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Delegations will find attached document D036121/04.

Encl.: D036121/04



Brussels, **XXX**
D036121/04
[...](2015) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

**amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council
on classification, labelling and packaging of substances and mixtures, for the purposes of
its adaptation to technical and scientific progress**

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, for the purposes of its adaptation to technical and scientific progress

(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) 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 of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances².
- (2) Proposals for new or updated 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, as well as on the comments received from the parties concerned, it is appropriate to introduce or update harmonised classification and labelling of certain substances by amending Annex VI to that Regulation.
- (3) With regard to the substance nitric acid ... % (EC number : 231-714-2), new scientific data has been made available for the hazard class 'acute toxicity' which suggests that the classification for this hazard class as recommended in the RAC opinion, which is based on older data, might not be appropriate. Therefore, this hazard class should not be included in Annex VI to Regulation (EC) No 1272/2008 until RAC has issued an

¹ OJ L 353, 31.12.2008, p.1.

² OJ L 196, 16.8.1967, p. 1.

opinion on the new information, while all other classes covered by the earlier opinion should be included.

- (4) With regard to the substance phenol, dodecyl-, branched (EC number : 310-154-3), the RAC is in the process of adopting a new opinion for the specific concentration limits to be applied to the hazard class 'toxic for reproduction'. Therefore, this hazard class should not be included in Annex VI to Regulation (EC) No 1272/2008 until that opinion is finalised.
- (5) 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. In addition, a certain period of time will be necessary to allow suppliers to comply with the registration obligations resulting from the new harmonised classifications for substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1A and 1B (Table 3.1) and categories 1 and 2 (Table 3.2), or as very toxic to aquatic organisms which may cause long term effects in the aquatic environment, in particular with those set out in Article 23 of 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/EC³.
- (6) 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.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

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

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

Article 2

By way of derogation from Article 3(2), the harmonised classifications set out in Annex to this Regulation may be applied before the date referred to in Article 3(2).

³ OJ L 396, 30.12.2006, p. 1.

Article 3

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. Article 1 shall apply in respect of substances and mixtures from 1 January 2017.

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

Done at Brussels,

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