

**Interim Technical Guidance for Assessing Screening Level Environmental
Fate and Transport of, and General Population, Consumer, and
Environmental Exposure to Nanomaterials
(17 June 2010)**

The following was prepared to serve as a guide when developing screening level exposure and environmental fate and transport assessments for nanomaterials, such as those submitted under the Toxic Substances Control Act New Chemicals program. The Environmental Protection Agency (EPA) is releasing this interim guidance in the hope that experienced scientists will find it helpful and will contribute to the further development and validation of this approach. This guide is applicable for neat nanomaterials (i.e., powdered or particulate forms) as opposed to nanoscale particles embedded within composites. At this time, the EPA does not have models or methods capable of predicting, with a high level of confidence, the fate of, or exposure to, nanoscale particulates in the environment. This fact, combined with the limited amount of measured data for nanomaterials, means that there is uncertainty in estimating removal efficiencies, degradation half-lives, partitioning, and transport of nanomaterials. To address the uncertainty, we recommend using a conservative (protective) bounding “what if” scenario which assumes that nanomaterials are not removed during wastewater treatment or incineration (i.e., 0% removal efficiency), are persistent (i.e., P3), are highly bioaccumulative (i.e., B3), and are highly mobile in groundwater unless measured data is available that proves otherwise. While this approach may ignore some of the recent findings suggesting high removal efficiencies for TiO₂, C60, and CNTs, a conservative (protective) approach is prudent at this time given the limited available data and lack of historical knowledge regarding the behavior of nanomaterials in the environment.

Although the following sections were prepared to present a conservative, bounding “what if” scenario for nanomaterials, the assessor should modify these assumptions according to the specific properties of each nanomaterial evaluated. For example, the assessor should consider how the presence of organic molecules and carboxyl or hydroxyl groups (i.e., functionalized) on the surface of nanomaterials affects their behavior.

Where test guidelines are listed, it should be noted that these guidelines were not developed nor have they been validated for use with nanomaterials. Acceptable test protocols with input from the EPA must be developed before reliable test results will be used to modify removal efficiencies or persistence ratings.

An understanding of environmental fate and transport is essential in assessing general population and environmental exposures. This guide is split into two sections where the fate endpoints are covered first, followed by the inputs required for running the EPA’s Exposure, Fate Assessment Screening Tool (E-FAST2) exposure assessment model.

I. Fate Section

The fate evaluation of nanomaterials consists of three parts, with the first part covering estimates for nanomaterial removal during wastewater treatment due to adsorption, stripping, and biodegradation. The second part covers nanomaterial persistence in the environment based on the rate of degradation due to aerobic and anaerobic biodegradation, hydrolysis, photolysis, and atmospheric oxidation. The third part covers nanomaterial transport and partitioning with estimates for sorption to soil and sediment, migration to groundwater, and volatilization from rivers and lakes.

1. Removal in WWT/POTW

All nanomaterials: 0 to 100%. Use a range for the overall removal of nanomaterials during wastewater treatment to reflect the uncertainty in removal efficiency due to the limited number of test results available at this time (see the following subsections for summary of available results). Using a range means that exposure assessors will use both 0% and 100% removal during wastewater treatment (WWT) when estimating releases to water bodies using E-FAST2. Removal efficiency of greater than 0% is possible, but reliable measured data based on testing for sorption to activated sludge (OPPTS 835.1110: Activated sludge sorption isotherm) and biodegradability is needed before a higher efficiency could be assigned.

Removal of nanomaterials during WWT will probably occur by sorption to biosolids along with coagulation and flocculation. This expectation is supported by recent findings where Kiser et al. (2009) reported 70 to 85% removal efficiency for engineered TiO₂ nanoparticles at 8 US WWT plants with most of the TiO₂ mass detected in the settled biosolids. Similar removal efficiencies and associations to sludge were reported for CeO nanoparticles (Limbach et al., 2008). The turbidity of wastewater containing SiO₂ nanoparticles was found to decrease by 99.7% after addition of polyaluminum chloride coagulant in the pH range from 5 to 7.5 (Lin and Yang, 2004). However, outside of this pH range, there was no observable change in turbidity after coagulant addition. While bare SiO₂ nanoparticles were found to be unsettlable in wastewater over typical primary-treatment residence times, SiO₂ nanoparticles coated with a surfactant (i.e., Tween 20) readily agglomerated and were removed during primary sedimentation (Jarvie et al., 2009).

