

COMMENTING TABLE

TITLE OF THE DOCUMENT: DRAFT SPSF Revision of OECD Test Guideline No. and OECD Guidance Document No. 318

Delegation: WPMN

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Note: Please include “GC” for *General Comments*, the paragraph number or line number. Please include only numbers in the left two columns.

Paragraph #	Line #	Expert Comments	<u>Proposed change</u>	response
	269-279 281-294 70-92,94-107 181-187	[Scope of Application and Technical Feasibility for Nanofibrous Materials] The proposal explains that OECD TG No. 318 was developed using metal and metal oxide nanomaterials and carbon-based nanomaterials, whereas the existing validation was conducted using only metal and metal oxide nanomaterials. It also states that the test principles may be applicable to other nanomaterials if appropriate analytical methods are available. However, based on our review, we could not identify specific descriptions of the scope of application, assumptions for sample preparation, effects of dispersants and sonication, changes in material state,	We suggest that the revised TG and GD clarify, for nanofibrous, high-aspect-ratio, and hydrophobic nanomaterials such as CNTs, the scope of application and unvalidated scope identified at present, the necessary analytical and material-related prerequisites, the effects of sample preparation and dispersion treatment, technical decision criteria, conditions under which the methods are inapplicable, and limitations on quantitative interpretation. Furthermore, before formally including these materials as standard test materials, it is appropriate to conduct a preliminary feasibility assessment and, based on its results, determine whether to include them within the scope of application and the scope of validation.	

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		conditions under which the method may be inapplicable, or limitations on quantitative interpretation for nanofibrous materials such as CNTs, high-aspect-ratio materials, or materials with bundle-forming properties. In addition, although the proposal identifies guidance on the handling of hydrophobic nanomaterials as an item for revision of TG No. 318, it does not provide technical decision criteria specific to nanofibrous materials such as CNTs.		
	140–187 □ 174–187 253–278 (273–278) □ 402–410	[Distinction Between Dispersion Preparation of Hydrophobic Nanomaterials and Test Objectives] The proposal indicates that guidance on the handling of hydrophobic nanomaterials will be added as part of the revision of OECD TG No. 318. It also plans to expand the test principles, tighten the requirements for determining the dissolved fraction, and harmonise test conditions, particularly the pH range. However, the SPSF reviewed does not set out specific preparation procedures	The revised TG and GD should clearly distinguish, at a minimum, the following as different test objectives: (1) the intrinsic dispersion stability of the material without the use of a dispersant; (2) behaviour in the presence of a specific dispersant or additive component; and (3) the environmental fate of nanofibrous materials released together with other components from a product or formulation. For results obtained for these test objectives, it should be clearly stated that direct comparison may not be possible when the material state, preparation conditions, and test objective differ. In addition, when dispersants or similar substances are used, the revised TG and GD could specify which information should be recorded and reported, including their type, purity, and concentration, amount added, order and method of addition;	

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		or methods for interpreting results when dispersants, surfactants, solvents, or other additive components are used to disperse hydrophobic nanomaterials, particularly nanofibrous materials such as CNTs, in aqueous media. When dispersants or similar substances are used, the interpretation should distinguish results intended to represent the intrinsic dispersion stability of the nanomaterial from results reflecting the combined effects of the nanomaterial, dispersant, and test medium	the type and residual amount of solvent; the energy, duration, and temperature of sonication and similar treatment; and the equipment, vessel, liquid volume, and treatment scale used. At the same time, clarification should be provided regarding a control system without a dispersant, a blank system containing only the dispersant, methods for distinguishing dispersed or dissolved components from undispersed or undissolved components, and the basis for relating the prepared state to the actual environment or actual conditions of product use. The use of dispersants should not be uniformly recommended as a general pretreatment. Rather, the need for their use should be determined according to the subject of evaluation and the test objective, and, when they are used, the effects of the preparation conditions on the meaning and scope of application of the test results should be described.	
	71–91 178–187 264–286 398–402	[Changes in the State of Nanofibrous Materials Caused by Dispersion Treatment and Representativeness of Actual Environmental Conditions] The proposal plans, in the revision of OECD TG No. 318, to clarify the protocol based on experience in its application and technical progress, expand the test principles, tighten the requirements for determining the dissolved fraction, add	In the revised TG and GD, dispersion preparation should be positioned not merely as sample pretreatment, but as an important test condition that affects the test results and their interpretation. At a minimum, requirements should be established to confirm and report, to the extent possible, changes before and after treatment in fibre length, diameter, bundle diameter, agglomerate diameter, the distributions of individual fibres, bundles, and agglomerates, fibre network structure, surface condition, and the state of dispersant adsorption. At the same time, clarification should also be provided regarding the dispersed or dissolved state of	

