Electronic Supplementary Material 1

Table S1. Overview of the information gathered about the availablity of metods, protocols and guidelines for the information requirements and waiving criteria and category of the highest-ranked category of identified methods needed to acquire/fulfill information requirements and assess if waiving criteria are triggered set by the European chemicals legislation REACH for nanomaterials (NMs). TGS: Internationally accecpted test guideline or standardSUD: Internationally accepted test guideline or standard under development; SCI: Established as standard method in scientific literature; O: Other method and/or more research needed; N: No method identified. Other abbreviations: TR: technical report; GD: guidance document; Organization for Economic Co-operation and Development (OECD); ISO: International Organization for Standardization; ECHA: the European Chemicals Agency; WNT: Working Group of the National Coordinators for the Test Guidelines Programme.

Information requirement	Waiving criteria	Methods, protocols and guidance	Method category
7.7 Solubility (and dissolution rate)		• OECD WNT Project 3.10: New TG on dissolution rate of NMs in aquatic environment ongoing.[1] • OECD WNT Project 1.5: GD on determination of solubility and dissolution rate of NMs in water and relevant synthetic biological media ongoing for new guidance document/test guideline.[1] • GD 318 for the testing of dissolution and dispersion stability of NMs, and the use of the data for further environmental testing and assessment.[2] The GD lists the following methods: 1. Batch test using Centrifugal ultrafiltration (not recommended ultracentrifugation or dialysis) 2. Dynamic testing of dissolution rates based on Koltermann-Jülly et al.[3] • Partially covered in ECHA Guidance.[4,5] • OECD TG 105[6]: not adapted to NMs specifically • ISO/TR 19057[7]: adapted to NMs • OECD GD 29 on Transformation/ Dissolution of Metals and Metal Compounds in Aqueous Media[8] is applicable for some NMs. E.g., Wasmuth et al.[9] applied it successfully to silver NMs. • Multiparameter matrix methods may be used to study dissolution and solubility. E.g., Xiao et al.[10] performed a multifactorial design for the water chemistry (based on OECD-TG-318 matrix of parameters: natural organic matter, ionic strength and pH). • Study of dissolution of metal NMs environmental (freshwater) conditions.[11,12]	TGSUD

	(7.7) Hydrolytically stability or readily oxidisable	• OECD Project 3.10 (New TG on dissolution rate of NMs in aquatic environment) includes a screening test for NMs to assess whether they fall into the category of rapidly dissolving NMs.[1] • **	TGSUD
7.8 Partition coefficient n-octanol/ water		• Partially covered in ECHA Guidance on registration and chemicals safety assessment of NMs.[4,5] • Dispersion stability to be considered when Kow is not applicable. For this, OECD TG 318[13] is available. • The OECD Working Party on Manufactured Nanomaterials (WPMN) has concluded that the octanol-water partition coefficient is not applicable for particulate, insoluble NMs. For rapidly soluble NMs the same approach would apply as for conventional chemicals.[14] • Surface hydrophobicity quantification by comparing binding affinity to specifically functionalized surfaces, proposed as alternative to octanol-water partition for NMs.[15]	O
	(7.8) The substance is inorganic	• *No method needed*	O
7.14bis Dustiness		• OECD Project 1.8: TG on Determination of the Dustiness of Manufactured Nanomaterials is aimed at developing guideline for NMs dustiness testing.[1] • Rotating drum method, continuous drop method and small rotating drum method,[14,16] for which British standards exist: EN 15051-1,[17] 15051-2[18] and EN 15051-3.[19]	TGSUD
	(7.14bis) Exposure to granular form of the substance during its life-cycle can be excluded	• No methods identified.	N
9.1.1 Short-term toxicity testing on invertebrates		• ISO/TS 20787:2017.[20] • OECD GD 317 on Aquatic and Sediment Toxicological Testing of Nanomaterials.[21]	SCI*

