

Experimental evaluation of OECD methods for analysis of physicochemical MNM properties

Deliverable 2.3

Introduction

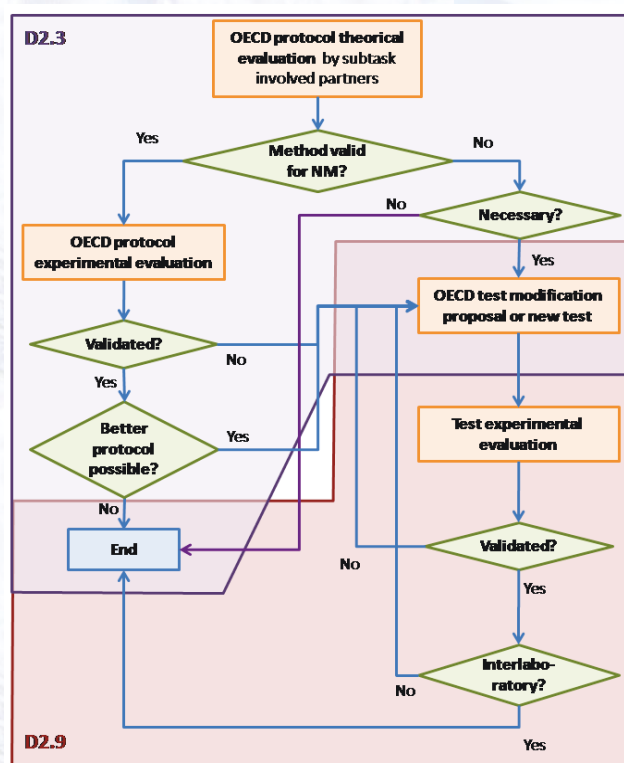
OECD Test Guidelines are a collection of the most relevant test methods to determine the safety of chemicals and chemical preparations, including pesticides and industrial chemicals. They cover tests for the physicochemical properties of chemicals, environmental effects, degradation and accumulation in the environment, human health effects, as well as other areas. The Guidelines are a unique tool for assessing the potential effects of chemicals on human health and the environment. They are accepted internationally as standard methods for safety testing.

There is reason to believe that not all the OECD Test Guidelines are appropriate for the characterization and the assessment of the toxicological properties of manufactured nanomaterials. This has to do with the unique properties of these materials. The OECD WPNM and the REACH Implementation Projects on Nanomaterials (RIP-oN2) have concluded that some OECD Test Guidelines are applicable, in some cases with reservations, while others are inadequate for testing Manufacture Nanomaterials (MN). For several Guidelines it has been concluded that there is a need to further test the applicability for nanomaterials and –if necessary- to establish new Test Guidelines.

Task 2.3 of the NANoREG project fills in this need for further review of the Test Guidelines selected in OECD and REACH context. If relevant this task also will come forward with proposals for modifications or new Test Guidelines. It will also evaluate the modified or new Test Guidelines. Deliverable 2.3 reports the results of the first two parts of this task: the evaluation of the selected OECD Test Guidelines and recommendations regarding the modification or development of new Test Guidelines.

Description of Work

The strategy that has been followed is summarized in the decision tree. In a first step, each OECD method is evaluated; these evaluations are based on compilation of literature results and on the expertise of partners in the task (LEITAT, UdL, EPFL, UNamur and NRCWE). Where relevant, the most recent specific advice and guidance from OECD’s Working Party on Manufactured Nanomaterials, REACH Implementation Projects on Nanomaterials, European Chemicals Agency, etc. is taken into account. From this evaluation, it will be decided if the method is applicable to nanomaterials (all nanomaterials or only some type), if small changes are necessary or if a complete new method is necessary. When the OECD method is considered as not applicable/not appropriate, a new protocol is elaborated by the partners. Protocol evaluations and modifications are reported in this deliverable (D2.3) case by case. The experimental evaluation and further validation of these protocols will be reported in D2.9.



Yes / No could be applicable only to some NM

Main Results

The results reported in the Deliverable are summarised in the table below. The results of the Future work, mentioned in the last column, will be reported in the Deliverable 2.9.

OECD Technical Guideline	Appropriate for NMs	Proposal	Future work
TG 109 (relative density)	Verification necessary.	Protocol evaluation	Gas displacement effect on the true density determination will be evaluated. Evaluation of the measurement of the density of agglomerates.
TG 110 (granulometry)	Method A is not applicable to nanomaterials. Method B is applicable with actualization.	Completely new protocols (CLS and DLS) are proposed. Electronic microscope use for fibres can be extended to nanomaterials	The proposed protocols will be evaluated and reported in D2.9. Work done in Task 2.2.
TG 106 (sorption-desorption)	Not applicable to nanomaterials, but may be applied to determine the partition between water and soil of nanomaterials in some cases.	Development of new detection and quantification methods (e.g. ICP-MS, radiolabelling)	Protocol and detection modification will be evaluated and reported in D2.9.
TG 105 (water solubility)	Not applicable. Requires a different approach. Several points need to be revised.	-Kinetic study. -Control of variables such as pH or dissolved gases. -Protocol for dispersibility determination.	Modifications to solubility protocol will be evaluated and reported in D2.9. Relevant SOPs for <i>in vitro</i> , <i>in vivo</i> and environmental dissolution testing will also be presented in Task 2.4 (D2.6, D2.7 and D2.8). Dispersibility protocol will be evaluated and proposed as new protocol to be considered for NM characterization.
TG 115 (surface tension)	Modifications necessary.	This protocol is considered relevant only for some NM.	Modifications will be evaluated and the relevancy will be analyzed.
TG 107/117/123 (n-Octanol-water part. coef)	Not applicable.	A partition coefficient as defined by OECD is not applicable to nanoparticles. It should be replaced by the determination of hydrophilicity/hydrophobicity.	Evaluation of new methods for testing hydrophilicity/hydrophobicity.
TG 112 (dissociation constant in water)	Not considered adequate for its application to NMs in its current form.	Develop protocols for other more relevant endpoints such as dissociation of water and hydration, surface acidity and iso-electric point.	Evaluation of dissociation of organic ligands from metallic and metal oxides NMs. Evaluation of existing SOPs of more relevant endpoints, such as ISO13099 for iso-electric point and surface charge.
TG 108 (complex formation in water)	Not considered adequate for its application to NMs in its current form. A similar protocol can be useful to determine NM as vector of toxic metals.	Guideline modification for focusing on the adsorption of trace metals on NMs.	Protocol evaluation with different metals in several conditions. This work will be reported in D2.9.