Commission Regulation (EU) 2018/1480 of 4 October 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 and correcting Commission Regulation (EU) 2017/776 (Text with EEA relevance)

COMMISSION REGULATION (EU) 2018/1480

of 4 October 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 and correcting Commission Regulation (EU) 2017/776

(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(1) 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 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 or delete harmonised classification and labelling of certain substances.

(3) Council Directive 67/548/EEC[(2)] and Directive 1999/45/EC of the European Parliament and of the Council[(3)] were repealed with effect from 1 June 2015. As a result, Part 3 of Annex VI to Regulation (EC) No 1272/2008 was amended by Commission Regulation (EU) 2016/1179[(4)] to remove Table 3.2. That amendment took effect on 1 June 2017. Annex VI to Regulation (EC) No 1272/2008 was further amended by Commission Regulation (EU) 2017/776[(5)] to delete references to Table 3.2, to convert references to Table 3.1 into references to Table 3 and to delete references to the repealed Directives. Under Article 2(2) of Regulation (EU) 2017/776, the majority of those amendments were to apply from 1 June 2017, while the remaining amendments were

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1480. (See end of Document for details)*

stated to apply from 1 December 2018. However, due to an oversight, Article 2(2) failed to list two further amendments that should have applied from 1 June 2017, including in particular the amendment changing the name of the Table from 'Table 3.1' to 'Table 3'. The second subparagraph of Article 2(2) of Regulation (EU) 2017/776 should therefore be corrected to include reference to those two amendments. This correction, although it has the effect of applying the two amendments retroactively, does not affect the rights and obligations of manufacturers, importers, downstream users or suppliers.

(4) Regulation (EU) 2017/776 also amended Annex VI to Regulation (EC) No 1272/2008 to add harmonised 'Acute Toxicity Estimate' (ATE) values in Table 3.1 as part of the information relating to the classification and labelling of certain substances for the purposes of the classification of mixtures. The ATE introduced for nicotine was expressed in mg/kg. In order to clarify how mixtures containing nicotine should be classified, the ATE for the oral and the dermal routes for nicotine should instead be expressed in 'mg/kg bw'[(6)]. The ATEs for three other substances, namely colecalciferol, 1,2-dihydroxybenzene and pinoxaden should also be expressed in the same way. In addition, in the title of the penultimate column of Table 3.1, a footnote should be added indicating what the abbreviation 'mg/kg bw' stands for.

(5) The Annex to Commission Regulation (EU) 2018/669[(7)] provides for the translation of the names of the substances included in Table 3.1 of Annex VI to Regulation (EC) No 1272/2008. As a consequence, the title of the second column of that Table, which currently refers to 'international chemical identifications', should be amended to take account of the fact that the 'international chemical identifications' will lose their international character once the Regulation providing for their translation in Annex VI becomes applicable. For the sake of consistency, this amendment should take effect when the translation of the names in Annex VI takes effect. The new title should reflect the terminology used in Article 18 of Regulation (EC) No 1272/2008.

(6) Compliance with the new or updated 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 or revised classifications and to sell existing stocks. That period of time will also be necessary to allow suppliers to adapt to and comply with other legislative obligations resulting from the new or updated harmonised classifications, 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[(8)], those set out in Article 50 of Regulation (EU) No 528/2012 of the European Parliament and of the Council[(9)] or those set out in Article 44 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(10)].

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

(8) In line with the transitional provisions of Regulation (EC) No 1272/2008 which allow for new provisions to be applied at an earlier stage on a voluntary basis, suppliers should be allowed to apply the new and updated harmonised classifications, and to adapt the labelling and packaging accordingly, on a voluntary basis before the date of application of those new or updated classifications.

(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

Amendment to Regulation (EC) No 1272/2008

Annex VI to Regulation (EC) No 1272/2008 is amended as set out in the Annex to this Regulation.

Article 2

Correction to Regulation (EU) 2017/776

In Regulation (EU) 2017/776, the second subparagraph of Article 2(2) is replaced by the following:

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

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*.

Point (1) and point (a) of point (2) of the Annex shall apply from 1 December 2019.

Points (b), (c), (d) and (e) of point (2) of the Annex shall apply from 1 May 2020.

By way of derogation from the third paragraph of this Article, substances and mixtures may, before 1 May 2020, 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, 4 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1480. (See end of Document for details)*

ANNEX

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

(1) in Part 1, the heading of point 1.1.1.4 is replaced by the following:

Chemical name;

(2) in Part 3, Table 3.1 is amended as follows:

(a) the title of the second column is replaced by the following: ‘Chemical name’;

(b) the title of the penultimate column is replaced by the following: ‘Specific Conc. Limits, M-factors and ATEs (*)

(*) ATEs for oral and dermal exposure routes are expressed in mg/kg bw, which stands for milligram per kilogram bodyweight.’;

(c) the entry corresponding to index number 607-414-00-6 is deleted;

(d) the entries corresponding to index numbers 006-044-00-7, 015-101-00-5, 016-096-00-2, 017-011-00-1, 025-002-00-9, 603-180-00-4, 604-014-00-3, 604-016-00-4, 604-090-00-8, 605-003-00-6, 606-047-009, 607-096-00-9, 607-103-00-5, 607-113-00-X, 607-373-00-4, 613-167-00-5, 613-205-00-0 and 614-001-00-4 are replaced by the following entries respectively:

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	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)		
‘006-044-00-7	isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea	251-835-4	34123-59-6	Carc. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H373 (blood) H400 H410	GHS08 GHS09 Wng	H351 H373 (blood) H410		M = 10 M = 10’	
‘015-101-00-5	phosmet (ISO); *S*-[(1,3-dioxo-1,3-dihydro-2*H*-isoindol-2-yl)methyl] *O*,*O*-dimethyl phosphorodithioate; *O*,*O*-dimethyl-*S*-	211-987-5	732-11-6	Repr. 2 Acute Tox. 4 Acute Tox. 3 STOT SE 1 Aquatic Acute 1	H361f H332 H301 H370 (nervous system) H400 H410	GHS08 GHS06 GHS09 Dgr	H361f H332 H301 H370 (nervous system) H410		M = 100 M = 100’	

	phthalimidomethyl phosphorodithioate			Aquatic Chronic 1						
‘016-096-00-2	rimsulfuron (ISO); methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate	431-480-8	79277-27-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 100 M = 100’	
‘017-011-00-1	sodium hypochlorite, solution … % Cl active	231-668-3	7681-52-9	Skin Corr. 1B Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H314 H318 H400 H410	GHS05 GHS09 Dgr	H314 H410	EUH031	M = 10 M = 1 EUH031: C ≥ 5 %	B’
‘025-002-00-9	potassium permanganate	231-760-3	7722-64-7	Ox. Sol. 2 Repr. 2 Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H272 H361d H302 H400 H410	GHS03 GHS08 GHS07 GHS09 Dgr	H272 H361d H302 H410’			
‘603-180-00-2	cholecalciferol; vitamin D_3	200-673-2	67-97-0	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1	H330 H310 H300 H372	GHS06 GHS08 Dgr	H330 H310 H300 H372			inhalation: ATE = 0,05 mg/L (dusts or mists) dermal: ATE =