	(9.1.1) The substance is highly insoluble in water***	• *See 7.7*	TGSUD
	(9.1.1) The substance is unlikely/has low potential to cross biological membranes	• Cellular uptake can be studied using flow-cytometry, microscopy, ICP-MS and TEM.[22] • The same in vitro assay(s) as used to investigate cytotoxicity and cytokine induction may be used.[22] This has e.g. been done in Gliga et al.[23] on silver nanoparticles in human lung cells and in Cronholm et al.[24] on metal silver and copper oxide NPs. • Biokinetics-oriented tests can be used to indicate whether a given NM are capable of cell penetration.[25,26]	O
9.1.2 Growth inhibition study aquatic plants		• OECD GD 317 on Aquatic and Sediment Toxicological Testing of Nanomaterials.[21]	SCI*
	(9.1.2) The substance is highly insoluble in water***	• *See 7.7*	TGSUD
	(9.1.2) The substance is unlikely/has low potential to cross biological membranes	• *See 9.1.1*	O
7.14ter Further information on physicochemical properties		• OECD decision tree for physical chemical characterisation is available and OECD framework on physical chemical characterisation was released in May 2019 and can be used indicatively for assessing relevance and applicability of existing methods/standards.[5] • OECD WNT Project 1.7: New TG on determination of surface hydrophobicity of manufactured NMs under development, which can be used to provide further information on physical chemical properties.[5] • ISO/TR 11360:2010 describes a classifying system, termed a "nano-tree", upon whose basis wide ranges of NMs can be categorized, including	TGS

		nano-objects, nanostructures and nanocomposites of various dimensionality of different physical, chemical, magnetic and biological properties.[5]	
9.1.3 Short-term toxicity testing on fish		• OECD GD 317 on Aquatic and Sediment Toxicological Testing of Nanomaterials.[21]	SCI*
	(9.1.3) The substance is highly insoluble in water***	• *See 7.7*	TGSUD
	(9.1.3) The substance is unlikely/has low potential to cross biological membranes	• *See 9.1.1*	O
9.1.4 Activated sludge respiration inhibition testing		• OECD GD 317 on Aquatic and Sediment Toxicological Testing of Nanomaterials.[21]	SCI*
	(9.1.4) The substance is highly insoluble in water***	• *See 7.7*	TGSUD

	(9.1.4) The substance is unlikely/has low potential to cross biological membranes	• *See 9.1.1*	O
	(9.1.4) The substance is readily biodegradable	• OECD TG 301 A-F.[27] Here, a material is considered readily biodegradable if 60 %/70 % of the organic carbon in the material is converted to CO_2 within certain time limits. The TG is only applicable to carbonaceous materials, as it is based on the total mineralisation of an organic chemical.[28]	TGS
	(9.1.4) The applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant	• No methods identified.	N
9.2 Degradation		• OECD WNT project 3.16 is working on a GD addressing abiotic transformations of NMs in environmental media.[1] • Abovementioned guidance, aims to cover abiotic core transformation and coating degradation. Both documents likely to be available in 2023 or 2024. It may be possible to conduct a qualitative assessment in the meantime.[5]	O
9.2.2.1 Hydrolysis as function of pH		• OECD TG 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media.[13] • Method chosen on basis of the following statement by ECHA to this information requirement: "*Consider nanomaterial dissolution rate and dispersion stability*".[5]	TGS

	(9.2.2.1) The substance is highly insoluble in water***	• *See 7.7*	TGSUD
	(9.2.2.1) The substance is readily biodegradable	• *See 9.1.4*	TGS
9.3.1 Adsorption/desorption screening		• Partially covered by ECHA Guidance.[4,5] • Study of functional changes upon exposure to aquatic environments, e.g. hydrophobicity using dye staining.[29] • Draft OECD GD on testing nanomaterial behaviour in soils using OECD test guideline 312[30] is expected in 2020 or 2021.[5]	O
	(9.3.1) Based on physicochemical properties, the substance is expected to have a low potential for adsorption (e.g. the substance has a low octanol-water partition coefficient)	• *See 9.3.1*	O
	(9.3.1) The substance and its relevant degradation products decompose rapidly	• OECD 301A-F.[27]	TGS
9.2.1.2 Simulation testing on ultimate degradation in surface water		• OECD TG 318: Dispersion Stability of Nanomaterials in Simulated Environmental Media.[13] • Method chosen on basis of the following statement by ECHA to this information requirement: "*Consider nanomaterials also dispersion stability*".[5]	TGS

