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)

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:

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.;

10. point 3.0.1 is replaced by the following:

3.0.1. The objective of the environmental hazard assessment shall be to determine the classification of a substance in accordance with Regulation (EC) No 1272/2008 and to identify the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No-Effect Concentration (PNEC).;

11. points 3.2.1 and 3.2.2 are replaced by the following:

3.2.1. The appropriate classification developed in accordance with the criteria in Regulation (EC) No 1272/2008 shall be presented and justified. Any M-factor resulting from the application of Article 10 of Regulation (EC) No 1272/2008 shall be presented and, if it is not included in Part 3 of Annex VI to Regulation (EC) No 1272/2008, justified.

3.2.2. 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.;

12. points 4.1 and 4.2 are replaced by the following:

4.1. **Step 1: Comparison with the criteria**

This part of the PBT and vPvB assessment shall entail the comparison of the available information with the criteria given in Section 1 of Annex XIII and a statement of whether the substance fulfils or does not fulfil the criteria. The assessment shall be conducted in accordance with the provisions laid down in the introductory part of Annex XIII as well as Sections 2 and 3 of that Annex.

4.2. **Step 2: Emission Characterisation**

If the substance fulfils the criteria or it is considered as if it is a PBT or vPvB in the registration dossier an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance.;

13. Part B of the table in Section 7 is amended as follows:

(a) points 5.3.1, 5.3.2 and 5.3.3 are deleted;

(b) points 5.5.1 and 5.5.2 are deleted;

(c) point 5.7 is replaced by the following:

5.7. Germ cell mutagenicity;

(d) points 5.9.1 and 5.9.2 are deleted.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 252/2011, Article 1.