8740de5b-368d-55a7-7955-094ef602d760

related to the substance groups referred to in those RAC opinions of 2019 and 2020, in order to address the situation in which several substances belonging to one of those groups are present together in a mixture and to provide that the applicable concentration limit for classification of the mixture is to be compared with the sum of the concentrations of those substances. Those notes were added to Part 1, section 1.1.3.2, of Annex VI to Regulation (EC) No 1272/2008 by Commission Delegated Regulation (EU) …/... amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards the addition of notes to Part 1, section 1.1.3, of Annex VI C(2023)2672 [4], as note 11 and note 12. It is therefore appropriate to add a reference to note 11 to the entries for boric acid, diboron trioxide, tetraboron disodium heptaoxide hydrate, disodium tetraborate anhydrous, orthoboric acid sodium salt, disodium tetraborate decahydrate and disodium tetraborate pentahydrate and a reference to note 12 to the entry for 2-ethylhexanoic acid and its salts.

(4) In its opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts, the RAC recommended adding a note to this entry, in order to address the possibility that, while the entry for this group of substances is based on the toxic properties of a common part of those substances, another, substance-specific, part of the substances may warrant classification in a higher category or classification with a broader scope, e.g. including additional differentiation, target organs and/or hazard statements, for certain substances in the entry. Such note was added to Part 1, section 1.1.3.1, of Annex VI to Regulation (EC) No 1272/2008 by Commission Delegated Regulation (EU) …/... amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards the addition of notes to Part 1, section 1.1.3, of Annex VI C(2023)2672 as note X. It is therefore appropriate to add a reference to note X to the entry concerning 2-ethylhexanoic acid and its salts.

(5) Member State experts consulted in the CARACAL expert group suggested that the current note A should be applicable to 2-ethylhexanoic acid and its salts. Note A prescribes that for substances covered by an entry with a general description, such as '…compounds' or '…salts', the supplier is required to state on the label the correct name. As the entry for 2-ethylhexanoic acid and its salts bears such a general description, a reference to note A should be added to the entry.

(6) As Commission Delegated Regulation (EU) …/... amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures as regards the addition of notes to Part 1, section 1.1.3, of Annex VI C(2023)2672 was adopted on 25 April 2023, the notes included in that Regulation could not be inserted in Table 3 of Annex VI at the time of the adoption of Commission Delegated Regulation (EU) 2021/849[5] and Commission Delegated Regulation (EU) 2022/692[6] which added the respective entries to Table 3 of Annex VI to Regulation (EC) No 1272/2008. It is therefore necessary to update the entries concerning boric acid; diboron trioxide; tetraboron disodium heptaoxide hydrate;

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4 OJ L …[PO add OJ reference to Commission Delegated Regulation which includes the notes once adopted]

5 OJ L188, 28.5.2021, p.27

6 OJ L129, 3.5.2022, p. 1

disodium tetraborate anhydrous; orthoboric acid sodium salt; disodium tetraborate decahydrate; disodium tetraborate pentahydrate, by adding reference to note 11 to each of them. It is also necessary to update entry concerning 2-ethylhexanoic acid and its salts by adding a reference to note 12 and note X to that entry.

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

(8) Compliance with the revised harmonised classifications should not be required immediately as suppliers need some time to adapt the labelling and packaging of substances and mixtures to the revised harmonised classifications and to sell existing stocks of substances and mixtures. That period of time would also allow suppliers to take the actions required to ensure compliance with other requirements set out in Regulation (EC) No 1272/2008, as amended by this Regulation. Suppliers should, however, have the possibility to apply the revised harmonised classifications, and to adapt the labelling and packaging accordingly, on a voluntary basis as from the entry into force 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

Amendments to Regulation (EC) No 1272/2008

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

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*.

Article 1 shall apply from … [***PO please insert the date corresponding to the first day of the month following the date 18 months after the entry into force of this Regulation].***

Suppliers may classify, label and package substances and mixtures listed in the Annex to this Regulation in accordance with Regulation (EC) No 1272/2008, as amended by this Regulation, as from [OP please insert 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, 2.5.2023

For the Commission
The President
Ursula VON DER LEYEN