Measuring the activated sludge isotherm for a chemical is one method for predicting its removal during WWT (i.e., OPPTS 835.1110). Westerhoff (2008) determined the activated sludge sorption isotherms for dispersed C60 and SiO₂ nanoparticles and reported Freundlich isotherm coefficients similar to those measured for TiO₂ nanoparticles (Kiser et al., 2009), suggesting that dispersed C60 and SiO₂ nanoparticle removal will be similar to that for TiO₂. We also anticipate similar removal efficiencies for CNTs given that humic acids readily adsorb to CNTs (Hyung et al., 2007) and the Freundlich coefficients for humic acids (Esparza-Soto and Westerhoff, 2003) are similar to those for TiO₂.

Although these preliminary results suggest that WWT removal efficiencies for nanomaterials are in the range of 70 to 85%, this observation is limited to TiO₂ and CeO nanoparticles with properties similar to the materials tested. Nanomaterials are new relative to industrial organic chemicals – for which estimating removal is difficult and highly uncertain – and our

knowledge base regarding nanomaterial behavior in the environment is limited. Therefore, it is prudent to be conservative (protective), and we recommend a range from 0 to 100% be used when estimating removal of nanomaterials during WWT to reflect the lack of testing data. This range covers the potential scenario of the nanomaterial being 1) released entirely to water during wastewater treatment (e.g., 0% removal); or 2) completely adsorbed to sludge during wastewater treatment removal (100% adsorption to sludge), and thus enables the development of default bounding “what if” estimates of potential exposure in the absence of data for use in a screening level risk characterization. As data accumulate, we will eventually be able to narrow the range of estimated removal efficiency.

1.A. Sorption **All nanomaterials: Low (1) to V. Strong (4).**

Stronger sorption to biosolids during WWT is expected for nanomaterials; however, reliable measured data based on testing for sorption to activated sludge (Activated sludge isotherm OPPTS 835.1110) is needed before a stronger sorption rating could be assigned.

Metal Oxides: Mineral oxides are not expected to interact with biosolids; however, CeO and TiO₂ were found in sludge samples (Limbach et al., 2008, and Westerhoff et al., 2009). Little information about “sorption” of metal oxide nanomaterials is available at this time.

C60: Based on the activated sludge isotherms (Westerhoff, 2008), rate of sorption to dissolved organic matter (Li et al., 2009), and estimated LogKow value of 6.67 (Jafvert and Kulkarni, 2008), C60s are anticipated to exhibit very strong adsorption to biosolids. However, C60 and derivatives have been observed to form highly negatively charged aggregates that remain suspended in water for many months (Ma and Bouchard, 2009) indicating the potential for C60 to remain separate from negatively charged biosolids.

CNT: While no measurements with sludge are currently available, CNTs have been shown to readily combine with dissolved organic matter (Hyung et al., 2007; Saleh et al., 2008), suggesting very strong adsorption to biosolids.

1.B. Stripping **All nanomaterials: Negligible (4).**

Nanomaterials are not thought to readily partition from water or solids into the gas phase by a diffusion process (i.e., concentration gradient or Fick’s Law). However, they may be transferred from water to air during aeration with the formation of aerosols (Beck and Radke, 2006; Bauer et al., 2002). For example, the concentration of sulfate found in aerosols with respect to the concentration in an aeration basin was 5.7×10^{-8} (Beck and Radke, 2006) and ranged from 10^{-10} to 10^{-6} for microorganism (Bauer et al., 2006). These results suggest Negligible to Low stripping based on analogous Henry’s coefficients of 10^{-9} to 10^{-5} atm-m³/mol.

1.C. Biodegradation **Removal: unknown and Destruction: unknown**

Biodegradation is possible; however, reliable measured data based on testing for biodegradability is needed before a higher removal rating could be assigned.

2. Aerobic Biodegradation

All nanomaterials: >Months

Metal Oxides: Are not anticipated to biodegrade. However, nanomaterials may be coated with degradable functional groups.

