[X1ANNEX VI

INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10

Editorial Information

X1 Substituted by Corrigendum 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 (Official Journal of the European Union L 396 of 30 December 2006).

GUIDANCE NOTE ON FULFILLING THE REQUIREMENTS OF ANNEXES VI TO XI

Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes according to Articles 10, 12, 13, 40, 41 and 46. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

STEP 1 — GATHER AND SHARE EXISTING INFORMATION

The registrant should gather all existing available test data on the substance to be registered, this would include a literature search for relevant information on the substance. Wherever practicable, registrations should be submitted jointly, in accordance with Articles 11 or 19. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. The registrant should also collect all other available and relevant information on the substance regardless whether testing for a given endpoint is required or not at the specific tonnage level. This should include information from alternative sources (e.g. from (Q)SARs, read-across from other substances, *in vivo* and *in vitro* testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests.

In addition, information on exposure, use and risk management measures in accordance with Article 10 and this Annex should be collected. Considering all this information together, the registrant will be able to determine the need to generate further information.

STEP 2 — CONSIDER INFORMATION NEEDS

The registrant shall identify what information is required for the registration. First, the relevant Annex or Annexes to be followed shall be identified, according to tonnage. These Annexes set out the standard information requirements, but shall be considered in conjunction with Annex XI, which allows variation from the standard approach, where it can be justified. In particular, information on exposure, use and risk management measures shall be considered at this stage in order to determine the information needs for the substance.

STEP 3 — IDENTIFY INFORMATION GAPS

The registrant shall then compare the information needs for the substance with the information already available and identify where there are gaps. It is important at this stage to ensure that the available data is relevant and has sufficient quality to fulfil the requirements.

STEP 4 — GENERATE NEW DATA/PROPOSE TESTING STRATEGY

In some cases it will not be necessary to generate new data. However, where there is an information gap that needs to be filled, new data shall be generated (Annexes VII and VIII), or

a testing strategy shall be proposed (Annexes IX and X), depending on the tonnage. New tests on vertebrates shall only be conducted or proposed as a last resort when all other data sources have been exhausted.

In some cases, the rules set out in Annexes VII to XI may require certain tests to be undertaken earlier than or in addition to the standard requirements.
NOTES

Note 1: If it is not technically possible, or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated, in accordance with the relevant provisions.

Note 2: The registrant may wish to declare that certain information submitted in the registration dossier is commercially sensitive and its disclosure might harm him commercially. If this is the case, he shall list the items and provide a justification.
INFORMATION REFERRED TO IN ARTICLE 10(a) (i) TO (v)

1. GENERAL REGISTRANT INFORMATION

1.1. Registrant

1.1.1. Name, address, telephone number, fax number and e-mail address

1.1.2. Contact person

1.1.3. Location of the registrant's production and own use site(s), as appropriate

1.2. Joint submission of data

Articles 11 or 19 foresee that parts of the registration may be submitted by a lead registrant on behalf of other registrants.

In this case, the lead registrant shall identify the other registrants specifying:
— their name, address, telephone number, fax number and e-mail address,
— parts of the present registration which apply to other registrants.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

Any other registrant shall identify the lead registrant submitting on his behalf specifying:
— his name, address, telephone number, fax number and e-mail address,
— parts of the registration which are submitted by the lead registrant.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

1.3 Third party appointed under Article 4

1.3.1. Name, address, telephone number, fax number and e-mail address

1.3.2. Contact person

2. IDENTIFICATION OF THE SUBSTANCE

For each substance, the information given in this section shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECS or ELINCs number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including SMILES notation, if available)

2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

2.3. Composition of each substance

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (… ppm, … %) of any additives (e.g. stabilising agents or inhibitors)

2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

3. INFORMATION ON MANUFACTURE AND USE(S) OF THE SUBSTANCE(S)

3.1. Overall manufacture, quantities used for production of an article that is subject to registration, and/or imports in tonnes per registrant per year in:

the calendar year of the registration (estimated quantity)

3.2. In the case of a manufacturer or producer of articles: brief description of the technological process used in manufacture or production of articles.

Precise details of the process, particularly those of a commercially sensitive nature, are not required.

3.3. An indication of the tonnage used for his own use(s)

3.4. Form (substance, **[**[F1]mixture**]** or article) and/or physical state under which the substance is made available to downstream users. Concentration or concentration range of the substance in **[**[F1]mixtures**]** made available to downstream users and quantities of the substance in articles made available to downstream users.

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

3.5. Brief general description of the identified use(s)

3.6. Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses

3.7. Uses advised against **[**F2(see Section 1 of the safety data sheet)**]**

Where applicable, an indication of the uses which the registrant advises against and why (i.e. non-statutory recommendations by supplier). This need not be an exhaustive list.

Textual Amendments

F2 Substituted by Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).

4. CLASSIFICATION AND LABELLING

[F1 4.1 The hazard classification of the substance(s), resulting from the application of Title I and II of Regulation (EC) No 1272/2008 for all hazard classes and categories in that Regulation,

In addition, for each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification),

4.2 The resulting hazard label for the substance(s), resulting from the application of Title III of Regulation (EC) No 1272/2008,

[F1 4.3 Specific concentration limits, where applicable, resulting from the application of Article 10 of Regulation (EC) No 1272/2008.**]]**

5. GUIDANCE ON SAFE USE CONCERNING:

This information shall be consistent with that in the Safety Data Sheet, where such a Safety Data Sheet is required according to Article 31.

5.1. First-aid measures (Safety Data Sheet heading 4)

5.2. Fire-fighting measures (Safety Data Sheet heading 5)

5.3. Accidental release measures (Safety Data Sheet heading 6)

5.4. Handling and storage (Safety Data Sheet heading 7)

5.5. Transport information (Safety Data Sheet heading 14)

Where a Chemical Safety Report is not required, the following additional information is required:

5.6. Exposure controls/personal protection (Safety Data Sheet heading 8)

5.7. Stability and reactivity (Safety Data Sheet heading 10)

5.8. Disposal considerations

5.8.1. Disposal considerations (Safety Data Sheet heading 13)

5.8.2. Information on recycling and methods of disposal for industry

5.8.3. Information on recycling and methods of disposal for the public.

6. INFORMATION ON EXPOSURE FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES PER YEAR PER MANUFATCURER OR IMPORTER

6.1. Main use category:

6.1.1.

(a) industrial use; and/or

(b) professional use; and/or

(c) consumer use.

6.1.2. Specification for industrial and professional use:

(a) used in closed system; and/or

(b) use resulting in inclusion into or onto matrix; and/or

(c) non-dispersive use; and/or

(d) dispersive use.

6.2. Significant route(s) of exposure:

6.2.1. Human exposure:

(a) oral; and/or

(b) dermal; and/or

(c) inhalatory.

6.2.2. Environmental exposure:

(a) water; and/or

(b) air; and/or

(c) solid waste; and/or

(d) soil.

6.3. Pattern of exposure:

(a) accidental/infrequent; and/or

(b) occasional; and/or

(c) continuous/frequent.**]**

Status:
Point in time view as at 01/12/2018.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, ANNEX VI.