	(9.2.1.2) The substance is highly insoluble in water***	• *See 7.7*	TGSUD
	(9.2.1.2) The substance is readily biodegradable	• *See 9.1.4*	TGS
9.3.2 Bioaccumulation in aquatic species, preferably fish		• OECD WNT Project 3.12: Assessing the Apparent Accumulation Potential of Nanomaterials During Fish Bioaccumulation Studies. • ICP-MS for analysis of NMs in dissolved fish tissue.[31] • Other methods include: In vivo and in vitro methods applicable to mammalian fluids/tissues/cell cultures, acellular dissolution in physiological fluids, environmental dissolution test guideline and environmental biodegradation.[32]	SCI
	(9.3.2) The substance has a low potential for bioaccumulation (for instance a log Kow ≤ 3)	• ICP-MS for analysis of NMs in dissolved fish tissue.[31] • Other methods include: In vivo and in vitro methods applicable to mammalian fluids/tissues/cell cultures, acellular dissolution in physiological fluids, environmental dissolution test guideline and environmental biodegradation.[32] • OECD WNT Project 3.12: Assessing the Apparent Accumulation Potential of Nanomaterials During Fish Bioaccumulation Studies.[1]	SCI
	(9.3.2) Direct and indirect exposure of the aquatic compartment is unlikely	• No methods identified.	N
9.3.3 Further information on adsorption desorption depending on the results of the study required in Annex		• Partially covered by ECHA Guidance.[4,5] • Study of functional changes upon exposure to aquatic environments, e.g. hydrophobicity using dye staining.[29] • Draft OECD GD on testing nanomaterial behaviour in soils using OECD test guideline 312 is expected in 2020 or 2021.[5]	O

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9.4 Effects on terrestrial organisms		• OECD GD 317 (on Aquatic and Sediment Toxicological Testing of Nanomaterials[21] may be updated for terrestrial organisms.[5] • According to REACH, the equilibrium partitioning method may be applied to assess the hazard to soil organisms in case of no toxicity data on soil organisms, however, according to the regulation this shall be scientifically justified. • Proposal on OECD TG 312 Leaching in Soil Columns as an alternative approach to the equilibrium partitioning method.[4,33,34] For this method, a draft for NMs is under development.[5] • OECD TG 303A on Particle Attachment and Removal from Wastewater[35] also proposed as an alternative approach to predict sorption of NMs.	SCI
	(9.4) Direct and indirect exposure of the soil compartment is unlikely	• No methods identified.	N
2.4.2 Number based particle size distribution with indication of the number fraction of constituent particles in the size range within 1 nm – 100 nm.		• Test guideline under development within OECD WNT project 1.4: New test guideline on particle size and size distribution of manufactured NMs.[1] • ISO/TS 19590:2017 Nanotechnologies — Size distribution and concentration of inorganic nanoparticles in aqueous media via single particle inductively coupled plasma mass spectrometry.[36] This method may not cover the whole size range of 1-100 nm of the requirement. • ISO 22412:2017 Particle Size Analysis –Dynamic Light Scattering (DLS)[36] applies, with certain restrictions,[38] such as not being able to qualitatively identify the number fraction of particles in the size range within 1-100 nm. • ISO/TS 21362:2018 Nanotechnologies — Analysis of nano-objects using	TGSUD