Carbon Based Nanomaterials: Might be biodegradable based on tests with horseradish peroxidase (Allen et al., 2008; Schreiner et al. 2009); however, no ready biodegradation tests have been performed. Metabolic activity of monocultures was impacted by C60 and CNTs, but no impact was observed with mixed cultures obtained from river water or secondary wastewater effluent (Kang et al., 2009).

Functionalized MWNT: Zeng et al. (2006) report that the caprolactone polymer coating was completely removed from the functionalized MWNT after 96 hours by the bioactive enzyme catalyst, pseudomonas lipase.

3. Anaerobic Biodegradation

All nanomaterials: >Months

Metal Oxides: Are not anticipated to biodegrade. However, nanomaterials may be coated with degradable functional groups. TiO₂ decreased cell viability of monocultures, but no impact to anaerobic digester sludge metabolic activity was observed (Gruden and Milejeva-Biebesheimer, 2009).

Carbon Based Nanomaterials: There was no impact of C60 on anaerobic digester sludge metabolic activity (Nyberg, et al., 2008). Carboxylated CNTs might undergo anaerobic digestion (Nyberg et al., 2009)

4. Hydrolysis

Hydrolysis: =>Months.

Hydrolysis may occur, for functionalized nanomaterials in particular, however, reliable measured data based on testing for hydrolysis (Hydrolysis OPPTS 835.2120 or OECD TG111) is needed before a faster hydrolysis rating could be assigned.

Metal Oxides: Are not anticipated to hydrolyze. However, nanomaterials may be coated with hydrolyzable functional groups.

Carbon Based Nanomaterials: Are not anticipated to rapidly hydrolyze; however, C60 and CNTs might slowly react with water, resulting in the addition of carboxyl or alcohol functional groups (Li et al., 2009). Also, nanomaterials may be coated with hydrolyzable functional groups.

5. Sorption to Soil and Sediment

All nanomaterials: V. Strong to Low

Stronger sorption is expected for nanomaterials; however, reliable measured data based on testing for sorption to soils or sediments (Sediment and soil adsorption/desorption isotherm OPPTS 835.1220 or Adsorption/desorption batch equilibrium OPPTS 835.1230 or OECD TG106) is needed before a stronger sorption rating could be assigned.

Metal Oxides: Mineral oxides are not expected to “adsorb” to soil or sediment; however, this will depend on nanoparticle surface coating.

C60: Based on the activated sludge isotherms (Westerhoff, 2008), rate of sorption to dissolved organic matter (Li et al., 2009), and estimated $\text{Log}K_{ow}$ value of 6.67 (Jafvert and Kulkarni, 2008) and $\text{Log}K_{oc}$ of 7.1 (Chen and Jafvert, 2009), C60s are anticipated to exhibit very strong adsorption to natural organic matter. However, C60 and derivatives have been observed to form highly negatively charged aggregates that remained suspended in water for many months (Ma and Bouchard, 2009) indicating the potential for C60 to remain separate from negatively charged soils.

CNT: While no measurements with soils are currently available, CNTs have been shown to readily combine with dissolved organic matter (Hyung et al., 2007; Saleh et al., 2008), suggesting very strong adsorption in soils containing natural organic matter.

6. Migration to Groundwater

All nanomaterials: Negligible to Rapid

Migration to groundwater is used in E-FAST2 to determine the concentration of a chemical in a hypothetical groundwater well 70 years after the chemical’s disposal into a nearby landfill. This scenario was developed by the EPA using the SESOIL and AT123D models, which are in the Internet Geographical Exposure Modeling System (IGEMS), for vadose zone and groundwater transport. After making assumptions about groundwater flow, soil type, and well location, the rating of migration to groundwater only requires knowing the K_{oc} value of the chemical to estimate the concentration in the groundwater well (see table below from p. 3-39 of E-FAST2 manual).

