

EPA ISSUES DRAFT NMSP CONCEPT PAPER AND TSCA INVENTORY PAPER

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On July 12, 2007, the U.S. Environmental Protection Agency (EPA) published in the *Federal Register* three separate notices related to the long-awaited Nanoscale Materials Stewardship Program (NMSP) under the Toxic Substances Control Act (TSCA). See 72 Fed. Reg. 38,079-38,085 (July 12, 2007). All of the notices and accompanying documents are available at <http://www.epa.gov/opptintr/nano/nmspfr.htm>. The first notice announces the availability of, and solicits public comment on, EPA's proposed Information Collection Request (ICR) under the Paperwork Reduction Act, including the draft form that NMSP participants would use to submit data to EPA; the second announces an Aug. 2, 2007 public meeting on the NMSP; and the third announces the availability of, and seeks public comment on, two draft documents: (1) the "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA" (NMSP Concept Paper); and (2) the "TSCA Inventory Status of Nanoscale Substances—General Approach" (TSCA Inventory Paper). The latter document addresses an issue of significant interest to TSCA practitioners, namely the regulatory status under TSCA of existing nanoscale materials that consist of chemical substances listed on the TSCA Inventory. Written comments on these documents, as well as on the ICR, must be submitted to EPA no later than **September 10, 2007**.

Draft NMSP Concept Paper

EPA developed the NMSP Concept Paper and its accompanying Annexes "to outline [EPA's] initial thinking on the design and development" of the NMSP, which will "complement and support [EPA's] new and existing chemical efforts on nanoscale materials" and "help address some of the issues identified in EPA's Nanotechnology White Paper." EPA states that the NMSP has the following specific objectives:

- Help EPA assemble existing data and information from manufacturers and processors of existing chemical nanoscale materials;
- Identify and encourage the use of risk management practices in developing and commercializing nanoscale materials;
- Encourage the development of test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions; and
- Encourage responsible development.

The NMSP will include, but not be limited to, engineered nanoscale materials manufactured or imported for commercial purposes within the meaning of 40 C.F.R. Section 720.3(r). Importantly, EPA explains that participation in the NMSP "would not relieve or replace any requirements under TSCA that a manufacturer, importer, or processor of nanoscale materials may otherwise have."

Annex A of the NMSP Concept Paper (Description of Nanoscale Materials for Reporting) contains "clarifications and descriptions" of various key terms used throughout the Concept Paper, including "engineered," "nanoscale," "engineered nanoscale material," and "nanotechnology."

With respect to participation in the NMSP, EPA foresees involvement by persons or entities that do or intend to do any of the following, with the corresponding intent to offer a commercially available product: manufacture or import engineered nanoscale materials, physically or chemically modify an engineered nanoscale material, physically or chemically modify a non-nanoscale material to create an engineered nanoscale material, or use engineered nanoscale materials in the manufacture of a product.

Both "new" and "existing" (for purposes of TSCA Section 5) engineered nanoscale materials can be included in the NMSP. Annex A also provides examples of materials that EPA believes would and would not be appropriate for inclusion in the program.

Consistent with the National Pollution Prevention and Toxics Advisory Committee Interim Ad Hoc Work Group on Nanoscale Materials' recommendations, EPA is considering a two-part NMSP: (1) a "basic" program that would request the reporting of "all known or reasonably ascertainable information regarding specific nanoscale materials," and (2) an "in-depth" program in which additional data would be developed and submitted to EPA over a longer timeframe. NMSP Concept Paper at 3. Annex B (Data Elements) delineates the types of data that participants in the basic program would be expected to report. Submitters would be encouraged, but not required, to submit their data through a data submission form that EPA has prepared. Data claimed as confidential business information (CBI) will be protected "in the same manner as CBI submitted under TSCA in accordance with procedures in 40 CFR parts 2 and 720" (*id.* at 13), and EPA encourages NMSP participants both "to give careful consideration to what they will and will not claim [as] CBI" and "to make as much data as possible available to the public."

As part of the "basic" program, NMSP participants would agree to implement a risk management program, as well as "agree to consider information provided by EPA that is relevant to [nanoscale material] risk management . . . and to provide information about the risk management practices and other aspects of their risk management program that are relevant to nanoscale materials."

The "in-depth" program would be informed by the basic program's results, and would involve a subset of the information reported under the basic program "in a greater amount of detail." *Id.* at 5. EPA states that "[i]n-depth data development would likely apply to a smaller set of representative nanoscale materials designated for further evaluation by mutual agreement of EPA and participants, with input from stakeholders." *Id.*

EPA will use the data from the NMSP "to gain an understanding of which nanoscale materials are produced, in what quantities, how they are used, and the data that is available for such materials." *Id.* The data will assist EPA scientists in making human health and environmental risk determinations, and may be

used to "[i]dentify the data that are missing to conduct an informed risk assessment of a specific nanoscale material" and "[i]dentify nanoscale materials or categories of nanoscale materials that may not warrant future concerns or actions, or should otherwise be treated as a lower priority for further consideration." *Id.* at 6. Significantly, EPA explains that if data submitted by an NMSP participant "indicates that the participant is manufacturing a nanoscale material that is reportable under [TSCA] section 5 . . . as a new chemical substance, EPA will immediately inform the participant of that situation and the applicable TSCA requirements." *Id.*

Roughly one year after commencement of the basic program, EPA will publish an interim report summarizing "the types of data available, the reasons some data were reported as not being available, additional data that would be needed for a better risk assessment and any activities for which data are being used." Two years after the launch of the NMSP, EPA will issue a more detailed evaluation of the program and simultaneously "determine the future direction of the basic reporting phase as well as in-depth data development."