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		guidance on the handling of hydrophobic nanomaterials, and harmonise test conditions. The TG/GD subject to revision are also positioned as methods for assessing dispersion stability and solubility under relevant environmental conditions and providing environmental fate descriptors. However, for nanofibrous materials such as CNTs, the SPSF reviewed does not specifically address the effects of dispersion operations, such as sonication, stirring, shearing, centrifugation, or filtration, in addition to the use of dispersants, on fibre length, diameter, bundle structure, agglomerates, network structure, surface condition, or fine fractions. Dispersion treatment may break down coarse agglomerates, while also potentially causing shortening of fibres, changes in bundle structure, desorption or rearrangement of surface-adsorbed components, or generation of fine fragments. In addition, if it is not possible to distinguish whether the dispersed	impurities and additive components, the distinction between dispersed or dissolved fractions and undispersed or undissolved fractions, and the presence or absence of fine fractions or fragments generated by the treatment. Furthermore, with respect to whether the sample after dispersion preparation represents actual conditions of use, the state of release from products, or the state expected in the environment, a basis and decision criteria should be provided to explain the relationship between the preparation conditions and the assumed environmental conditions. If these material states and their representativeness cannot be adequately confirmed, the revised TG and GD should specify that the results are not to be treated as directly indicating the intrinsic environmental fate of nanofibrous materials, but are to be interpreted in a limited manner as apparent dispersion behaviour under the specified dispersion preparation and pretreatment conditions.	

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		fraction consists of individual fibres, bundles of a small number of fibres, fine agglomerates, or complexes containing a dispersant, it may be difficult to interpret the meaning of the measurement results unambiguously. The SPSF reviewed does not set out specific analytical or reporting requirements for these matters.		
	84-91 180-187 92-139 265-288	[Limitations on the Application of DLS to Nanofibrous Materials] The proposal suggests introducing Dynamic Light Scattering (DLS) into OECD TG No. 318 as an additional test principle and deriving an agglomeration coefficient or attachment efficiency α for homoagglomeration as a quantitative result for dispersion stability. It also states that the suitability of the DLS-based protocol for the purposes of TG No. 318, its transferability to other laboratories, and its reproducibility need to be verified, and sets out a plan to conduct a validation study, including a multi-laboratory ring trial.	Rather than treating DLS as a measurement method that is inherently applicable to nanofibrous materials, at least the following matters should be validated in the revised TG and GD. • Validity of analytical models for non-spherical particles and nanofibrous materials • Effects of fibre length, diameter, aspect ratio, bundle diameter, and number of constituent fibres • Effects of agglomerates and network structures • Effects of concentration, multiple scattering, sedimentation, and measurement time • Adsorption to vessel walls, pretreatment, and changes in sample state during measurement	

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		On the other hand, the proposal reviewed does not specify the limitations on the application of DLS to nanofibrous materials such as CNTs, non-spherical and polydisperse materials, or high-aspect-ratio materials. In particular, no specific validation items, analytical methods, or decision criteria are provided regarding the effects of fibre length, diameter, aspect ratio, bundle diameter, number of fibres constituting a bundle, coarse agglomerates, and network structures on DLS measurement results or α. The hydrodynamic diameter calculated by DLS does not necessarily directly represent the actual fibre length, diameter, bundle structure, or agglomeration state of non-spherical and polydisperse nanofibrous materials. In addition, concentration, multiple scattering, sedimentation, measurement time, adsorption to vessel walls, pretreatment conditions, variation in operator handling, and the choice of analytical model, collision model, and fitting model may affect the	• Variation among measurement facilities and operators • Effects of the collision model, fitting model, and analytical method used to calculate α • Comparison of DLS results with microscopy, image analysis, fractionation methods, and other complementary methods In addition, it should be clearly stated that α obtained from DLS is to be treated not as a universal constant intrinsic to the material, but as a method-dependent and condition-dependent parameter that depends on the test medium, material concentration, pretreatment, measurement conditions, analytical model, and calculation method. Furthermore, the revised TG and GD should clarify the conditions under which quantitative interpretation of DLS results or α may be limited because of the morphology, agglomeration state, sedimentation, or measurement conditions of nanofibrous materials. Where supported by validation, they should also clarify the conditions under which the method may not be applicable. If these limitations on application cannot be adequately validated, it is appropriate not to interpret the hydrodynamic diameter or α obtained from DLS as a value that directly represents the actual fibre length, bundle structure, agglomeration state, or intrinsic environmental behaviour of nanofibrous materials, but to treat it in a limited manner as a	

