A common European approach to the regulatory testing of nanomaterials

Protocol for characterization and categorization of MNM in powders and liquid dispersions
Deliverable 2.5

Introduction

For regulatory use, a practical system for the definition and categorisation of nanomaterials is needed which is clear concise and, in particular, understandable by end-users. Different systems with different pros and cons have already been proposed. For identification of a nanomaterial, ISO for example uses the size and dimensions of the nano-object as the key criteria. However, size alone is insufficient for chemicals classification of nanomaterials. Nanomaterials, as modern materials in general, may be structurally and chemically complex. Hence, other parameters must be taken into account, including general composition, the number and abundance of compounds, and the surface chemistry.

This deliverable comes forward with a proposal for an advanced categorization scheme as an outcome of reviewing and processing already existing paradigms and systems. The scheme takes into account REACH naming and identification guidance to fit the existing European chemicals regulation.

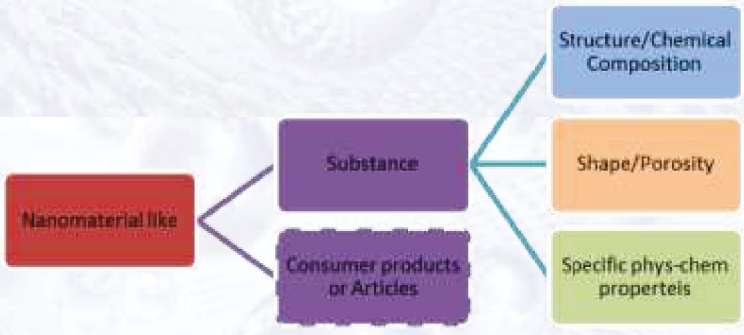
Description of Work

The proposed scheme for categorization and naming of MNMs, is based on three consecutive steps:

1. Reasoned review of existing scientific publications and reports published by various international organizations on nomenclature and procedures for substance identification and reporting (for REACH);
2. Evaluation of the suitability of existing categorization paradigms. Case studies have been performed for several materials from the NANoREG core list of nanomaterials covering a reasonable range of physicochemical parameter values. Both the ISO and Regulatory Cooperation Council (RCC) approaches have been applied
3. Establishment of a proposal for a suitable nomenclature and categorization paradigm for MNM.

Main Results and evaluation

The proposed MNM categorization scheme serves as a possible procedure for a range of nanomaterials. The main assumption of the scheme is that we deal with a nanomaterial according to a regu-latory definition accepted by EU authori-ties, whatever this definition could be.



Since the scope is MNM categorization and naming, only substances as defined by REACH have been considered. Consequently, information criteria for consumer products and articles are out of the scope of this exercise.

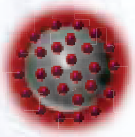
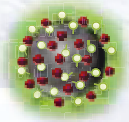
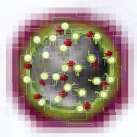
The scheme introduces relevant physicochemical properties of MNM by subgrouping them into:

1) Structure/Chemical composition,
2) Shape/Porosity,
3) Specific Physicochemical properties.

It is a rational approach to synthesize the information, and to use the information to establish a proper MNM nomenclature. Each subgroup is discussed and elaborated in the deliverable. The applicability of the proposed scheme was assessed by applying it to specific NANoREG core-nanomaterials and available data from the NANoREG Technical Data Sheets. The proposed classification scheme seems to fit well with the majority of the nanomaterials, and after further testing it could be proposed as a system for MNM classification. Unless otherwise stated, the terminologies used in the scheme are coherent with Regulation (EC) No 1907/2006 (REACH) and ISO standards.

For each group, validated methods to measure the MN properties are needed to allow a proper categorization. In NANoREG, Deliverable 2.10 present SOPs for the quantitative size and shape analysis of manufactured nanomaterials using TEM. Deliverable 2.11, present a SOP for reliable determination of the porosity and volume specific surface area (VSSA) of nanomaterials. Deliverable 2.4, provide methods enabling identification and quantitative analysis of both inorganic and organic surface coatings of manufactured nanomaterials are provided. D2.9 provides revised and new SOPs for relevant OECD Technical Guidelines for characterization.

Deliverable 2.5 finally also presents a system of nomenclature for nanomaterials on the basis of physical and chemical properties. It provides a minimum set of descriptors that enables one to immediately understand the chemical composition and structural relationships of a substance. Though, the approach for naming is generic, each material-group such as metals, metal oxides, carbon, organics etc., must be considered as individual cases. The deliverable gives examples for metal oxides and carbon nanotubes, to define their naming and compatibility to the classification scheme.

Simple Nomenclature	Fully described Nomenclature	Simplified Image	Description
SiO_2 (Amorphous) – $1G_n$	SiO_2 (Amorphous) – $1G_{99}$ (1% Al_2O_3)		Above 99% pure amorphous Silica with 1% of acceptable impurities Al_2O_3
SiO_2(Amorphous) – $2GIC_n$	SiO_2(Amorphous) – $2GI_{(CdS)}C_5$		Second generation silica shell on a core of 5 wt% CdS (core-shell type)
SiO_2(Amorphous) – $2GIE_n$	SiO_2(Amorphous) – $2GI_{(Fe2O3)}$ E_5		Second generation silica with 5 wt% of Fe_2O_3 coated on silica
SiO_2(Amorphous/ Maghemite) – $3GO_nI_n$	SiO_2(Amorphous/ Maghemite) – $3GO_{10}I_5$ (10%APES, 5% Fe_2O_3)		Third generation External surface of silica is functionalized with 10 wt% APES and further coated with 5 wt% Fe_2O_3.
SiO_2(Amorphous/ Maghemite) – $3GO_nI_n$ /O_nI_n	SiO_2(Amorphous/ Maghemite) – $3GO_{10}I_5$ /$O_{10}I_5$		Third generation, a mixture of silica containing 10 wt% of functional groups, APES and coated with 5 wt% Fe_2O_3.

For more details about NANoREG please visit the official website **www.nanoreg.eu.**

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