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 (Text with EEA relevance)

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

(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) and Article 53 thereof,

Whereas:

(1) In respect of precautionary statement P210 set out in table 6.2 Part 1 of Annex IV to Regulation (EC) No 1272/2008 the 5th revision of the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter 'GHS') of the United Nations has brought about changes which were not fully taken into account in Commission Regulation (EU) No 487/2013[(2)]. For reasons of consistency it is necessary to provide for full alignment between the GHS and Regulation (EC) No 1272/2008.

(2) 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 substances[(3)]. Those two lists need to be amended to include updated classifications for substances already subject to those harmonised classifications and to include new harmonised classifications.

(3) The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) has issued opinions on proposals for harmonised classification and labelling of substances which had been submitted to ECHA pursuant to Article 37 of Regulation (EC) No 1272/2008. Based on those opinions, as well as on the comments received

from the parties concerned, it is appropriate to amend Annex VI to Regulation (EC) No 1272/2008 in order to harmonise the classification and labelling of certain substances.

(4) The harmonised classifications set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008, as amended by this Regulation, should not apply immediately, as a certain period of time will be necessary to allow operators 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 operators 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/EC[(4)].

(5) With regard to the substance pitch, coal tar, high-temp. (EC Number: 266-028-2), an extended period of time will be necessary to allow operators to comply with the obligations resulting from the new harmonised classification for substances classified as very toxic to aquatic organisms which may cause long term effects in the aquatic environment, in particular with those set out in Article 3 and Annex III of Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods[(5)]. Therefore, a longer transition time should be foreseen before the harmonised classification has to be applied.

(6) With regard to the substance gallium arsenide (EC Number: 215-114-8), the RAC is in the process of adopting a new opinion for the hazard class ‘toxicity to reproduction’. Therefore, this hazard class should not be included in Annex VI to Regulation (EC) No 1272/2008 until that opinion is finalised.

(7) With regard to the substance polyhexamethylene biguanide hydrochloride (CAS number 27083-27-8 or 32289-58-0), new scientific data has been made available for the hazard class ‘acute toxicity (inhalation)’, 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 had the opportunity to deliver an opinion on the new information, while all other hazard classes covered by the earlier RAC opinion should be included.

(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 harmonised classifications set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008, as amended by this Regulation, and of

adapting the labelling and packaging accordingly on a voluntary basis before the dates by which the harmonised classifications will become mandatory.

(9) 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:

(1) Annex IV is amended in accordance with the Annex I to this Regulation;

(2) Part 3 of Annex VI is amended as follows:

(a) Table 3.1 is amended as follows:

(i) The entries set out in Annex VI to Regulation (EC) No 1272/2008 corresponding to the entries set out in Annex II to this Regulation are replaced by the entries set out in Annex II to this Regulation;

(ii) The entries set out in Annex III to this Regulation are inserted in accordance with the order of the entries set out in Table 3.1.

(b) Table 3.2 is amended as follows:

(i) The entries set out in Annex VI to Regulation (EC) No 1272/2008 corresponding to the entries set out in Annex IV to this Regulation are replaced by the entries set out in in Annex IV to this Regulation;

(ii) The entries set out in Annex V to this Regulation are inserted in accordance with the order of the entries set out in Table 3.2.

Article 2

1 By way of derogation from Article 3(2) substances and mixtures may, before 1 December 2014 and 1 June 2015 respectively, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

2 By way of derogation from Article 3(2), substances classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 and placed on the market before 1 December 2014, shall not be required to be relabelled and repackaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation until 1 December 2016.

3 By way of derogation from Article 3(2) mixtures classified, labelled and packaged in accordance with Directive 1999/45/EC of the European Parliament and of the Council[6] or Regulation (EC) No 1272/2008 and placed on the market before 1 June 2015, shall not be required to be relabelled and repackaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation until 1 June 2017.

4 By way of derogation from Article 3(3) the harmonised classifications set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008, as amended by this Regulation, may be applied before the dates referred to in Article 3(3).

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(1) shall apply in respect of substances from 1 December 2014 and in respect of mixtures from 1 June 2015.

3 Article 1(2) shall apply from 1 January 2015 for all entries except for the entry pitch, coal tar, high-temp. (EC Number 266-028-2), for which Article 1 shall apply from 1 April 2016.

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

Done at Brussels, 2 October 2013.

For the Commission

The President

José Manuel BARROSO

ANNEX I

In Part 1, Table 6.2 of Annex IV to Regulation (EC) No 1272/2008, Code P210 is replaced by the following:

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.	Explosives (section 2.1)	Divisions 1.1, 1.2, 1.3, 1.4, 1.5	
		Flammable gases (section 2.2)	1, 2	
		Aerosols (section 2.3)	1, 2, 3	
		Flammable liquids (section 2.6)	1, 2, 3	
		Flammable solids (section 2.7)	1, 2	
		Self-reactive substances and mixtures (section 2.8)	Types A, B, C, D, E, F	
		Pyrophoric liquids (section 2.9)	1	
		Pyrophoric solids (section 2.10)	1	
		Oxidising liquids (section 2.13)	1, 2, 3	
		Oxidising solids (section 2.14)	1, 2, 3	
		Organic peroxides (section 2.15)	Types A, B, C, D, E, F	

ANNEX II

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-Factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		