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		measurement results or the value of α . The materials reviewed contain no specific description of these matters.	measurement result dependent on the specified test medium, pretreatment, measurement conditions, and analytical method.	
	69–91 111–116 183–187 263–280 288–293	[Analytical Methods for Nanofibrous Materials and the Feasibility of Assessing Their Distribution State] The revision of OECD TG No. 318 is planned to introduce DLS as an additional test principle, derive a quantitative homo-agglomeration coefficient/attachment efficiency (α) for dispersion stability, tighten the requirements for determining the dissolved fraction, and harmonise test conditions. It also sets out a plan to conduct a validation study, including a multi-laboratory ring trial, to verify the suitability of the DLS-based protocol for the purposes of TG No. 318, its transferability to other laboratories, and its reproducibility. On the other hand, the materials reviewed do not specify a particular	When nanofibrous materials such as CNTs are covered, the revised TG and GD should establish a procedure for confirming the applicability of the analytical method before the start of testing. At a minimum, requirements should be established to confirm selectivity from coexisting components such as NOM, limits of detection and quantification, total recovery from environmental media and recovery by fraction, stability during sample storage and pretreatment, losses to vessel walls and filter media, structural changes caused by separation operations, and differences in analytical response due to material type, surface treatment, and similar factors. In addition, a distinction should be made between the technical existence of an analytical method and its ability to be implemented reproducibly across multiple laboratories in industrial and regulatory practice. When assessing distribution state, bundle structure, agglomerates, and fine fractions, not only measurement accuracy but also the required workload, equipment requirements, cost, complexity of data analysis, and feasibility of inter-laboratory standardisation should be evaluated. If such applicability, recoverability, material stability, and inter-laboratory reproducibility cannot be adequately confirmed, it is appropriate not to interpret the results as directly indicating the	

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		analytical method for distinguishing nanofibrous materials such as CNTs from natural organic matter, suspended particles, mineral particles, and other carbon-containing components in environmental media. The materials reviewed do not explicitly state whether measurement of total carbon or bulk carbon alone can provide sufficient selectivity to identify and quantify the concentration, dispersion state, agglomeration state, dissolved fraction, or fine fraction of the target substance. Furthermore, no specific evaluation methods or reporting requirements are provided regarding the possibility that separation, concentration, filtration, or centrifugation of samples may alter the bundles, agglomerates, fibre structures, or distribution state of nanofibrous materials. The materials reviewed also contain no specific description of losses to vessel walls or filter media, material stability during sample storage and pretreatment, or differences in analytical response due to material type, surface treatment, impurities, or matrix.	concentration of nanofibrous materials or their distribution state in environmental media, but to treat them in a limited manner as results dependent on the specified analytical method, sample preparation, separation operation, and measurement conditions.	

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		The proposal states that application to other nanomaterials requires the availability of appropriate analytical methods. However, for nanofibrous materials such as CNTs, it does not clarify the required levels of selectivity, limit of detection, limit of quantification, recovery, and reproducibility, or how the dispersed, colloidal, agglomerated, and sedimented fractions are to be distinguished and quantified.		
	35–45 185–187 183–208 374–409	[Distinction Among the Dissolved Fraction, Fine Fraction, and Agglomerated Fraction] The proposal indicates that the requirements for determining the dissolved fraction will be tightened and that test conditions will be harmonised as part of the revision of OECD TG No. 318. For OECD GD No. 318, it is planned to include harmonisation with OECD TG No. 322, additional advice on testing and reporting, an SOP for continuous-flow experiments on dissolution rate, a detailed SOP for dispersion stability testing based on	For nanofibrous materials, the revised TG and GD should, at a minimum, distinguish, define, and report, to the extent possible, (1) truly dissolved chemical species, (2) soluble impurities or transformation products, (3) individual nanofibrous materials and small bundles, (4) colloidal or submicrometre fine fractions, (5) large agglomerates, and (6) fragments derived from composite materials. For filtration, ultrafiltration, centrifugation, and other separation methods, the effects of pore size, adsorption to membranes, pressure, centrifugal force, treatment time, and sample handling on the apparent dissolved fraction, dispersed fraction, bundle structure, or agglomeration state should also be evaluated. Before applying a separation method, requirements should preferably be established to confirm its applicability to the target material and test medium, recovery	

