# Commission Regulation (EU) No 286/2011 of 10 March 2011 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 286/2011

## of 10 March 2011

## 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 53 thereof,

Whereas:

(1) Regulation (EC) No 1272/2008 harmonises the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the European Union.

(2) That Regulation takes into account the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as 'the GHS') of the United Nations (UN).

(3) The classification criteria and labelling rules of the GHS are periodically reviewed at UN level. The third revised edition of the GHS was adopted in December 2008 by the United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonised System of Classification and Labelling of Chemicals (UNCETDG/GHS). It contains amendments concerning, inter alia, the provisions for the allocation of hazard statements and for the labelling of small packaging, new sub-categories for respiratory and skin sensitisation, the revision of the classification criteria for long-term hazards (chronic toxicity) to the aquatic environment and a new hazard class for substances and mixtures hazardous to the ozone layer. It is therefore necessary to adapt the technical provisions and criteria in the Annexes to Regulation (EC) No 1272/2008 to the third revised edition of the GHS.

(4) The GHS allows authorities to adopt supplemental labelling provisions to protect individuals already sensitised to a specific chemical that may elicit a response at

very low concentration. Requirements should be introduced to add the name of such chemical on the label even if present at very low concentration in a mixture.

(5) The terminology of different provisions in the Annexes and certain technical criteria should also be amended to facilitate implementation by operators and enforcement authorities, to improve consistency of the legal text and to enhance clarity.

(6) To ensure that suppliers of substances can adapt to the new classification, labelling and packaging provisions introduced by this Regulation, a transitional period should be foreseen and the application of this Regulation should be deferred. This should allow for the possibility to apply the provisions laid down in this Regulation on a voluntary basis before the transitional period is over.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee established pursuant to Article 133 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[(2)],

HAS ADOPTED THIS REGULATION:

*Article 1*

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

(1) Article 25(5) is deleted;

(2) the following new section (e) is inserted in Article 26(1):

(e) if the hazard pictogram “GHS02” or “GHS06” applies, the use of the hazard pictogram “GHS04” shall be optional.;

(3) Annex I is amended in accordance with Annex I to this Regulation;

(4) Annex II is amended in accordance with Annex II to this Regulation;

(5) Annex III is amended in accordance with Annex III to this Regulation;

(6) Annex IV is amended in accordance with Annex IV to this Regulation;

(7) Annex V is amended in accordance with Annex V to this Regulation;

(8) Annex VI is amended in accordance with Annex VI to this Regulation;

(9) Annex VII is amended in accordance with Annex VII to this Regulation.

*Article 2*

**Transitional provisions**

1 By way of derogation from the second paragraph of Article 3, substances and mixtures may, before 1 December 2012 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 the second paragraph of Article 3, substances classified, labelled and packaged in accordance with Regulation (EC) No 1272/2008 and placed on the market before 1 December 2012, are not required to be relabelled and repackaged in accordance with this Regulation until 1 December 2014.

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

*Article 3*

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply in respect of substances from 1 December 2012 and in respect of mixtures from 1 June 2015.

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) No 286/2011. (See end of Document for details)*

# ANNEX I

A. Part 1 of Annex I to Regulation (EC) No 1272/2008 is amended as follows:

(1) in section 1.1.2.2.2, the Note under Table 1.1 is replaced by the following:
Note:

Generic cut-off values are in weight percentages except for gaseous mixtures for those hazard classes where the generic cut-off values may be best described in volume percentages.;

(2) in section 1.1.3.1, the beginning of the first sentence is replaced by 'If a tested mixture';

(3) sections 1.1.3.2, 1.1.3.3 and 1.1.3.4 are replaced by the following:

1.1.3.2. Batching

The hazard category of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same commercial product, when produced by or under the control of the same supplier, unless there is reason to believe there is significant variation such that the hazard classification of the untested batch has changed. If the latter occurs, a new evaluation is necessary.

1.1.3.3. Concentration of highly hazardous mixtures

In the case of the classification of mixtures covered by sections 3.1, 3.2, 3.3, 3.8, 3.9, 3.10 and 4.1, if a tested mixture is classified in the highest hazard category or sub-category, and the concentration of the components of the tested mixture that are in that category or sub-category is increased, the resulting untested mixture shall be classified in that category or sub-category without additional testing.

1.1.3.4. Interpolation within one toxicity category

In the case of the classification of mixtures covered by sections 3.1, 3.2, 3.3, 3.8, 3.9, 3.10 and 4.1, for three mixtures (A, B and C) with identical components, where mixtures A and B have been tested and are in the same hazard category, and where untested mixture C has the same hazardous components as mixture A and B but has concentrations of those hazardous components intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same hazard category as A and B.;

(4) in section 1.1.3.5, the last sentence is replaced by the following:

If mixture (i) or (ii) is already classified based on test data, then the other mixture shall be assigned the same hazard category.;

(5) sections 1.2, 1.2.1, 1.2.1.1, 1.2.1.2 and 1.2.1.3 are replaced by the following:

1.2. Labelling

1.2.1. General rules for the application of labels required by Article 31

1.2.1.1. Hazard pictograms shall be in the shape of a square set at a point.

1.2.1.2. Hazard pictograms as laid down in Annex V shall have a black symbol on a white background with a red frame sufficiently wide to be clearly visible.

1.2.1.3. Each hazard pictogram shall cover at least one fifteenth of the minimum surface area of the label dedicated to the information required by Article 17. The minimum area of each hazard pictogram shall not be less than 1 $cm^2$.

1.2.1.4. The dimensions of the label and of each pictogram shall be as follows:

TABLE 1.3

Minimum dimensions of labels and pictograms

| **Capacity of the package** | **Dimensions of the label (in millimetres) for the information required by Article 17** | **Dimensions of each pictogram (in millimetres)** |
|---|---|---|
| Not exceeding 3 litres: | If possible, at least 52 × 74 | Not smaller than 10 × 10<br>If possible, at least 16 × 16 |
| Greater than 3 litres but not exceeding 50 litres: | At least 74 × 105 | At least 23 × 23 |
| Greater than 50 litres but not exceeding 500 litres: | At least 105 × 148 | At least 32 × 32 |
| Greater than 500 litres: | At least 148 × 210 | At least 46 × 46 |

(6) the introductory sentence in section 1.5.2.1.3 is replaced by the following:

> The pictogram, the signal word, the hazard statement, and the precautionary statement linked to the hazard categories listed below may be omitted from the label elements required by Article 17 where:;

(7) in section 1.5.2.2, point (b) is replaced by the following:

(b) The classification of the contents of the soluble packaging is exclusively one or more of the hazard categories in 1.5.2.1.1 (b), 1.5.2.1.2 (b) or 1.5.2.1.3 (b); and.

B. Part 2 of Annex I to Regulation (EC) No 1272/2008 is amended as follows:

(1) section 2.1.4.1 is amended as follows:

(a) the footnote under Figure 2.1.1 is replaced by the following: