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[...](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) 2018/669**

(Text with EEA relevance)

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

Whereas:

Table 3 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.

- (1) 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, delete or leave unchanged harmonised classification and labelling of certain substances.
- (2) It is appropriate and scientifically justified to follow RAC's opinions regarding the hazard classes proposed for the harmonised classification and labelling of certain substances.
- (3) 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 facilitate the harmonisation of the classification of mixtures and provide support for enforcement authorities. Following further scientific assessments on some substances, ATE values have been calculated and should be inserted in the penultimate column of Table 3 of Part 3 of Annex VI to Regulation 1272/2008. The substances concerned are methylmercuric chloride, pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate, N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid), pentasodium

¹ OJ L 353, 31.12.2008, p.1.

(carboxylatomethyl)iminobis(ethylenitrilo)tetraacetate, ethylene oxide; oxirane and metaldehyde (ISO); 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane.

- (4) In its scientific opinion of 22 September 2017 on the substance cobalt, RAC proposed to classify that substance as carcinogen category 1B with a specific concentration limit of $\geq 0,01$ %. However, the methodology used to determine a specific concentration limit required further assessment in particular of its applicability to metal compounds. It is therefore appropriate not to introduce, for the time being, any specific concentration limit in Table 3 of Part 3 of Annex VI to Regulation (EC) No 1272/2008 for cobalt, in which case the general concentration limit of $\geq 0,1$ % should apply, in accordance with Table 3.6.2 of Annex I to that Regulation.
- (5) In its scientific opinion of 14 September 2017 on the substance titanium dioxide, RAC proposed to classify that substance as carcinogen category 2 by inhalation. As titanium dioxide induced-lung carcinogenicity is associated with inhalation of respirable titanium dioxide particles, retention and poor solubility of the particles in the lung, it is appropriate to define respirable titanium dioxide particles in the titanium dioxide entry. The deposited particles, but not solutes of titanium dioxide, are assumed to be responsible for the observed toxicity in the lung and subsequent tumour development. In order to avoid unjustified classification of non-hazardous forms of the substance specific exemptions for the classification and labelling of the substance and mixtures containing it are warranted. In addition, as some dangerous dust or droplets could be formed during the use of mixtures containing titanium dioxide, it is necessary to inform the users on the precautionary measures that need to be taken to minimise the hazard for human health.
- (6) Regulation (EC) No 1272/2008 should therefore be amended accordingly.
- (7) Commission Regulation (EU) 2018/669² provides for the translation of chemical names into all official languages of the Union, except Irish. Regulation (EU) 2018/669 contains the harmonised classification, labelling and packaging for the substance pitch, coal tar, high temp. as applicable on 1 January 2016. However, Commission Regulation (EU) No 944/2013³ amended the harmonised classification, labelling and packaging of that substance as from 1 April 2016. Due to an administrative oversight, Regulation (EU) 2018/669 did not take into account the amendments introduced with Regulation (EU) No 944/2013. As Regulation (EU) 2018/669 will become applicable as of 1 December 2019, it will erroneously re-introduce the original classification, labelling and packaging for the entry pitch, coal tar, high temp. Regulation (EU) 2018/669 should therefore be corrected accordingly.
- (8) To ensure that suppliers of substances and mixtures have time to adapt to the new classification and labelling provisions, the application of this Regulation should be deferred.
- (9) 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

² Commission Regulation (EU) 2018/669 of 16 April 2018 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 115, 4.5.2018, p. 1).

³ Commission Regulation (EU) No 944/2013 of 2 October 2013 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 261, 3.10.2013, p. 5).

should have the possibility of applying the new classification, labelling and packaging provisions on a voluntary basis before the date of application of this Regulation.

- (10) 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 of the European Parliament and of the Council⁴,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1272/2008

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

- (1) Annex II is amended as set out in Annex I to this Regulation.
- (2) Annex III is amended as set out in Annex II to this Regulation.
- (3) Annex VI is amended as set out in Annex III to this Regulation.

Article 2

Correction to Regulation (EU) 2018/669

The Annex to Commission Regulation (EU) 2018/669 is corrected as set out in Annex IV to this Regulation.

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*.

It 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.]

Article 2 shall apply from 1 December 2019.

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

⁴ 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, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p.1).

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

Done at Brussels,

For the Commission

The President

[...]