Commission Regulation (EU) No 252/2011 of 15 March 2011 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex I (Text with EEA relevance)

COMMISSION REGULATION (EU) No 252/2011

of 15 March 2011

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex I

(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 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[(1)], and in particular Article 131 thereof,

Whereas:

(1) 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[(2)] harmonises the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the Community, taking into account the classification criteria and labelling rules of the Globally Harmonised System of Classification and Labelling of Chemicals.

(2) Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(3)] and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(4)] were amended several times. Directives 67/548/EEC and 1999/45/EC will be replaced over a transitional period according to which substances must be classified, labelled and packaged according to Regulation (EC) No 1272/2008 from 1 December 2010 and mixtures from 1 June 2015, although from 1 December 2010 until 1 June 2015 classification of substances according to both Directive 67/548/EEC and Regulation

(EC) No 1272/2008 is required. Both Directives will be repealed in full by Regulation (EC) No 1272/2008 with effect from 1 June 2015.

(3) Annex I to Regulation (EC) No 1907/2006 should be amended to adapt it to the criteria for classification and other relevant provisions laid down in Regulation (EC) No 1272/2008.

(4) Article 58(1) of Regulation (EC) No 1272/2008 modifies Article 14(4) of Regulation (EC) No 1907/2006 to adapt it to the classification criteria in Regulation (EC) No 1272/2008. This also has consequences for Annex I to Regulation (EC) No 1907/2006, which was not amended by Regulation (EC) No 1272/2008. It is therefore necessary to adapt Annex I to Regulation (EC) No 1907/2006 to the new text in its Article 14(4).

(5) Regulation (EC) No 1272/2008 introduces substantive changes in terminology compared to those used in Directive 67/548/EEC. Annex I to Regulation (EC) No 1907/2006 was not amended by Regulation (EC) No 1272/2008 and should be updated to reflect these changes and ensure consistency throughout.

(6) Furthermore, references to Directive 67/548/EEC should be replaced by appropriate references to Regulation (EC) No 1272/2008.

(7) In accordance with Regulation (EC) No 1907/2006, registrations including chemical safety reports will have been submitted by the date of application of this Regulation. Changes in classification criteria and other relevant provisions resulting from Regulation (EC) No 1272/2008 apply to substances from 1 December 2010, in accordance with the second paragraph of Article 62 of that Regulation. In order to ensure a smooth transition for the updating of registrations, a transitional period should be provided.

(8) Annex I to Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(9) 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,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1907/2006 is amended as follows:

1. point 0.6 is replaced by the following:

0.6. Steps of a chemical safety assessment

0.6.1. A chemical safety assessment performed by a manufacturer or an importer for a substance shall include the following steps 1 to 4 in accordance with the respective sections of this Annex:

1. Human health hazard assessment.

2. Human health hazard assessment of physicochemical properties.

3. Environmental hazard assessment.

4. PBT and vPvB assessment.

0.6.2. In the cases referred to in point 0.6.3 the chemical safety assessment shall also include the following steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:

5. Exposure assessment.

5.1. The generation of exposure scenario(s) (or the identification of relevant use and exposure categories, if appropriate).

5.2. Exposure estimation.

6. Risk characterisation.

0.6.3. Where as a result of steps 1 to 4 the manufacturer or importer concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 or is assessed to be a PBT or vPvB, the chemical safety assessment shall also include steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, and 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9, and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1.

0.6.4. A summary of all the relevant information used in addressing the points above shall be presented under the relevant heading of the Chemical Safety Report (Section 7).;

2. point 1.0.1 is replaced by the following:

1.0.1. The objectives of the human health hazard assessment shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008; and to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).;

3. point 1.0.2 is replaced by the following:

1.0.2. The human health hazard assessment shall consider the toxicokinetic profile (i.e. absorption, metabolism, distribution and elimination) of the substance and the following groups of effects:

(1) acute effects such as acute toxicity, irritation and corrosivity;

(2) sensitisation;

(3) repeated dose toxicity; and

(4) CMR effects (carcinogenity, germ cell mutagenicity and toxicity for reproduction).

Based on all the available information, other effects shall be considered when necessary.;

4. point 1.1.3 is replaced by the following:

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 252/2011. (See end of Document for details)*

1.1.3. All non-human information used to assess a particular effect on humans and to establish the dose (concentration) – response (effect) relationship, shall be briefly presented, if possible in the form of a table or tables, distinguishing between *in vitro*, *in vivo* and other information. The relevant test results (e.g. ATE, LD50, NO(A)EL or LO(A)EL) and test conditions (e.g. test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.;

5. points 1.3.1 and 1.3.2 are replaced by the following:

1.3.1. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified. Where applicable, Specific Concentration limits resulting from the application of Article 10 of Regulation (EC) No 1272/2008 and Articles 4 to 7 of Directive 1999/45/EC shall be presented and, if they are not included in Part 3 of Annex VI to Regulation (EC) No 1272/2008, justified.

The assessment should always include a statement as to whether the substance fulfils or does not fulfil the criteria given in Regulation (EC) No 1272/2008 for classification in the hazard class carcinogenicity category 1A or 1B, in the hazard class germ cell mutagenicity category 1A or 1B or in the hazard class reproductive toxicity category 1A or 1B.

1.3.2. If the information is inadequate to decide whether a substance should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.;

6. the second sentence of point 1.4.1 is replaced by the following:

'For some hazard classes, especially germ cell mutagenicity and carcinogenicity, the available information may not enable a toxicological threshold, and therefore a DNEL, to be established.';

7. point 2.1 is replaced by the following:

2.1. The objective of the hazard assessment for physicochemical properties shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008.;

8. point 2.2 is replaced by the following:

2.2. As a minimum, the potential effects to human health shall be assessed for the following physicochemical properties:

— explosivity,

— flammability,

— oxidising potential.

If the information is inadequate to decide whether a substance should be classified for a particular hazard class or category, the registrant shall indicate and justify the action or decision he has taken as a result.;

9. point 2.5 is replaced by the following:

2.5. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified.;