<u>Migration Descriptor</u>	<u>Log K_{oc}</u>	<u>Groundwater concentration (GWC) (mg/L per kg release)</u>
Negligible - no migration		None
Negligible to slow	≥ 4.5	3.21E-6
Slow	<4.5 to 3.5	2.67E-5
Moderate	<3.5 to 2.5	5.95E-5
Rapid	<2.5	7.55E-5

Assuming that nanomaterials behave as colloids in the environment, then instead of adsorption to soil organic matter (i.e, K_{oc}), there are two alternative removal processes for colloidal particles. One is the traditional attachment of colloids to soil grain surfaces (Clean

Bed Filtration Theory) and the second is physical straining or the trapping of particles in pores that are too small to allow particle passage (Bradford et al., 2007). The attachment of colloids to soil grains is independent of K_{oc} and instead depends on the physical processes of sedimentation, interception, and diffusion. The colloid to soil grain interaction is dependent on colloidal diameter, aqueous chemistry, and the arrangement of soil grains. This interfacial behavior can be characterized by a soil attachment efficiency (α) coefficient, which is a unique coefficient for a given soil solution and colloidal suspension (see Pennell et al, 2008 for details). Determining the attachment efficiency (α) allows for the prediction of the distance that nanomaterials can travel until their release concentration has been reduced by 99.9% (i.e., 3-log removal). Assuming that nanomaterials are analogous to viruses – virus diameters are between 20 and 200 nm and ionizable functional groups are present on the viral surface – then the distance that nanomaterials can travel until their release concentration has been reduced by 99.9% can range from 3 to 1,600 meters (Elimelech et al., 1995a). Attachment efficiency (α) can be measured using the standard experimental setups (Elimelech et al. (1995a).

C60: Transport distances in sand packed columns for 3-log removal ranged from 0.1 to 14 m for C60 particles (Pennell et al., 2008). Cheng et al. (2005) reported 3-log removal distances between 0.31 and 1.32 m. Lecoanet et al. (2004) reported transport distance for 3-log removal of 10 m in water with 10 mM NaCl. However, these results are for controlled laboratory experiments and may not be representative of field conditions.

CNTs: SWNT travel distances in sand packed columns for 3-log removal were 0.2 m in water with 10 mM KCl and 1.7 m in water with 1 mM KCl. These results suggest limited subsurface transport due to the heterogeneity typical of subsurface environments; even for CNT-humic acid aggregates (see Jaisi et al., 2008).

7. Volatilization/Aerosolization

All nanomaterials: Rapid.

Volatilization of nanomaterials into air from water or moist soil due to a concentration gradient (i.e., Fick's Law) is not expected. Instead, a mechanical process may occur during which suspended particles entrained in water droplets become airborne as aerosols. Aerosols are thought to be the main mechanism for the transport of viruses across the air-sea interface and can transport the viruses over long distances. For example, virus concentrations were found to be 10 times greater in aerosols than in water samples collected from the Long Island Sound (Aller et al., 2005). Thus, the rate of volatilization through the formation of aerosols is considered rapid. Atmospheric transport via incomplete incineration and aerosolization is thought to be possible (Colvin, 2009)

8. Photolysis

All Nanomaterials: Negligible to Rapid

Photolysis may occur; however, reliable measured data based on testing for direct photolysis (OPPTS method 835.2210 or OECD TG316) is needed before a faster photolysis rating could be assigned. For indirect photolysis on soil consider OPPTS 835.2410 or

Phototransformation of Chemicals on Soil Surfaces (Draft OECD Guideline July, 2005). For indirect photolysis in water consider OPPTS 835.5270.

Metal oxides: No photodegradation is expected, however, functionalized metal oxides may undergo photolysis.

C60: C60 rapidly degrades in aqueous suspensions exposed to sunlight (Taylor et al., 1991; Hou and Jafvert, 2009; Kong et al., 2009). The degradation products are unknown, but are probably hydroxylated/carboxylated products that can be further degraded.

CNT: Probably degraded by sunlight, similar to C60.

9. Atmospheric Oxidation

All nanomaterials: Negligible to Slow. Possible since C60 and CNTs are degraded by peroxides, however, no information available at this time.

10. Persistence and Bioaccumulation

All nanomaterials: High persistence with degradation half-lives of greater than 180 days and high bioaccumulation potential with BCFs/BAFs greater than 5,000 (P3B3).

Bioaccumulation of nanomaterials is complicated and traditional approaches for predicting their bioaccumulation may not be appropriate (Petersen et al., 2010). Lower trophic organisms have been shown to ingest and retain nanomaterials (Roberts et al., 2007; Petersen et al., 2008 and 2009; Zhu et al., 2009a). This observation led to speculation that nanomaterials could be biomagnified via predator consumption (Zhu et al., 2009b). Bioaccumulation and magnification of particulates are not well understood at this time.

