EUROPEAN
COMMISSION

Brussels, XXX
[…](2022) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

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 1.1.3.1, of Annex VI

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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. Subsection 1.1.3. of Part 1 of Annex VI of that Regulation lists notes which may be assigned to one or more harmonised classification and labelling entries and relate to the identification, classification and labelling of substances as well as the classification and labelling of mixtures. The purpose of these notes is to provide legal clarity and certainty in applying harmonised classification and labelling.

It was recommended by the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) and requested by Member States experts in the CARACAL expert group to include additional notes in subsection 1.1.3. of Part 1 of Annex VI of CLP to address the appropriate classification of certain substances belonging to a group entry, and of certain mixtures that contain several substances belonging to a group of related substances. It is considered appropriate to add those notes in subsection 1.1.3. of Part 1 of Annex VI.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

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 53(1) 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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(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 53(1) thereof,

Whereas:

(1) Part 1, section 1.1.3.1, of Annex VI to Regulation (EC) No 1272/2008 contains the list of notes which may be assigned to one or more harmonised classification and labelling entries and relate to the identification, classification and labelling of substances as well as the classification and labelling of mixtures.

(2) In its opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts[2], the Committee for Risk Assessment (RAC) under the European Chemicals Agency recommended to add a new note to Part 1, section 1.1.3.1, of Annex VI to Regulation (EC) No 1272/2008, to clarify that the classification covering a group of substances in the same entry is only based on the hazardous properties of that part of the substance which is common to all substances in that entry. According to RAC, for the non-common parts of a substance, it is necessary to assess if their hazardous properties may warrant a more severe classification (higher category) or a broader classification (including additional differentiation, target organs and/or hazard statements) for the same hazard class. A new note X should therefore be added to Part 1, section 1.1.3.1, of Annex VI to Regulation (EC) 1272/2008. As that note is likely to be assigned to other substances with the same properties in the future, it should be worded in such way that it is not limited to that specific entry.

(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[3] as well as the RAC's opinion of 11 June 2020 concerning 2-ethylhexanoic acid and its salts, described scientific evidence that the reproductive toxicity of each of these substance groups is due to a molecular entity common to all

1 OJ L 353, 31.12.2008, p. 1.
2 https://echa.europa.eu/documents/10162/8740de5b-368d-55a7-7955-094ef602d760
3 https://echa.europa.eu/documents/10162/584263da-199c-f86f-9b73-422a4f22f1c3

members of the respective group. When considering proposals for harmonised classification of certain boron compounds and of 2-ethylhexanoic acid and its salts, Member State experts consulted in the CARACAL expert group (Competent Authorities for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging (CLP)) requested to add new notes in Part 1, section 1.1.3.2, of Annex VI to Regulation (EC) No 1272/2008. According to the discussion in the CARACAL expert group, these notes are necessary to allow a more accurate identification of the hazard of mixtures, which contain several substances belonging to the same 'group entry'. The principle of additivity should apply to substances whose hazard is due to the presence or formation of a common molecular entity. As a consequence, it is necessary to take account of the contribution of these substances to the overall hazardous property of the mixture in proportion to their concentration, by comparing the applicable generic or specific concentration limit with the sum of the concentrations of the substances present. Therefore, two new notes, note 11 and 12, should be added to Part 1, section 1.1.3.2, of Annex VI to Regulation (EC) 1272/2008. As note 11 should be assigned to boric acids and its salts only, in view of the specificity of the concerned entries, it should be worded in such way that it is specific for those entries. As note 12 is likely to be assigned in the future to substances other than 2-ethylhexanoic acid and its salts, it should be worded in such way that it is not limited to that specific entry.

(4) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

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

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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