Commission Regulation (EU) 2017/776 of 4 May 2017 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) 2017/776

of 4 May 2017

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) 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 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.

(3) The 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 would facilitate the harmonisation of the classification of mixtures and provide support for enforcement authorities. The ATE values harmonised in accordance with Article 37 should be added in the penultimate column of Table 3.1 of Part 3 of Annex VI to that Regulation. Pursuant to Article 38(1)(e) those values are to be mentioned in the opinions and decisions for harmonised classification. The title of the column of Table 3.1 of Part 3 as well as section 1.1.2.3 of Part 1 of Annex VI to Regulation (EC) No 1272/2008 should be amended consequently.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/776. (See end of Document for details)*

(4) Compliance with the new harmonised classifications and the new provision on the ATE in section 1.1.2.3 of Part 1 of Annex VI to Regulation (EC) No 1272/2008 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. That 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 set out in Article 22(f) or Article 23 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(2)], those set out in Article 50 of Regulation (EU) No 528/2012 of the European Parliament and of the Council[(3)] or those set out in Article 44 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(4)].

(5) Table 3.2 of Annex VI to Regulation (EC) No 1272/2008, which lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Council Directive 67/548/EEC[(5)], has been deleted with effect from 1 June 2017. For reasons of consistency, the references to Table 3.2 in Parts 1 and 3 of Annex VI to Regulation (EC) No 1272/2008 should be deleted with effect from the same date. For reasons of clarity, Table 3.1 of Annex VI to Regulation (EC) No 1272/2008 should become Table 3 and all references to Table 3.1 in that Annex should be changed accordingly.

(6) Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council[(6)] have been repealed with effect from 1 June 2015. For reasons of consistency, the references to those Directives in the introductory part and in Parts 1 and 3 of Annex VI to Regulation (EC) No 1272/2008 should be deleted simultaneously with the changes regarding the references to Tables 3.1 and 3.2 of Annex VI to that Regulation with effect from 1 June 2017, which is the date provided for in Article 61(4) of Regulation (EC) No 1272/2008 before which mixtures which are classified, labelled and packaged in accordance with Directive 1999/45/EC and placed on the market before 1 June 2015 need not to be relabelled and repackaged in accordance with Regulation (EC) No 1272/2008.

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

(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

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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2017/776. (See end of Document for details)*

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 1 December 2018.

[[F1]In the Annex, point (1), point (2) and points (a), (b) and (c) of point (3) shall apply from 1 June 2017.**]**

3 By way of derogation from paragraph 2, substances and mixtures may, before 1 December 2018, be classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 as amended by this Regulation.

Textual Amendments

F1 Substituted by 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).

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2017/776. (See end of Document for details)*

ANNEX

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

(1) the introductory paragraphs are replaced by the following:

Part 1 of this Annex provides an introduction to the list of harmonised classification and labelling, including information listed for each entry and related classifications and hazard statements in Table 3.

Part 2 of this Annex lays down general principles for preparing dossiers to propose and justify harmonised classification and labelling of substances at Union level.

Part 3 of this Annex lists hazardous substances for which harmonised classification and labelling have been established at Union level. In Table 3 the classification and labelling are based on the criteria in Annex I to this Regulation.;

(2) Part 1 is amended as follows:

(a) the title of Section 1.1.2 is replaced by the following:
1.1.2.***Information related to the classification and labelling of each entry in Table 3;***

(b) Section 1.1.2.3 is replaced by the following:

1.1.2.3. *Specific concentration limits, M-factors and Acute Toxicity Estimates (ATE)*

Specific concentration limits (SCL), where different from the generic concentration limits given in Annex I for a certain category, are given in a separate column together with the classification concerned using the same codes as under 1.1.2.1.1. Also harmonised ATEs are listed in the same column of table 3. The SCLs and harmonised ATEs must be used by the manufacturer, importer or downstream user for the classification of a mixture containing this substance. When applying an ATE, the additivity formula as described in 3.1.3.6 of Annex I shall be used. Where no specific concentration limits are given in this Annex for a certain category, the generic concentration limits given in Annex I must be applied for the classification of substances containing impurities, additives or individual constituents or for mixtures. If harmonised ATE values are missing for acute toxicity the correct value has to be established by using the available data.

Unless otherwise shown, the concentration limits are a percentage by weight of the substance calculated with reference to the total weight of the mixture.

In case an M-factor has been harmonised for substances classified as hazardous to the aquatic environment in the categories Aquatic Acute 1 or Aquatic Chronic 1, that M-factor is given in Table 3 in the same column as the specific concentration limits. In case an M-factor for Aquatic Acute 1 and an M-factor for Aquatic Chronic 1 have been harmonised, each M-factor shall be listed in the same line as its corresponding differentiation. Where a single M-factor is given in Table 3 and the substance is classified as Aquatic Acute 1 and Aquatic Chronic 1, that M-factor shall be used by the manufacturer, importer or downstream user for the classification of a mixture containing this substance for acute and long-term aquatic hazards using the summation method. Where no M-factor is given in Table 3, M-factor(s)

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based on available data for the substance shall be set by the manufacturer, importer or downstream user. For the setting and use of M-factors, see Section 4.1.3.5.5.5 of Annex I.;

(c) Section 1.1.3.1 is amended as follows:

(i) Note E is deleted;

(ii) Note K is replaced by the following:
Note K:

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w 1,3-butadiene (Einecs No 203-450-8). If the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (P102-)P210-P403 should apply. This note applies only to certain complex oil-derived substances in Part 3.;

(iii) Note P is replaced by the following:
Note P:

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (Einecs No 200-753-7).

When the substance is not classified as a carcinogen at least the precautionary statements (P102-)P260-P262-P301 + P310-P331 shall apply.

This note applies only to certain complex oil-derived substances in Part 3.;

(iv) Note S is replaced by the following:
Note S:

This substance may not require a label according to Article 17 (see Section 1.3 of Annex I) (Table 3).;

(v) in Note U, the title is replaced by the following:
Note U (Table 3):;

(d) Section 1.1.3.2 is amended as follows:

(i) Note 1 is replaced by the following:
Note 1:

The concentration stated or, in the absence of such concentrations, the generic concentrations set out in this Regulation are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture.;

(ii) Note 8 is added as follows:
Note 8:

The classification as a carcinogen need not apply if it can be shown that the maximum theoretical concentration of releasable formaldehyde, irrespective of the source, in the mixture as placed on the market is less than 0,1 %.;