

EPA Issues Draft Papers on Nanoscale Materials

On July 12, 2007, EPA published notice in the Federal Register announcing the availability of two draft documents relating to the Agency's positions on nanoscale materials. 72 Fed. Reg. 38083. The Agency also has posted the documents on its website at <http://www.epa.gov/oppt/nano/nmspfr.htm>. The first draft document -- "TSCA Inventory Status of Nanoscale Substances -- General Approach" -- represents the Agency's first guidance paper on determining whether a nanoscale material is a "new chemical substance" subject to the TSCA premanufacture notification requirements, or is covered by an existing listing on the TSCA Chemical Substance Inventory.

The draft document adheres closely to past EPA nomenclature positions and to the language of TSCA and does not adopt the more expansive positions encouraged by some non-governmental organizations (NGOs). Key points from the document are:

1. A confirms that the Agency will rely strictly on the molecular identity of a nanoscale material to determine whether it is covered by an existing Inventory listing. EPA appears to reject arguments by some NGOs that the Agency should use physical and/or toxicological criteria to determine whether a chemical is covered by an existing listing.
2. When determining whether a chemical is listed on the Inventory, EPA will not consider whether the chemical has been aggregated to a particular particle size or into varying physical forms.
3. If a substance with a particular molecular identity is placed on the Inventory, both its nanoscale and non-nanoscale forms will be considered listed, if the two forms have the same molecular identity.
4. When determining whether a chemical has the same molecular identity as a listed chemical, EPA will consider whether the chemicals (1) have different molecular formulas; (2) have the same molecular formula but different atom "connectivities," i.e., they are different structural isomers or positional isomers; (3) have the same molecular formulas and atom connectivities but have different spatial arrangements of atoms, i.e., are isomeric; (4) have the same types of atoms but have different crystal lattices; (5) are different allotropes of the same element, e.g., graphite versus diamond; and (6) have different isotopes of the same elements. EPA states that the Agency will consider chemical substances that differ in any of these structural or compositional features to be different chemical substances for TSCA purposes.
5. EPA recognizes that the chemical industry is still developing nomenclature conventions for nanoscale materials. As a result, the Agency will list new nanoscale materials/chemicals on the Inventory to the best of EPA's ability, but will not describe different physical forms of such materials. EPA notes that the names and perhaps even Inventory status of the chemicals may change once new nomenclature conventions are developed that use additional data elements to permit more precise descriptions of the molecular identities of nanoscale materials.
6. EPA encourages companies intending to manufacture or import nanoscale substances to use requests for Inventory searches under the *bona fide* intent to manufacture regulations, or to use the pre-notice coordination process to determine whether a premanufacture notification is necessary.

EPA has solicited comments on the draft "Inventory Status" document and on a related document, "Concept Paper for the Nanoscale Materials Stewardship Program Under TSCA" that discusses the Agency's voluntary Nanoscale Materials Stewardship Program. EPA has set a deadline for comments of 60 days after the Federal Register announcement, i.e., by September 10. The Agency has established a docket, No. EPA-HQ-OPPT-2004-0122, which may be accessed at <http://www.regulations.gov>. Comments may be submitted electronically through that portal or by mail.

CONTACTS

For more information, please contact any of the attorneys or public policy advisors at McKenna Long & Aldridge with whom you regularly work. You may also contact:

Thomas B. Johnston
202.496.7656

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