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		heteroagglomeration, and additional advice based on the revised TG No. 318. These revision policies are important for appropriately assessing and interpreting solubility, dissolution rate, and dispersion stability. On the other hand, the materials reviewed do not provide a specific definition, for nanofibrous materials such as CNTs, of whether the “dissolved fraction” means only truly dissolved chemical species or may include soluble impurities or transformation products, individual fibres, small bundles, colloids, or submicrometre fine fractions. Nor could any specific requirements be confirmed for distinguishing large agglomerates, fragments derived from composite materials, fibre fragments generated by sample preparation, or transformed components from the dissolved fraction or fine fraction. Furthermore, no analytical method or decision criteria are provided for distinguishing truly dissolved chemical species from fine particulate matter.	by fraction, and changes in material state before and after treatment. In particular, a fraction that has passed through a filter or membrane, or the supernatant after centrifugation, should not be regarded as the “dissolved fraction” without confirmation of suitability and recovery. If truly dissolved chemical species cannot be distinguished from fine particulate matter, the fraction should not be treated simply as a dissolved fraction, but should appropriately be reported as an apparent passing fraction or separated fraction dependent on the separation method used and its conditions. To support application of the revised TG and GD to nanofibrous materials, we recommend addressing fraction classifications, the effects of separation operations, recovery, and relevant decision criteria in greater detail. These are matters that should be incorporated into the revised TG and GD as additional detail for applying to nanofibrous materials the revision policy of tightening the requirements for determining the dissolved fraction.	

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	43–46 134–136 185–198 203–211	The proposal indicates that OECD GD No. 318 will be updated in light of the revision of OECD TG No. 318, OECD TG No. 322, technical advances arising from the development and validation of TG No. 322, and technical advances in dispersion stability testing based on heteroagglomeration. It is also planned to revise the advice on dispersion stability testing based on heteroagglomeration in consideration of recent scientific and methodological advances and to add a more detailed and practical SOP. Furthermore, for OECD TG No. 318, it is indicated that the test principles, including DLS, will be expanded so that a homoagglomeration coefficient or attachment efficiency α can be quantitatively derived. On the other hand, the materials reviewed do not provide a specific procedure for distinguishing, for nanofibrous materials such as CNTs, homoagglomeration among fibres from heteroagglomeration with natural organic	The revised GD should consider establishing, to the extent possible, separate test systems consisting of (1) nanofibrous materials only, (2) natural particles or environmental components serving as agglomeration partners only, (3) nanofibrous materials and agglomeration partners, (4) blank and recovery-confirmation systems, and (5) control systems for confirming adsorption to vessel walls and sedimentation. Requirements should also be established to distinguish, evaluate, and report, to the extent possible, at least homoagglomeration among nanofibrous materials, heteroagglomeration between nanofibrous materials and environmental particles, sedimentation, adsorption to vessel walls, losses through filtration and centrifugation, and fractions that cannot be analysed or recovered. When calculating α for heteroagglomeration, the type and conditions of the environmental medium, the concentration and characteristics of the target particles, collision frequency, the calculation model used, the fitting method, and uncertainty should be specified. Furthermore, decision criteria based on mass balance, recovery, or control systems should preferably be established for determining whether an observed decrease in concentration is attributable to heteroagglomeration. The materials reviewed do not specify the above test systems, control systems, blanks, recovery confirmation, distinction of non-specific losses, or detailed calculation requirements for α	

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		matter, mineral particles, suspended particles, or sediment components. Nor could any decision criteria be confirmed for distinguishing whether a decrease in the concentration of the target substance in the aqueous phase is due to heteroagglomeration, sedimentation, adsorption to vessel walls, retention by filter media, separation by centrifugation, a change in the measurement target, or non-specific loss caused by sample preparation.	concerning heteroagglomeration. These should appropriately be incorporated into the revised GD as additional proposals for applying the SOP for dispersion stability testing based on heteroagglomeration to nanofibrous materials.	
	78–91 94–109 121–136 273–291 293–316	[Phased Approach to Validation Including Nanofibrous Materials] For the revision of OECD TG No. 318, the proposal presents a plan to conduct experimental work from spring 2027 to spring 2028 and a multi-laboratory ring trial and evaluation from autumn 2027 to spring 2028. It is also planned to introduce DLS into TG No. 318 as an additional test principle and derive a quantitative homoagglomeration coefficient α for dispersion stability. For the DLS-based	In Essential Information 7 and Proposed Work Plan and Resource Needs 2, the following phased validation procedure should preferably be added for material groups including nanofibrous materials such as CNTs. 1. Confirmation of technical feasibility Confirm whether sample preparation and dispersion operations are reproducible, whether the target substance can be identified and quantified, whether the dispersion state and agglomeration state can be measured, and whether the measurement results can be scientifically interpreted. 2. Preliminary validation in a single laboratory Evaluate the effects of pretreatment conditions, dispersants	