Annex C of the NMSP Concept Paper (OPPT TSCA Framework) contains a brief summary of the TSCA regulatory framework, while Annex D (Issues and Challenges) discusses various issues and challenges regarding nanotechnology and nanoscale materials that the Office of Pollution Prevention and Toxics (OPPT) in particular, and EPA more generally, faces.

Draft TSCA Inventory Paper

The TSCA Inventory Paper "describes how EPA currently determines whether a nanoscale substance is a 'new' chemical only for the purposes of the [TSCA] Inventory." TSCA Inventory Paper at 1. EPA cautions that its approach to the "new" versus "existing" chemical distinction, which is so crucial to the premanufacture notice (PMN) requirement set forth in TSCA Section 5(a), does not "establish[] a precedent on how nanotechnology issues arising under other EPA programs, other Federal Government agencies, or other federal statutes will be addressed."

Initially, EPA stresses that this paper “informs the public of the approach EPA has historically taken under TSCA in evaluating whether chemical substances are new, and further informs the public of EPA’s intention to follow this approach for nanomaterials that are chemical substances.” EPA explains that the determination of whether a chemical substance is a new or existing chemical turns solely on “whether the chemical substance has the same molecular identity as a substance already on the Inventory. A chemical substance with a molecular identity that is not identical to any chemical substance on the TSCA Inventory is considered to be a new chemical substance (*i.e.*, not on the Inventory); a chemical substance that has the same molecular identity as a substance listed on the Inventory is considered to be an existing chemical substance.” Specifically with respect to nanoscale substances, EPA states:

Although a nanoscale substance that has the same molecular identity as a non-nanoscale substance listed on the Inventory differs in particle size and may differ in certain physical and/or chemical properties resulting from the difference in particle size, EPA considers the two forms to be the same chemical substance because they have the same molecular identity. The Inventory listing in this case is considered to represent both the nanoscale and non-nanoscale forms of the substance and, as such, does not distinguish between two forms having the same molecular identity that differ only in particle size and/or physical/chemical properties resulting from the difference in particle size.

Id. at 6. In the paper, EPA outlines for the first time precisely how it construes the term “molecular identity.” EPA indicates that it “views molecular identity as being based on such structural and compositional features as the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of the atoms in the molecule, and the spatial arrangement of the atoms within the molecule,” and that “chemical substances that differ in any of these structural and compositional features . . . have different molecular identities.” EPA offers the following examples of when substances are deemed to have different molecular identities:

- When they have different molecular formulas, *i.e.*, they have the same types of atoms but a different number of atoms, *e.g.*, ethane (C₂H₆) and propane (C₃H₈), or they have the same number of atoms but different types of atoms, *e.g.*, bromomethane (CH₃Br) and chloromethane (CH₃Cl), or they differ in both the types and numbers of atoms.
- When they have the same molecular formulas but have different atom connectivities, *i.e.*, they have the same types and number of atoms but are structural isomers (*e.g.*, n-butane and isobutane) or positional isomers (*e.g.*, 1-butanol and 2-butanol).
- When they have the same molecular formulas and atom connectivities but have different spatial arrangements of atoms, *e.g.*, they have the same types, number, and connectivity of atoms but are isomeric (*e.g.*, (*Z*)-2-butene and (*E*)-2-butene).
- When they have the same types of atoms but have different crystal lattices, *i.e.*, they have different spatial arrangements of the atoms comprising the crystals, *e.g.*, anatase (atoms arrayed tetragonally) and brookite (atoms arrayed orthorhombically) forms of titanium dioxide.
- When they are different allotropes of the same element, *e.g.*, graphite (carbon atoms arranged in hexagonal sheets with each atom bonded to three other atoms in the plane of a given sheet) and diamond (carbon atoms arranged in a tetrahedral lattice with each atom bonded to four other atoms).
- When they have different isotopes of the same elements.

Specifically with respect to nanoscale substances, EPA reiterates that “[a] chemical substance with a molecular identity that is not identical to any substance on the TSCA Inventory is considered to be a new chemical,” and points out that “[a] nanoscale substance might not

have a non-nanoscale counterpart with the same molecular identity (e.g., nanotubes and carbon fullerenes), or a substance might be found in both nanoscale and non-nanoscale forms, but if the substance has not been reported previously to EPA and placed on the Inventory in either form, it is considered a new chemical.” On the subject of adding a nanoscale substance to the Inventory, EPA states as follows:

Systematic chemical nomenclature conventions may not exist for all nanoscale substances identified as new chemicals. In these cases, EPA will likely need to apply new nomenclature conventions to fully, uniquely, unambiguously, and consistently identify and name these new chemical substances for the purposes of the TSCA Inventory. As with existing nomenclature conventions, EPA expects that new nomenclature conventions developed for Inventory listing of these novel substances will include data elements necessary to describe and distinguish their unique molecular identities but will not describe different physical forms (e.g., particle sizes) of these new substances. In the interim, EPA intends to describe new chemical substances (including new substances that exist in nanoscale forms) to the best of its ability for listing these substances on the Inventory, recognizing that names assigned to these substances and even their Inventory status may change once nomenclature conventions are developed. As necessary, EPA will provide interim guidance on molecular identity data elements that could be used by the notifier and [EPA] to identify and name these new chemical substances for listing on the Inventory.

Id. at 5-6. EPA concludes the TSCA Inventory Paper by urging manufacturers or importers of nanoscale substances “to contact the [OPPT] New Chemicals Program to arrange a pre-notice consultation or to submit a request for an Inventory search under the *bona fide* intent to manufacture provision in 40 CFR [Section] 720.25.”

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