A common European approach to the regulatory testing of nanomaterials

Framework and procedures for characterization and reporting of MNMs for regulatory use
Deliverable 2.12

Introduction

The REACH regulations oblige companies operating on the European Market to identify and manage risks linked to the substances they manufacture and market in the EU. They have to register their substances and in this context, carry out a chemical safety assessment aimed at defining and describing the conditions under which the risks of the substance are controlled. To facilitate this registration process ECHA (The European Chemicals Agency) provides guidance on what information should be provided and what methods can be applied for generating the data on properties of substances, for predicting exposure levels and for risk assessment.

REACH and the guidance documents mentioned above focus on “traditional chemicals”. Revisions of existing guidance documents and supporting appendixes are currently under development to support registration and grouping of nanomaterials (NMs). This however, does not yet completely cover the need for a specific and consistent approach for this category of materials.

Deliverable 2.12 provides recommendations for revision of the guidance documents which address NMs and conceptual harmonization for materials in general. The recommendations are related to schemes for substance identification and methods to generate the minimum sets of physicochemical end-points required for the substance identification, grouping, QSAR and read-across schemes for NMs in REACH. The recommendations stem from an over-arching activity bridging several tasks of Work Package 2 of the NANoREG project.

Main results and evaluation

Characterization and identification of nanomaterials

The analysis of the current (draft) guidance documents and Q&As on substance identification reveals that the guidance with respect to substance identification in the different documents is not consistent. The key parent document for substance identification (ECHA-16-B-37-EN) states that “the current state of development is not mature enough to include guidance on the identification of substances in the nanoform in this document”. Several annexes however express the need for specific information on NMs like size/size-range, shape and surface chemistry. It is recommended to harmonize the schemes for substance identification and substance specific profiles irrespective whether it is a NM or not.

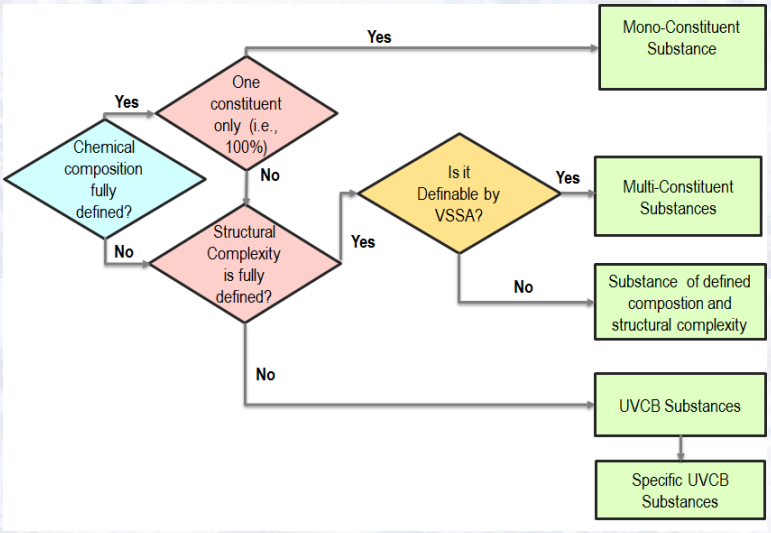
The deliverable comes forward with several concrete proposals for modification, such as reporting of particle size distribution and adjustment of the scheme for morphological categorization to be used as basis for grouping and read across purposes. In this context already developed schemes for shape type classification by ISO are mentioned as a more solid base.

Reporting on surface-chemistry as required in Appendix 4. is considered as an important improvement. However, surface-chemistry is not the only chemical modification that should be included in the information requirements for NMs. Nanomaterials may be modified in many different ways in modern material design including atomic substitution, doping, porosity-filling, physical coating and chemical functionalization. They all should be reported since all these modifications potentially change the properties, reactivity, fate and hazard of the NM.

Proposed revision substance identification scheme and material categorisation

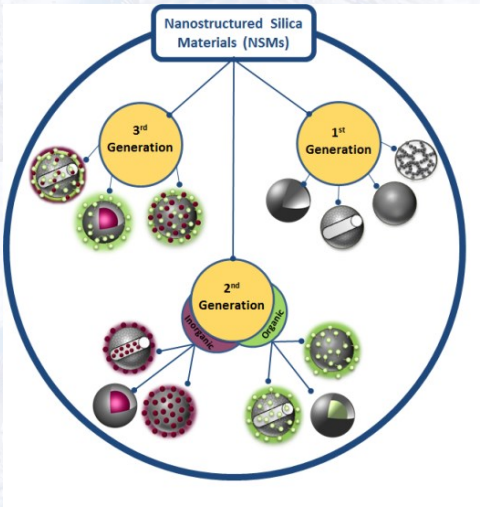
This project has received funding from the European Union Seventh Framework Programme (FP7/2007-2013) under grant agreement no 310584

In Deliverable 2.05 a proposal for a modified categorization scheme was presented that took into account the results of the above mentioned analysis of REACH guidance on substance identification, categorization and grouping.



It was also suggested that the final identification and reporting should include characterization of physicochemical properties according to the (nano-)materials by sub-grouping them into 1) Structure/Chemical composition, 2) Shape/Porosity, and 3) Specific Physicochemical properties. The number of characterization end-points under "Specific physicochemical properties" could vary from limited to rather extensive depending on the material type and information needs.

The specific categorization of the materials was suggested to be done according to the principal nature of the 1st generation NM (solid, capsule/hollow, porous) and then subsequently according to the physical location and extent of structural and chemical modifications to achieve the 2nd generation NM (modified internally or externally by either organic or inorganic compounds) or 3rd generation NM with organic and inorganic chemical modifications. The proposed classification and proposed descriptive codes enables quick identification of various NMs by their complexity, which could also be an easy way to identify requirements for new risk assessments. The figure shows an example of this structure considering nanostructured silica NMs.



Methods to support data generation

In the ECHA Guidance Documents information on a minimum of 13 physicochemical characterization end-points is requested. Recommendations on how to generate the data also are given. However, it is mentioned that the methods are rarely fully applicable for characterisation of NMs.

NANoREG developed and demonstrated SOPs for identification of NM by sizing, using electron microscopy and BET gas-adsorption and de-sorption profiles (NANoREG D2.10 and D2.11). Procedures were developed for several other end-points of regulatory relevance, including identification and quantification of surface chemical modifications (NANoREG D2.04) as well as dissolution testing, and reactivity (NANoREG D2.08). Revisions of several of the OECD TGs were proposed or proposed to be replaced with alternative or new methods and presented in NANoREG D2.09. The established SOPs for sizing dispersed near-spherical particles and primary nano-objects in agglomerates and aggregates are already documented by interlaboratory testing in 9 laboratories (NANoREG D2.10).

It is evident that further testing and/or acceptance of the other SOPs is urgently needed to establish international guidelines and standard methods to support the regulatory process. A revision to clarify the guidance and recommended characterization methods in general would be of great benefit for the registrants of REACH.

For more details about NANoREG please visit the NANoREG Results Repository.