Characterisation of (inorganic) nanomaterials under REACH

19 February 2014

This document is based on a recommendation made to the Precious Metals and Rhenium Consortium (c/o EPMF aisbl) by EBRC Consulting GmbH, following the assessment of the REACH guidance on nanomaterials, the EU definition on nanomaterials and other pertinent documents. Discussion between industry, authorities and researches on the definition and characterisation of nanomaterials are currently on-going. Therefore, neither EBRC nor PMC can be made liable for any follow up efforts or costs, in case the experimental work suggested below is not accepted or is deemed insufficient by authorities.

Recommended characterisation steps to be performed by each legal entity for each type of nanomaterial in order to satisfy the requirements/expectations of ECHA and other authorities are:

1. **Select and prepare adequate sample:** Cf. e.g. ISO 14887:2000 and OECD's "Guidance Notes on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials" (2012)

2. **Determine substance composition:** The recommended technique will depend on the nature of the substance and on the type of information which needs to be provided (elemental, oxidation state, compounds, species, etc.). The information provided needs to be sufficient to demonstrate the identity of the substance, confirm sameness across joint registrants of the substance, and demonstrate suitability of the risk assessment (i.e. that the substance registered is properly covered by the (worst case/conservative) working assumptions and scope of the assessment). The technique shall be able to identify:
   - Main and minor constituent(s);
   - Impurities (normally resulting from the process used to manufacture the substance); and
   - Additives necessary to preserve the stability of the substance and which cannot be separated without affecting the stability of the substance or changing its composition (e.g. coating preventing a nanomaterial from agglomerating).

3. **Determine particle size distribution:**
   - Determine the volume based distribution (by Dynamic Light Scattering (DLS) / laser diffraction);
     NOTE: DLS only is not appropriate or sufficient as it is heavily weighted towards detection of larger agglomerates; the intensity of the DLS signal varies in proportion to the sixth power of the diameter of the particle (Domingoes *et al*. 2009).

   AND
   - Determine the number based distribution (it can theoretically be calculated from the volume based distribution, but with some uncertainty). At this point in time, it appears most feasible to use image analysis of REM/TEM images, i.e. counting of particles of different sizes on the images. This can be done (semi-)automatically by some laboratories.

4. **Determine surface area:**
   - For dry powders: BET.
   - For suspensions: estimate surface area on the basis of particle size distribution (if shape of particles is more or less spherical).

5. **Report detailed morphology:**
   - Digital light microscopic images;

   AND
   - TEM or REM to qualitatively describe the shape and the agglomeration behaviour of the particles.

6. **Report information on coating:**
   - Generic name of the coating
   - Chemical name of the coating
   - Classification of the coating
   - Function of the coating

An example of how the above information looks like and should be provided to the PMC Secretariat and included in the concerned company's individual registration file is available below.

The results of this characterisation work will need to be attached to the registrants' individual IUCLID 5 files and reported to the entity preparing the joint registration dossier so the individual registrants' information can be reported in an aggregated manner in the joint dossier and provide an indication of the boundaries of applicability/coverage of the scope of the dossier.

The information resulting from the above measurements are aimed at identifying and characterising a material, not at inferring on the hazard or risk that the substance may pose.

EXAMPLE
(to prepare input to company-specific IUCLID 5 file)

Parameter	**Deliverable in individual registrant's IUCLID 5 file: method used and results**
1. Sample preparation	• Add method description of sample preparation in section 1.4, i.e. how the sample tested to generate the information below was prepared • Attach any relevant document describing the sample preparation and the characteristics of the sample, as prepared, for other parameters than those listed below, in section 1.4
2. Substance composition	• Add description of method(s) that was(ere) used to determine the substance composition in section 1.4 • Add legal entity-specific composition(s) in section 1.2 of IUCLID 5 file • Attach substance composition result(s) in section 1.4
3. Particle size	• Add description of method(s) that was(ere) used to determine the particle size distribution in section 1.4 • Attach particle size distribution result(s) in section 1.4
4. Surface area	• Add description of method(s) that was(ere) used to determine the surface area in section 1.4 • Attach surface area result(s) in section 1.4
5. Morphology	• Add description of method(s) that was(ere) used to determine the morphology in section 1.4 • Attach morphology determination result(s) in section 1.4
6. Coating	• Add description of method to determine identity and characteristics of coating in section 1.4 • Add name, and typical and min/max ranges of coating(s) as additives in section 1.2. Add classification and function of coating in remarks field of additive in section 1.2 • Flag as confidential as relevant (NOTE: Confidentiality Flags may trigger additional ECHA fees)

NOTE: Deliverables are to be prepared and reported in IUCLID 5 for each and all (commercial) form(s) of the substance as manufactured and/or imported by the registrant. Ideally, the method and the results can be reported in a one and only report to be attached in section 1.4 of IUCLID 5. More information on the completion of the IUCLID 5 file is available in the PMC Guidance on registration.