	asymmetrical-flow and centrifugal field-flow fractionation.[39] • Imaging methods such as electron microscopy with following sizing and counting of particles. Limitations of the methods are described in,[40] one of them being challenges associated with quantification. • Nanoparticle Tracking Analysis (NTA) is a batch technique used for particle measurement in the range of 10 to 1000 nm. Advantages and limitation of the techniques can be found in.[41]	
2.4.3 Description of surface functionalisation or treatment and identification of each agent including IUPAC name and CAS or EC number.	• ECHA Guidance[41]: Analytical techniques (e.g. IR, NMR, TGA, ICP-MS, XRF, XPS, EDX, GC-MS, MALDI-TOF, etc.) may be used for the identification and the quantification of the surface treatment. Choice of technique depend on the nature of the treating agent (e.g. inorganic or organic). Protocols have been developed for quantitative analysis of both inorganic and organic surface coatings: NANoREG[42] and ISO/TR 14187:2011[44] (revised version available[45]). • OECD WNT project 1.6: GD on identification and quantification of the surface chemistry and coatings on nano- and microscale materials[1] under development. • Methods for chemical composition (impurities, surface chemistry): ICP-MS for inorganic composition, TGA for organic coatings, EM and XPS for inorganic shell.[32,38] FTIR and UV-VIS to characterise the surface chemical functionality. OECD Test guideline 101 UV-VIS Absorption Spectra (Spectrophotometric Method) considered applicable, however WPMN concluded that it is only to solutions and some NMs.[39] • Auger electron spectroscopy (AES) to analyze surface composition, however only applicable to NMs that are stable under ultra-high vacuum (e.g. metals and CNTs).[14] • FTIR/ATR and Raman spectroscopy for kinetic studies of adsorption of solution ligands and molecules to NMs, changes in composition and stability of organic coatings etc.[e.g. 11,23]	SCI*
2.4.4 Shape, aspect ratio and other morphological characterisation: crystallinity, information on	• Advice from OECD WNT project 1.4: New TG on particle size and size distribution of manufactured NMs currently under development on particle size regarding determination of length and aspect ratio for fibres (elongated particles). 2D NMs not covered by the test guideline.[5] • Currently, there are protocols from research projects and/or standard methods and/or scientific literature available for determination of crystallinity/assembly structure.[5]	TGSUD

assembly structure	• Electron microscopy (EM) is considered one of the few methodologies with enough resolution to deliver reliable images on the shape of NMs.[14]	
2.4.5 Surface area (specific surface area by volume, specific surface area by mass or both)	• OECD WNT Project 1.3: New TG on determination of the (volume) specific surface area of manufactured NMs ongoing. Finalisation expected by 2021. Based on the same techniques as the ISO standard.[5] • ISO/TR 14187[44,45] provides an introduction to (and some examples of) the types of information that can be obtained about nanostructured materials using surface-analysis tools. Of equal importance, both general issues or challenges associated with characterising nanostructured materials and the specific opportunities or challenges associated with individual methods are identified.[5] • ISO 9277:2010[46] Determination of the specific surface area of solids by gas adsorption — BET method. The method is suitable for nanomaterials that do not absorb the gas used and it can only be applied to dry solid samples.[14]	TGSUD
5.2.3 Characterisation the particle aggregation and the agglomeration	• Development of a new OECD TG or GD on determination of aggregation/agglomeration status of NMs is under consideration.[14] • Certain imaging methods, such as electron microscopy.[40] De Temmerman et al.[47] used a method based on transmission electron microscopy (TEM) and on image analysis to characterise aggregates and agglomerates of silica NMs. • Some of the methods that are used to assess if a material is a nanomaterial according to the EC recommendation on nanomaterial definition[48] can be used to determining aggregation and agglomeration.[22] That is e.g. electron microscopy image and transmission electron topography image.[49]	SCI

*Guidance Document(s) included

** In this context, hydrolytically unstable or readily oxidisable relates to rapidly dissolving NMs (half-life less than 12h).

*** For nanoforms, the study may not be waived on the basis of high insolubility in water alone.[50]

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