Incineration

While incineration destruction and removal efficiency (DRE) is often assumed to be 99.9%, it is recommended that 0% DRE be chosen for nanomaterials. This assumption is justified by the fact that 40 CFR part 264.344 states:

- (a) The owner or operator of a hazardous waste incinerator may burn only wastes specified in his permit and only under operating conditions specified for those wastes under §264.345.

Although C60 and CNTs are most likely removed at higher DRE, there are no data demonstrating this, and these items are probably not listed on the incinerator permit. Thus, for purposes of preparing a conservative, screening level assessment, we assume 0% DRE. The submission of reliable measured data is needed before higher DREs could be assigned.

II. Exposure Section

The following sections are used to estimate the screening level exposures for nanomaterials. These screening level estimates are used to determine if manufacture, processing, or use of nanomaterials result in releases sufficient to warrant control. A qualitative assessment is prepared for these scenarios in the absence of additional reliable data and information. At this time, there is insufficient information to estimate potential exposures to consumers or general populations from the down-the-drain disposal scenario: see 2. Data Needs and Test Recommendations for Exposure Assessments for the information required to complete these assessments.

1. Screening Level Estimates

The following sections describe default bounding “what if” scenarios for nanomaterials. However, the fate portion of the assessment should be reviewed to capture any ratings that differ from the following default parameters. There will be two exposure scenarios completed for nanomaterials. One will consist of simulating releases to water (0% Wastewater Treatment Removal) and the second will simulate releases from sludge (100% Adsorption to Wastewater Treatment Sludge). Both simulations will consider releases to air (0% Fugitive and Stack Air Emissions Removal). These scenarios are intended to account for the uncertainty due to the lack of information and test results when estimating the environmental exposure to nanomaterials.

Water Release Scenario

For nanomaterial submittals that provide site specific release information, an end of pipe release scenario will be used to simulate discharges to a stagnant water body with a site-specific mixing zone and dilution factor of one. This bounding “what if” scenario assumes that the concentration of the nanomaterial in the plant effluent is equal to the concentration in the environment (i.e., no aggregation or sedimentation is assumed). If no site-specific effluent flow is provided, then discharge into a stream with flow data from the SIC code for electronic components will be used.

The following is a screen capture of the E-FAST2 PChem/Fate Inputs Screen containing the default input parameters for the water release scenario.

PChem/Fate Inputs Screen

Chemical ID:

Chemical Name:

Bioconcentration Factor: No BCF available?

Wastewater Treatment Removal: %

Adsorption to Wastewater Treatment Sludge: %

Drinking Water Treatment Removal: %

Groundwater Migration Descriptor:

Fugitive Air Emissions Removal: %

Stack Air Emissions Removal: %

Select This Chemical ID

The default input parameters for the water release scenario are as follows:

- BCF value of 5000 for a highly bioaccumulative (B3) chemical
- 0% Wastewater Treatment Removal
- 0% Adsorption to Wastewater Treatment Sludge
- 0% Drinking Water Treatment Removal
- Rapid Groundwater Migration
- 0% Fugitive Air Emissions Removal
- 0% Stack Air Emissions Removal

Choosing these default values assumes, as a bounding “what if” scenario, that nanomaterials will not be removed during treatment processes, will accumulate in fish, and will rapidly migrate to groundwater after disposal to a landfill.

Sludge Release Scenario

The following is a screen capture of the E-FAST2 PChem/Fate Input Screen containing the default input parameters for the sludge release scenario.

The screenshot shows the PChem/Fate Inputs Screen with the following parameters:

Chemical ID:	tmpcas	
Chemical Name:	Nanomaterial	
Bioconcentration Factor:	5,000.00	<input type="checkbox"/> No BCF available?
Wastewater Treatment Removal:	100.00 %	
Adsorption to Wastewater Treatment Sludge:	100.00 %	
Drinking Water Treatment Removal:	0.00 %	
Groundwater Migration Descriptor:	Rapid	
Fugitive Air Emissions Removal:	0.00 %	
Stack Air Emissions Removal:	0.00 %	

Modules:

