



Council of the
European Union

013736/EU XXVI. GP
Eingelangt am 06/03/18

Brussels, 6 March 2018
(OR. en)

6868/18

COMPET 137
ENV 160
CHIMIE 8
MI 153
ENT 40
SAN 75
CONSOM 57

COVER NOTE

From:	European Commission
date of receipt:	2 March 2018
To:	General Secretariat of the Council
No. Cion doc.:	D054354/03
Subject:	COMMISSION 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 and correcting Commission Regulation (EU) 2017/776

Delegations will find attached document D054354/03.

Encl.: D054354/03



EUROPEAN
COMMISSION

Brussels, **XXX**
D054354/03
[...](2018) **XXX** draft

COMMISSION 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 and correcting
Commission Regulation (EU) 2017/776**

(Text with EEA relevance)

COMMISSION 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 and correcting Commission Regulation (EU) 2017/776

(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 37(5) and Article 53(1) thereof,

Whereas:

- (1) Table 3.1 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 pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on the opinions on those proposals issued by the Committee for Risk Assessment of the Agency (RAC), as well as on the comments received from the parties concerned, it is appropriate to introduce, update or delete harmonised classification and labelling of certain substances.
- (3) Council Directive 67/548/EEC² and Directive 1999/45/EC of the European Parliament and of the Council³ were repealed with effect from 1 June 2015. As a result, Part 3 of Annex VI to Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) 2016/1179⁴ to remove Table 3.2. That amendment took effect on 1 June 2017. Annex VI to Regulation (EC) No 1272/2008 was further amended by Commission

¹ OJ L 353, 31.12.2008, p.1.

² Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p. 1).

³ Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p.1).

⁴ Commission Regulation (EU) 2016/1179 of 19 July 2016 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 (OJ L 195 20.7.2016, p.11).

Regulation (EU) 2017/776⁵ to delete references to Table 3.2, to convert references to Table 3.1 into references to Table 3 and to delete references to the repealed Directives. Under Article 2(2) of Regulation (EU) 2017/776, the majority of those amendments were to apply from 1 June 2017, while the remaining amendments were stated to apply from 1 December 2018. However, due to an oversight Article 2(2) failed to list two further amendments that should have applied from 1 June 2017, including in particular the amendment changing the name of the Table from "Table 3.1" to "Table 3". The second subparagraph of Article 2(2) of Regulation (EU) 2017/776 should therefore be corrected to include reference to those two amendments. This correction, although it has the effect of applying the two amendments retroactively, does not affect the rights and obligations of manufacturers, importers, downstream users or suppliers.

- (4) Regulation (EU) 2017/776 also amended Annex VI to Regulation (EC) No 1272/2008 to add harmonised 'Acute Toxicity Estimate' (ATE) values in Table 3.1 as part of the information relating to the classification and labelling of certain substances for the purposes of the classification of mixtures. The ATE introduced for nicotine was expressed in mg/kg. In order to clarify how mixtures containing nicotine should be classified, the ATE for the oral and the dermal routes for nicotine should instead be expressed in 'mg/kg bw'⁶. The ATEs for three other substances, namely colecalciferol, 1,2-dihydroxybenzene and pinoxaden should also be expressed in the same way. In addition, in the title of the penultimate column of Table 3.1, a footnote should be added indicating what the abbreviation 'mg/kg bw' stands for.
- (5) The Annex to Commission Regulation (EU) XX/2017⁷ [*OP: please insert number of the Regulation here and reference it in the footnote*] provides for the translation of the names of the substances included in Table 3.1 of Annex VI to Regulation (EC) No 1272/2008. As a consequence, the title of the second column of that Table, which currently refers to 'international chemical identifications', should be amended to take account of the fact that the 'international chemical identifications' will lose their international character once the Regulation providing for their translation in Annex VI becomes applicable. For the sake of consistency, this amendment should take effect when the translation of the names in Annex VI takes effect. The new title should reflect the terminology used in Article 18 of Regulation (EC) No 1272/2008.
- (6) Compliance with the new or updated harmonised classifications should not be required immediately as a certain period of time will be 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. That period of time will also be necessary to allow suppliers to adapt to and comply with other legislative obligations resulting from the new or updated harmonised classifications, such as those set out in Article 22(f) or Article 23 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁸, those set out in Article 50 of Regulation (EU) No 528/2012 of the European

⁵ Commission Regulation (EU) 2017/776 of 4 May 2017 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 (OJ L 116 5.5.2017, p. 1).

⁶ Body weight

⁷ Commission Regulation (EU) XX/201X 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 [*OP: please insert reference of this future Commission Regulation here it should be adopted in the first quarter of 2018 and concerns the translation of the names of the chemical substances into the official languages of the EU*]

⁸ 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).

Parliament and of the Council⁹ or those set out in Article 44 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹⁰.

- (7) Regulation (EC) No 1272/2008 should therefore be amended accordingly.
- (8) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow for new provisions to be applied at an earlier stage on a voluntary basis, suppliers should be allowed to apply the new and updated harmonised classifications, and to adapt the labelling and packaging accordingly, on a voluntary basis before the date of application of those new or updated classifications.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment 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

Correction to Regulation (EU) 2017/776

In Regulation (EU) 2017/776, the second subparagraph of Article 2(2) is replaced by the following:

"In the Annex, point (1), point (2) and points (a), (b) and (c) of point (3) shall apply from 1 June 2017."

Article 3

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*.

Point (1) and point (a) of point (2) of the Annex shall apply from [OP: please insert date to be determined as follows: Date of application of Regulation XX – see also recital 5].

Points (b), (c), (d) and (e) of point (2) of the Annex shall apply from [OP: please insert date to be determined as follows: Date of entry into force plus 18 months – the date should be the 1st day of the following month.]

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).

⁹ 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).

¹⁰ 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).

By way of derogation from the third paragraph of this Article, substances and mixtures may, before [*OP: please insert specific date of application determined under the third paragraph*], be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

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

Done at Brussels,

For the Commission
The President
[\[...\]](#)