VERBAND DER CHEMISCHEN INDUSTRIE e.V.
(German Chemical Industry Association)

Requirements of the REACH Regulation on Substances which are Manufactured or Imported also as Nanomaterials

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1. Introduction

Nanomaterials are understood to be either so-called *nano-objects* or *nanostructured materials* according to the draft definition of the ISO Technical Committee 229 "Nanotechnologies" which was taken over as working definition by the OECD. *Nano-objects* are materials which are confined in one, two, or three dimensions at the nanoscale (approximately 1 – 100 nm); typical examples are nanoplates, nanorods and nanoparticles. *Nanoparticles* are nano-objects with three dimensions at the nanoscale. *Nanostructured materials* have an internal structure at the nanoscale. Typical examples are aggregates and agglomerates of nano-objects. Chemically, nanomaterials can be, for example, pure or mixed oxides, salts, metals, and organic substances.

With a few exceptions, listed in Article 2 of the REACH Regulation, all substances, regardless of their physical state (e.g. their particle size), fall under REACH.

The purpose of the REACH Regulation is to ensure a high level of protection of human health and the environment. As explicitly stated in Article 1 of the REACH Regulation, the provisions of the Regulation are underpinned by the precautionary principle. The precautionary principle is, therefore, already the base for all information requirements for the registration of substances according to Article 12 which are specified in detail in the Annexes VII – X.

REACH requires that all substances, independent of the manufactured or imported quantity, do not adversely affect human health or the environment. For substances manufactured or imported, by a single manufacturer or importer, in quantities of more than one tonne per year a substance registration must be submitted to the European Chemicals Agency.

It should be noted that there are also legal requirements below the threshold of 1 tonne per year for a REACH registration: Obligations for, e.g., risk assessment, classification and labelling, occupational health and safety, as well as the Chemical Agents Directive 98/24/EEC, continue to apply; and there are no volume thresholds for these obligations. This means that manufacturers or importers must classify substances, or even specific products, according to the hazardous properties of the substances or products, label them if necessary, and provide specific safety information. It is possible that some nanomaterials have a different wording in specific chapters of the safety data sheet and a different classification and a different labelling than corresponding bulk products of the same chemical composition. Different classification and different labelling of products with the same chemical identity is not uncommon and occurring e. g. in the case of pyrophorous metal powders and different allotropes of phosphorous.

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2. Substance definition

In Article 3 of the REACH Regulation, "substance" is defined as a chemical element and its compounds in the natural state or obtained by any manufacturing process. This definition of a substance includes all physical states, crystal structures, and dimensions of particles of the substance in powder form or in suspension – even if the particle size would go beyond the nanoscale to individual atoms or molecules.

The European Chemicals Agency has stated on 3 December 2007 at the European NanOSH Conference in Helsinki that REACH treats both, the bulk material and the nanosized material, as the same substance. The Agency added that this, however, does not prevent the registrant from identifying dangerous properties of this substance depending on its size and classify the different types accordingly.

Requirements for substance identification are specified in Annex VI, section 2 of the REACH Regulation.

3. Registration

For substances which are manufactured or imported, by a single manufacturer or importer, in quantities of more than one tonne per year, a registration dossier must be submitted to the European Chemicals Agency. If now a solid matter substance is, at the same time, manufactured as an ingot, as coarse crystals, as fine, ultrafine or nanoscale powder, and as a suspension of fine, ultrafine or nanoscale particles in a liquid, all these products, regardless with which process they are manufactured, fall under the definition of the same substance und must, diligently, be included in the registration dossier of this substance. The European Chemicals Agency has stated on 3 December 2007 at the European NanOSH Conference in Helsinki that the whole weight of the substance, nanoscale or not, counts for the threshold above which a registration dossier has to be submitted.

According to Annex VI, section 3 of the REACH Regulation, the registration dossier must include information on the manufacturing process(es) and all identified uses, i.e. also the identified uses of the substance in its nanomaterial state.

For the risk assessment of substances, the REACH registration requires a set of physicochemical, toxicological and ecotoxicological information in the technical dossier, duely reflecting the spectrum of all identified uses of the substance, i.e. also the identified uses of the substance in its nanomaterial state. The minimum information requirements for different tonnage levels of the substance according to Article 12 of the REACH Regulation are specified in detail in the Annexes VII – X. It should be noted that apart from what is required according to the tonnage level, Article 12 also states that the technical dossier must include any other physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant. To support manufacturers and importers in the process of completing the technical dossier, VCI has issued the document “Guidance for a Tiered Gathering of Hazard Information for the Risk Assessment of Nanomaterials”.

It should be noted that the requirement to include all identified uses of a substance in the registration dossier of this substance also applies to identified uses with volumes of less than one tonne per year if those uses are no longer scientific research and development (R&D) according to Article 3, No. 23 of the REACH Regulation.

Uses of a substance for product and process oriented R&D are exempt for five years from the obligation to be included in the registration dossier of this substance according to Article 9, No. 1 of the REACH Regulation; this exemption can be extended according to Article 9, No. 7. Other obligations, e.g. for risk assessment, classification and labelling, and occupational health and safety, nevertheless, apply.

After a REACH registration, the registrant is responsible, according to Article 22 of the REACH Regulation, to update, without undue delay, the registration dossier if relevant new information is available which includes e. g. new identified uses for which the substance is manufactured, or new knowledge on the risk of the substance to human health and/or the environment which leads to changes in the safety data sheet or the chemical safety report.

4. Chemical safety report

A chemical safety report is mandatory for substances in quantities of more than ten tonnes per year per registrant. All uses of a substance identified in the registration dossier, i.e. also the identified uses of the substance in its nanomaterial state, must, diligently, be included in the chemical safety report of this substance. This applies also to identified uses with volumes of less than ten tonnes per year.

For substances classified as dangerous in accordance with Directive 67/548/EEC, or are assessed to be a PBT or vPvB, exposure scenarios have to be developed for the identified uses, i.e. also the identified uses of the substance in its nanomaterial state, and information be provided on how risks can be avoided or controlled by providing adequate risk management measures, duely reflecting all identified uses of the substance.

5. Information in the supply chain according to Title IV of the REACH Regulation

VCI is has issued a specific guidance document on how to appropriately fill in the safety data form sheet for nanomaterials.

It is common practice in the German chemical industry to use safety data sheets for the communication with downstream users for all products, even if the product is not classified as dangerous in accordance with Directive 67/548/EEC. This includes, of course, also the generation of safety data sheets for nanomaterials which are not classified as dangerous.