- General Population and Ecological Exposure From Industrial Releases
 - Surface Water
 - Landfill
 - Ambient Air
- Down-the-Drain
- Consumer Exposure Pathway
- Probabilistic Dilution Model (PDM)

Select This Chemical ID

The default input parameters are as follows:

- BCF value of 5000 for a highly bioaccumulative (B3) chemical
- 100% Wastewater Treatment Removal due to sorption to sludge
- 100% Adsorption to Wastewater Treatment Sludge
- 0% Drinking Water Treatment Removal
- Rapid Groundwater Migration
- 0% Fugitive Air Emissions Removal
- 0% Stack Air Emissions Removal

Choosing these values assumes as a bounding “what if” scenario, that nanomaterials will be removed during wastewater treatment by adsorption to sludge and will rapidly migrate to groundwater after disposal to a landfill; however, they will be released during incineration and other air emissions.

2. Data Needs and Test Recommendations for Exposure Assessments

Environmental release estimates. Provide estimates for releases to water, air, and soil from manufacturing, processing, formulating, industrial use, commercial use, consumer use, recycling and/or remanufacturing of nanomaterials.

Use of Nanomaterials in Consumer Products. List the fraction of nanomaterials in the consumer product(s).

Provide the form(s) of the consumer product(s), e.g., aerosol, foam, pump spray, article, etc. If the nanomaterial is contained within an article, provide detailed information on its form in the article, e.g., crosslinked with other chemicals, embedded but not reacted, etc.

Provide the potential route(s) of exposure (dermal, inhalation, and/or ingestion) including possible secondary exposure routes, e.g., nanomaterials on food which is ingested.

Provide details on consumer disposal options (e.g., down-the-drain, municipal landfill). If product is to be recycled, provide details of processing.

Test Recommendations. For all testing recommendations, a test protocol should be developed and provided to the Agency for review.

Aerosol and spray products. Develop indoor air emissions testing protocols to determine the rate of nanomaterials release from aerosol and spray products to support potential inhalation/dermal/ingestion exposure assessment. In addition, the protocol should develop data that show whether the nanomaterial of interest settles onto surfaces and thus can become available for ingestion, dermal and secondary exposure (e.g., re-entrained into air via vacuuming, etc.)

Paints and coatings. Develop data for exposure via hand application using aerosol spray cans and/or automatic paint sprayers/rollers. Does the coating, when sanded, break down into nano-sized particles? What is the rate of nanomaterial release due to prolonged exposure of the coated or painted surface? What is the resulting particle size distribution of the released nanomaterial? Do the particles migrate to surface water resulting in exposures to aquatic organisms?

TiO₂: Kaegi et al (2008) reported that TiO₂ nanoparticles were released from painted surfaces and migrated to nearby receiving waters.

Articles of clothing. Develop data to determine the potential for dermal and inhalation exposures to nanomaterials embedded into articles of clothing. Also, provide the amount of nanomaterial that will be released from the clothing during normal wear, from clothes washing and drying, and after disposal.

Nanomaterials: Wallace (2005) showed that natural gas fuelled clothes dryers were a significant source of nanoparticles in the indoor air environment when drying clothes that did not contain nanoparticles. The source of nanoparticles was suggested to be from the gas burner; however, the exact source of particles was not determined.

General purpose cleaners, car waxes, laundry detergents, etc. Develop data for exposure via hand application using aerosol spray cans, pump spray bottles, pastes for products containing nanomaterials. We assume that the nanomaterials in these products will be released into the environment after application unless demonstrated otherwise.

Bound nanomaterials. Determine the rate at which nanomaterials embedded into the article(s), for example, polymers, pressed wood, etc, are released into water and air. The rate of release should be determined under conditions of product use. For example, for products that will hold food during heating (i.e. heating trays), the rate of nanomaterial release while heating the food should be determined. The rate of release will be used to calculate the concentration of nanomaterials for modeling inhalation and water exposures. Exposure can occur when the article's matrix containing the nanomaterial degrades or erodes thus releasing persistent nanomaterials into the environment.

Carbon Black: Car tires contain up to 30% carbon black, which is composed of nanoparticles. Dahl et al. (2006) reported that between 3.7×10^{11} and 3.1×10^{12} carbon black nanoparticles per vehicle per kilometer were released for vehicles travelling at speeds of 31 to 43 mph.

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