



Council of the
European Union

Brussels, 24 August 2021
(OR. en)

11358/21

ENT 138
MI 619
COMPET 598
CHIMIE 82
ENV 582
SAN 512
CONSOM 181
DELECT 175

COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 23 August 2021

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.: C(2021) 5932 final

Subject: COMMISSION DELEGATED REGULATION (EU) .../... of 12.8.2021 correcting 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) 5932 final.

Encl.: C(2021) 5932 final



Brussels, 12.8.2021
C(2021) 5932 final

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

of 12.8.2021

**correcting 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

CONTEXT OF THE DELEGATED ACT

The Commission has become aware of errors due to an oversight in Annex III to Commission Delegated Regulation (EU) 2020/217¹. It concerns a signal word code that corresponds to a signal word that needs to be put on the labels of some hazardous substances and, as the case may be, mixtures containing those substances. Labelling requirements such as signal words are linked to a specific hazard class as provided in Annex I to the Regulation (EC) No 1272/2008² (the CLP Regulation). Annex III of Commission Delegated Regulation (EU) 2020/217 erroneously contains the signal word code ‘Dgr’ (danger) instead of ‘Wng’(warning) for three substances (pentapotassium 2,2’,2’’,2’’’,2’’’’(ethane-1,2-diyl(nitrilo)pentaacetate; N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA)). Those substances are classified, *inter alia*, as specific target organ toxicant – repeated exposure (category 2) and their corresponding entries in Annex III should therefore contain the signal word code ‘Wng’ instead of the signal word code ‘Dgr’ that indicates a more severe hazard. This error should be corrected.

In order not to penalise producers, importers or downstream users who would already have labelled and packaged their substances or mixtures in accordance with Regulation (EU) 2020/217 before the entry into force of this regulation, they should be allowed not to relabel and repackage them in accordance with this regulation.

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 in the expert group CARACAL (Competent authorities for REACH and CLP) have been consulted. Furthermore, the draft Commission Delegated Regulation has been transmitted to the European Parliament and the Council which are invited to participate in the CARACAL expert group meetings in accordance with points 10 and 11 of the Annex to the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016³.

Stakeholders were consulted in the CARACAL expert group in accordance with point 6 of the Annex to the Interinstitutional Agreement on Better Law-Making of 13 April 2016.

LEGAL ELEMENTS OF THE DELEGATED ACT

The legal act corrects an error made due to an oversight in Commission Regulation (EU) 2020/217, which had previously amended Regulation (EC) No 1272/2008.

¹ Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 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 and correcting that Regulation (OJ L 44, 18.2.2020, p.1).

² 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.)

³ OJ L 123, 12.05 2016, p. 1.

Commission Delegated Regulation (EU) .../... of 12.8.2021 correcting 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

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 37(5) thereof,

Whereas:

- (1) Verification has revealed errors in Annex VI to Regulation (EC) No 1272/2008. Commission Delegated Regulation (EU) 2020/217², which amended that Annex, added a number of substances in Table 3 of Part 3 thereof. The entries concerning the substances pentapotassium 2,2',2'',2''',2''''(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra (acetic acid) and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate contain errors related to the signal word. Those substances are classified, inter alia, as specific target organ toxicant repeated exposure category 2 and should therefore be labelled by using the signal word 'Warning' corresponding to the signal word code 'Wng' in accordance with Table 3.9.5. of Part 3 of Annex I to Regulation (EC) No 1272/2008. Delegated Regulation (EU) 2020/217 however mistakenly introduced the signal word code 'Dgr' (an abbreviation of 'Danger') for those substances. Those errors should be corrected.
- (2) Regulation (EC) No 1272/2008 should therefore be corrected accordingly.
- (3) As the provisions of Delegated Regulation (EU) 2020/217 containing the mistake apply from 1 October 2021, the correction thereof should also apply from that date.
- (4) Similarly, in order to reflect the provisions of Delegated Regulation (EU) 2020/217, suppliers should be allowed to apply the corrections made by this Regulation to substances and mixtures before its date of application on a voluntary basis.
- (5) Suppliers should not be required to change the labels and packages of substances and mixtures which have been placed on the market before the entry into force of this Regulation in accordance with Regulation (EC) No 1272/2008, to avoid unnecessary costs. As the erroneous signal word code corresponds to a more severe hazard class maintaining the corresponding signal word on the label does not decrease the level of protection of human health,

¹ OJ L 353, 31.12.2008, p.1.

² Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 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 and correcting that Regulation (OJ L 44, 18.2.2020, p.1).

HAS ADOPTED THIS REGULATION:

Article 1

The signal word code 'Dgr' in the seventh column 'Pictogram, Signal Word Code(s)' of Table 3 in Part 3 of Annex VI to Regulation (EC) No 1272/2008 regarding the entries concerning pentapotassium 2,2',2'',2'''',2''''(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra (acetic acid) and pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate is replaced by the signal word code 'Wng'.

Article 2

Suppliers shall not be required to change, as indicated in Article 1, the label or the packaging of substances or mixtures containing them, which they have placed on the market in accordance with Regulation (EC) No 1272/2008 before ... [*Publications Office: please insert the date – the date of entry into force of this amending Regulation*].

Article 3

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

It shall apply from 1 October 2021.

By way of derogation from the second paragraph of this Article, the substances referred to in Article 1 of this Regulation and the substances and mixtures containing them may, before 1 October 2021, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as corrected by this Regulation.

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

Done at Brussels, 12.8.2021

For the Commission
The President
Ursula VON DER LEYEN