EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) No …/..

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) Part 3 of Annex VI to Regulation (EC) No 1272/2008 contains two lists of harmonised classification and labelling of hazardous substances. Table 3.1 lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to Regulation (EC) No 1272/2008. Table 3.2 lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Annex VI to Council Directive 67/548/EEC[2].

(2) Since Directive 67/548/EEC has been repealed with effect from 1 June 2015, Table 3.2. in Part 3 of Annex VI should be deleted. However, in order to ease the transition to full applicability of Regulation (EC) No 1272/2008, that deletion should not take effect until 1 June 2017.

(3) 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.

(4) With regard to the substance lead, RAC proposes in its scientific opinion of 5 December 2013 to classify it as toxic for reproduction category 1A. However, in view of the lack of certainty regarding the degree of bioavailability of lead in the massive form, a distinction needs to be made between the massive form (particle size of more than 1 mm) and the powder form (particle size up to 1 mm). It is therefore appropriate, for the time being, to introduce a specific concentration limit (SCL) of ≥

[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).

0,03% for the powder form and a generic concentration limit (GCL) of ≥ 0,3% for the massive form.

(5) With regard to the copper substances, the environmental classification recommended in the RAC opinions of 4 December 2014 should be included in Annex VI of Regulation 1272/2008 since sufficient scientific evidence is available justifying this new classification. However, the proposed M-factors should not be included since they require further assessment by RAC in view of new available scientific data on aquatic toxicity.

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

(7) Compliance with the new 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 classifications and to sell existing stocks. This period of time will also be necessary to allow suppliers to adapt to and to comply with other legislative obligations resulting from the new harmonised classifications for substances such as those provided for in Article 22(f) or Article 23 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3], those provided for in Article 50 of Regulation (EU) No 528/2012 of the European Parliament and of the Council[4] or those in Article 44 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[5].

(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,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1272/2008 is amended as follows:

(1) Annex VI is amended in accordance with the Annex to this Regulation.

(2) In Annex VI, table 3.2. is deleted.

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3 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, OJ L 396, 30.12.2006, p. 1.

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).

5 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).

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 [*Date of entry into force plus 18 months*]

   Article 1(2) shall apply from 1 June 2017.

3. By way of derogation from paragraph 2, substances and mixtures may, before [*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.

4. By way of derogation from paragraph 2, substances and mixtures classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 and placed on the market before [*date of applicability determined under the first subparagraph of paragraph 2*] shall not be required to be relabelled and repackaged in accordance with this Regulation before [*date of applicability determined under the first subparagraph of paragraph 2 plus 2 years*].

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

Done at Brussels,

For the Commission
The President
[…]