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		protocol, the plan is to verify its suitability for the purposes of TG No. 318, its transferability to other laboratories, and its repeatability, and to evaluate the robustness of the method and the variability of results within and among laboratories through a ring trial. Furthermore, as preparation for the ring trial, it is indicated that laboratories will be recruited, online Q&A sessions and in-person training for participating laboratories will be conducted, and, during the testing phase, a multi-laboratory ring trial, collection and evaluation of results, and preparation of a validation report will be carried out. On the other hand, for nanofibrous materials such as CNTs, the materials reviewed do not present a plan to separately evaluate variability arising from sample preparation, selection of dispersants and solvents, sonication and shearing conditions, disassembly of bundles, shortening of fibres or structural changes, sedimentation, adsorption to vessel walls, separation and recovery,	and solvents, separation and recovery operations, DLS measurement conditions, data processing, and analytical models. Also compare DLS results with complementary analytical methods to the extent possible. 3. Limited inter-laboratory comparison Before the multi-laboratory ring trial, confirm sample preparation, measurement, and analytical conditions that can be standardised, and distinguish conditions reproducible among laboratories from variability specific to the material or pretreatment. 4. Decision on inclusion in the ring trial Material groups should be considered for inclusion in the formal multi-laboratory ring trial after preliminary work has established technical feasibility and sufficiently defined the test conditions. The ring trial should then evaluate reproducibility across laboratories. If CNTs or similar materials are included, they should not be treated uniformly as standard materials within the scope of application, but should be positioned as material groups for validating the limits of applicability. In validation, a plan and reporting method should also be presented for separately evaluating, to the extent possible, at least (1) variability arising from sample preparation, (2) variability arising from measurement, (3) variability arising from separation and recovery, (4) variability arising from data	

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		data analysis, and interpretation of results, apart from variability arising from the measuring instrument. The materials reviewed do not specify a phased validation procedure for nanofibrous materials. Such a procedure could first confirm technical feasibility and reproducibility of sample preparation in a single laboratory, then conduct a limited inter-laboratory comparison, and finally determine inclusion in the multi-laboratory ring trial based on applicability, reproducibility, and identified sources of variability.	analysis, and (5) variability arising from interpretation of results. If CNTs or similar materials are immediately included in the ring trial without establishing criteria for phased validation and inclusion decisions, the trial may evaluate variability due to differences in sample preparation, pretreatment, or material state rather than the validity of the measurement method. Therefore, for nanofibrous materials, it is appropriate to specify in the revised TG and GD a procedure for determining their inclusion within the scope of application and the scope of validation on the basis of the results of preliminary validation and limited inter-laboratory comparison.	
	43–46 158–174 176–187 270–282	[Harmonisation of Standard Test Conditions and Their Representativeness for Nanofibrous Materials] The proposal states that the objective is to update and streamline OECD TG No. 318 and harmonise its test procedures and descriptions with OECD TG No. 322. It is also planned to update OECD GD No. 318 in light of the revision of TG No. 318, TG No. 322, and related technical	Harmonising conditions and establishing that those conditions are representative for nanofibrous materials such as CNTs should be treated separately. The revised TG and GD should clarify, at a minimum, (1) the scientific basis for selecting the standard pH and ionic conditions, (2) the relationship between the standard conditions and alternative conditions based on environmental scenarios, (3) mandatory conditions and conditions that may be modified, (4) the method for justifying the use of alternative media, (5) the effects of deviations from the standard conditions on comparability, and (6) the representativeness	

