[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).

[F1NOTE 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.

A substance is defined in accordance with Article 3(1) and identified in accordance with section 2 in this Annex. A substance is always manufactured or imported in at least one form. A substance can also occur in more than one form.

For all nanoforms covered by the registration certain specific information items shall be provided. Nanoforms shall be characterised as provided for in this Annex. The registrant shall justify why the information provided in the joint registration, covering the information requirements for the registered substances with nanoforms, is adequate for assessing the nanoforms. Information relevant to cover information requirements for such a substance can also be submitted separately by individual registrants, where justified in accordance with Article 11(3).

More than one dataset may be required for one or more information requirements whenever there are significant differences in the properties relevant for the hazard, exposure and risk assessment and management of nanoforms. The information shall be reported in such a manner that it is clear which information in the joint submission pertains to which nanoform of the substance.

Where technically and scientifically justified, the methodologies set out in Annex XI.1.5 shall be used within a registration dossier when two or more forms of a substance are ‘grouped’ for the purposes of one, more or possibly all the information requirements.

The requirements specific to nanoforms apply without prejudice to requirements applicable to other forms of a substance.

Definition of a nanoform and a set of similar nanoforms:

> On the basis of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial[(1)], a nanoform is a form of a natural or manufactured substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, including also by derogation fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm.

For this purpose, ‘particle’ means a minute piece of matter with defined physical boundaries; ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components and ‘aggregate’ means a particle comprising of strongly bound or fused particles.

A nanoform shall be characterised in accordance with section 2.4 below. A substance may have one or more different nanoforms, based on differences in the parameters in points 2.4.2 to 2.4.5.

A ‘set of similar nanoforms’ is a group of nanoforms characterised in accordance with section 2.4 where the clearly defined boundaries in the parameters in the points 2.4.2 to 2.4.5 of the individual nanoforms within the set still allow to conclude that the hazard assessment, exposure assessment and risk assessment of these nanoforms can be performed jointly. A justification shall be provided to demonstrate that a variation within these boundaries does not affect the hazard assessment, exposure assessment and risk assessment of the similar nanoforms in the set. A nanoform can only belong to one set of similar nanoforms

The term ‘nanoform’, when it is referred to in the other Annexes, shall refer to a nanoform or a set of similar nanoforms, when one has been defined, as defined in this Annex.**]]**

(1) **[**[X1]**[**[F1]OJ L 275, 20.10.2011, p. 38.**]]**

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Textual Amendments

F1 Substituted by Commission Regulation (EU) 2018/1881 of 3 December 2018 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 Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances (Text with EEA relevance).

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, NOTE ON FULFILLING THE REQUIREMENTS OF ANNEXES VI TO XI.