



EUROPEAN
COMMISSION

Brussels, XXX
[...] (2026) 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 addition of notes**

(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 1272/2008¹ on classification, labelling and packaging of substances and mixtures (the CLP Regulation) are to ensure: (i) a high level of protection of human health and the environment; and (ii) the free movement of substances, mixtures and articles. To contribute to fulfilling these objectives, harmonised classifications and labelling elements have been established at Union level. In this context, the list of harmonised classifications and labelling in Part 3, Table 3, of Annex VI to the CLP Regulation is being amended to include substances identified as endocrine disruptors, as persistent, bioaccumulative and toxic (PBT) or as very persistent and very bioaccumulative (vPvB) under Regulation (EC) No 1907/2006² (the REACH Regulation), Regulation (EC) No 1107/2009³ on plant protection products, or Regulation (EU) No 528/2012⁴ on biocidal products.

Section 1.1.3 of Part 1 of Annex VI lists notes which may be assigned to harmonised classification and labelling entries in Table 3 of Part 3 of that annex. This is to provide legal clarity and certainty when applying those entries. Some entries in that table cover substances that are quasi-identical and have a similar mode of action, making it appropriate to establish additivity rules⁵ for those groups on a case-by-case basis. In this context, this Delegated Act introduces new notes. Most of the notes (i) specify that concentrations of individual substances in a mixture covered by the same entry are to be added up for classification purposes and (ii) identify to which entries and for which hazard classes or differentiations within them such additivity rules apply.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

(To be completed after the public consultation)

¹ 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 (OJ L 353, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

² 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, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>).

⁴ 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, <http://data.europa.eu/eli/reg/2012/528/oj>).

⁵ The principle of additivity should apply to substances whose hazard is due to the presence or formation of a common toxic 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 these substances present.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal act amends Regulation (EC) No 1272/2008. The legal basis for this Delegated Act is Article 53(1) of Regulation (EC) No 1272/2008.

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COMMISSION DELEGATED REGULATION (EU) .../...

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amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council as regards the addition of notes

(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 1907/2006¹, and in particular Article 53(1) thereof,

Whereas:

- (1) Part 1, Section 1.1.3, of Annex VI to Regulation (EC) No 1272/2008 contains the notes which may be assigned to one or more harmonised classification and labelling entries. The notes relate to the identification, classification and labelling of substances and to the classification and labelling of mixtures.
- (2) As it cannot be ascertained whether substances containing less than 0,1 % w/w octamethylcyclotetrasiloxane have to be classified as persistent, bioaccumulative and toxic (PBT), it should be left to manufacturers, importers and downstream users to 'self-classify' those substances in accordance with Title II of Regulation (EC) No 1272/2008. To clarify how the harmonised classification applies to such substances, Note Y should be introduced.
- (3) The names of certain entries in Part 3, Table 3, of Annex VI to Regulation (EC) No 1272/2008 refer to groups of substances rather than to individual substances. However, in some specific cases, where an individual substance from the group of substances covered by this entry is placed on the market, the supplier should be able to provide a specific name for this individual substance falling within the scope of such entries, including the corresponding identification number (where available). To clarify the rules applying in such cases, Note Z should be introduced.
- (4) Some of the entries included in Part 3, Table 3, of Annex VI to Regulation (EC) No 1272/2008 in accordance with Delegated Regulation [*Office of Publications, please add the reference to Commission Delegated Regulation XX once adopted*] contain several substances that are quasi-identical and have similar intrinsic properties or a similar mode of action. Therefore, it is appropriate to set additivity rules in specific notes for those groups of substances on a case-by-case basis.
- (5) Notes 14 to 17 should be introduced to clarify that the concentrations of individual substances in a given mixture and covered by the same entry in Annex VI to

¹ [OJ L 353, 31.12.2008, p. 1](#), ELI: [CL2008R1272EN0310010.0001_cp 1..2](#)

Regulation (EC) No 1272/2008 are to be added up for the purpose of classifying that mixture for the respective hazard class or differentiations respectively quoted in those notes. As notes 14 to 17 are assigned to various entries within it and are likely to be assigned in the future to substances other than those in Delegated Regulation [*Office of Publications, please add the reference to Commission Delegated Regulation XX once adopted*], they should be worded in such a way that they are not limited to those specific entries but to a specific hazard class or differentiations within it.

- (6) Some substances may be grouped for the hazard class or differentiations within it, listed above and should therefore be subject to the same additivity rules. However, one or more substances in those groups may be already subject to harmonised classification for additional hazard classes or differentiations. This results in more than one entry in Annex VI to which additivity rules should apply. Therefore, notes 18 to 21 should be introduced to identify to which entries and for which hazard class or differentiation additivity rules should apply. As notes 18 to 21 should be assigned to selected entries, in view of the specificities of the entries concerned, each note should be worded in such a way that it is specific for a respective set of entries.
- (7) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

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.

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