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		advances. Furthermore, it is indicated that unnecessary differences between TG No. 318 and TG No. 322 will be addressed and the two TGs will be fully harmonised. The revision items for TG No. 318 include expansion of the test principles, stricter requirements for determining the dissolved fraction, addition of advice on the handling of hydrophobic nanomaterials, and harmonisation of test conditions, particularly the pH range. Harmonisation of these conditions and procedures is considered useful for improving the comparability of test results obtained under TG No. 318 and TG No. 322. On the other hand, the materials reviewed do not specify the numerical value of the standard pH or specific conditions for ionic strength, divalent cations, natural organic matter, temperature, target-substance concentration, mixing energy, test duration, dispersants, or other coexisting components.	and limits of applicability when applying the standard conditions to special materials such as nanofibrous materials including CNTs. In particular, when interpreting results obtained under the standard conditions as representative of the overall environmental behaviour of nanofibrous materials, it is necessary to specify the scope of application in consideration of the morphology, aspect ratio, bundle-forming properties, hydrophobicity, and agglomeration characteristics of the target material. If these matters cannot be confirmed, it is appropriate to interpret the results in a limited manner as dispersion and agglomeration behaviour under the relevant standard conditions and not to treat them as values directly representative of the environmental behaviour of nanofibrous materials in general.	

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		The materials reviewed do not specify: (1) the scientific basis for selecting standard test conditions; (2) the relationship between standard and scenario-based alternative conditions; (3) which conditions are mandatory or may be modified; (4) how alternative media should be justified; or (5) how deviations from standard conditions affect comparability. Although TG No. 318 was developed using metal and metal oxide nanomaterials and carbon-based nanomaterials, the validation described in the materials reviewed does not, by itself, establish applicability or reproducibility for CNTs and similar materials. It is also stated to be applicable to other nanomaterials if appropriate analytical methods are available, and the additional measurement principles are planned to include carbon-based nanomaterials such as polymeric particles. For nanofibrous materials such as CNTs, no description could be confirmed		

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		showing that conditions such as standard pH, ionic conditions, divalent cations, natural organic matter, temperature, target-substance concentration, mixing energy, test duration, or dispersants have been verified as representative of actual environmental behaviour.		
	176–279	[Interpretation of Test Results and Scope of Regulatory Use] The proposal positions the solubility, dissolution rate, and dispersion stability of nanomaterials under relevant environmental conditions as important parameters for regulatory environmental risk assessment. It also links these parameters to decisions on the need for additional nano-specific testing and to the basis for nano-specific grouping and read-across. Furthermore, TG No. 318 is planned to introduce DLS as an additional test principle, quantitatively derive a homo-agglomeration coefficient/attachment efficiency (α), and tighten the	The revised TG and GD should state that the environmental fate data obtained need to be interpreted together with material properties, test conditions, exposure conditions, transformation processes, analytical methods, toxicity and ecotoxicity data, and risk management measures. They should also clarify that these values alone should not be regarded as sufficient grounds for hazard classification, grouping, read-across, regulatory measures, or restrictions on use for dispersion stability, solubility, dissolution rate, heteroagglomeration, or α. When used for grouping or read-across, requirements should be established to confirm, at a minimum, the comparability of material properties, fibre, bundle, and agglomeration states, dispersants, test media and pH, concentration, test duration, transformation processes, and analytical methods, and to report differences and uncertainties. For nanofibrous materials such as CNTs and other materials	

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		requirements for determining the dissolved fraction. GD No. 318 indicates that testing and reporting advice and SOPs concerning dissolution rate and heteroagglomeration will be added. These data should be treated as indicating specific environmental fate characteristics obtained under defined test media, pH, dispersants, concentration, test duration, pretreatment, measurement methods, and analytical methods. On the other hand, the materials reviewed do not explicitly state that these data alone do not determine hazard, exposure, or environmental risk, or that hazard classification, grouping, read-across, regulatory measures, or restrictions on use should not be determined solely from values for dispersion stability, solubility, dissolution rate, heteroagglomeration, or α. In particular, for nanofibrous materials such as CNTs, measurement results may vary depending on material morphology, fibre length, bundle	for which technical validity, applicability, or reproducibility has not been sufficiently confirmed, the results should be interpreted in light of those limitations. Their use in regulatory assessment should be supported by an evaluation of method applicability and, where appropriate, additional validation or complementary evidence. It is not necessary to uniformly exclude CNTs and similar materials from the scope of the revision; however, before making them standard subjects of application of the revised TG or materials routinely included in the ring trial, it is appropriate to validate in stages the technical feasibility, limits of applicability, and reproducibility of sample preparation, analytical methods, measurement methods, separation operations, and interpretation of results.	

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		structure, agglomeration state, hydrophobicity, dispersants, test media, and analytical methods. Although TG No. 318 was developed using carbon-based nanomaterials, the validation described in the materials reviewed is limited to metal and metal oxide nanomaterials; accordingly, those materials do not demonstrate applicability and reproducibility for CNTs and similar materials.		

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