EUROPEAN
COMMISSION

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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

(Text with EEA relevance)

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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

(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) 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 for new, updated or deleted harmonised classification and labelling of certain substances have been submitted to the European Chemicals Agency (ECHA) 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 ECHA (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) The Acute Toxicity Estimates (ATE) are mainly used to determine the classification for human health acute toxicity of mixtures containing substances classified for acute toxicity. The inclusion of harmonised ATE values in the entries listed in Annex VI to Regulation (EC) No 1272/2008 would facilitate the harmonisation of the classification of mixtures and provide support for enforcement authorities. The ATE values harmonised in accordance with Article 37 should be added in the penultimate column of Table 3.1 of Part 3 of Annex VI to that Regulation. Pursuant to Article 38(1)(e) those values are to be mentioned in the opinions and decisions for harmonised classification. The title of the column of Table 3.1 of Part 3 as well as section 1.1.2.3 of Part 1 of Annex VI to Regulation (EC) No 1272/2008 should be amended consequently.

(4) Compliance with the new harmonised classifications and the new provision on the ATE in section 1.1.2.3 of Part 1 of Annex VI to Regulation (EC) No 1272/2008 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 classifications and to sell existing stocks. That period of time will also be necessary to

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

allow suppliers to adapt to and to comply with other legislative obligations resulting from the new harmonised classifications for substances 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 Council[2], those set out in Article 50 of Regulation (EU) No 528/2012 of the European Parliament and of the Council[3] or those set out in Article 44 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[4].

(5) Table 3.2 of Annex VI to Regulation (EC) No 1272/2008, which lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Council Directive 67/548/EEC[5], has been deleted with effect from 1 June 2017. For reasons of consistency, the references to Table 3.2 in Parts 1 and 3 of Annex VI to Regulation (EC) No 1272/2008 should be deleted with effect from the same date. For reasons of clarity, Table 3.1 of Annex VI to Regulation (EC) No 1272/2008 should become Table 3 and all references to Table 3.1 in that Annex should be changed accordingly.

(6) Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council[6] have been repealed with effect from 1 June 2015. For reasons of consistency, the references to those Directives in the introductory part and in Parts 1 and 3 of Annex VI to Regulation (EC) No 1272/2008 should be deleted simultaneously with the changes regarding the references to Tables 3.1 and 3.2 of Annex VI to that Regulation with effect from 1 June 2017, which is the date provided for in Article 61(4) of Regulation (EC) No 1272/2008 before which mixtures which are classified, labelled and packaged in accordance with Directive 1999/45/EC and placed on the market before 1 June 2015 need not to be relabelled and repackaged in accordance with Regulation (EC) No 1272/2008.

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

(8) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new harmonised classifications and of adapting the labelling and packaging accordingly on a voluntary basis before the deadline for compliance.

(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,

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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).

3 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).

4 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).

5 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).

6 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).

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

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

2. This Regulation shall apply from [OPOCE: 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.]

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

3. By way of derogation from paragraph 2, substances and mixtures may, before [OPOCE: please insert specific date of applicability determined under the first subparagraph of paragraph 2], 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
[…]