The EPA's Toxic Substances Control Act: What you must know

Got approval? Does your nanomaterial need it? Here's a guide to the EPA's new paper, TSCA Inventory Status of Nanoscale Substance

***Small Times*, September 2007**

BY LYNN L. BERGESON

Does the nanoscale substance you are producing or using require approval under the U.S. Environmental Protection Agency's (EPA) Toxic Substances Control Act (TSCA)? It does if it's new. But what exactly is "new?"

Nanotechnology innovators face challenges in commercializing their products-and pre-manufacture notification (PMN) requirements under the TSCA, the federal law governing chemical substances, is one of them. The EPA considers nanoscale materials that meet the TSCA definition of "chemical substance" to be "new"-and thus subject to PMN requirements-if they are not listed on the TSCA Inventory, a listing of chemicals in commerce.

The cost and timing of satisfying PMN requirements are difficult to predict and inject uncertainty into an already uncertain business environment. So let's look at the EPA's general approach to determining whether a nanoscale substance is "new" for TSCA purposes based on EPA guidance issued on July 12, 2007 (see www.epa.gov/oppt/nano/nmspfr.htm for details).

It's chemistry

Materials that have structures 1nm to 100nm long are generally referred to as engineered nanoscale materials or substances. Those that meet the TSCA definition of "chemical substance" are subject to TSCA because they may exhibit properties different from the same substances in the bulk scale. A chemical substance means, in relevant part, "any organic or inorganic substance of a particular molecular identity."

A threshold question for nanoscale material developers to answer before moving to commercial manufacture is whether their new materials are "new." If a nanoscale material is listed on the TSCA Inventory, it is considered "existing," and it is not subject to new chemical reporting requirements. If it is not Inventory-listed, EPA considers the substance "new" and, unless a PMN exemption applies, the manufacturer must submit a PMN to the EPA at least 90 days before commencing commercial manufacture or import. (PMN exemptions important for nano innovations include the exemption for chemical substances having no separate commercial purpose; the polymer exemption; and the research and development exemption.)

A PMN requires information on the submitter's identity, the chemical substance's identity, production volume, uses, exposures, and environmental fate. Data need not be produced, but must be submitted if available. If the PMN submitter does not hear from the EPA within 90 days of PMN submission, then it may commence manufacture or import of the substance after submission of a Notice of Commencement of Manufacture or Import (NOC). Submission of the NOC adds the substance to the Inventory and changes the status of the substance from a "new" substance to an "existing" one.

Important realities

Not readily apparent from this summary are important realities. The review process can take longer-sometimes considerably longer-than 90 days. The standard against which EPA assesses the "registerability" of a substance is whether it poses unreasonable risks of injury to health or the environment. If the EPA believes a new substance poses such risk, then the submitter has every reason to allow the EPA more time to conclude otherwise, and the submitter will typically acquiesce to EPA's request that it "toll" the 90-day clock. Absent tolling, the submitter must endure a finding that the substance may pose unreasonable risks, or withdraw the PMN to avert this finding and the adverse implications it inspires.

If the EPA flags concern with the substance, then PMN resolution can take several forms. The EPA may resolve issues and drop the PMN from further review, clearing the way for commercial manufacture. The agency may require the development and submission of toxicity or other data as a condition of approval-which is costly and time-consuming, with uncertain results. Or, the EPA may impose limitations on the substance's manufacture, use, distribution, or disposal, terms that could make it less competitive. Finally, the EPA could conclude that the substance does not meet the TSCA standard for registration and take steps to prohibit its manufacture. While the decision can be appealed, the process is costly and the result is uncertain, and commercial manufacture is disallowed during the proceeding.

What's new, really?

Conceding that nanoscale materials that meet the definition of chemical substances are subject to TSCA, the narrow issue becomes what provisions apply.

Plainly "new" nanoscale materials, just as "new" bulk materials, require new chemical notification. Prominent groups, including the Natural Resources Defense Council, have urged the EPA to require new chemical notification for the manufacture of existing nanoscale substances. They argue that the TSCA status of existing bulk substances should not include their nanoscale counterparts because this interpretation fails to account for the very properties that make nanoscale materials novel and potentially cause them to have risk profiles different from their bulk counterparts.

Others, particularly nanoscale material manufacturers, assert that whether a nanoscale substance is "new" depends not on its size, but whether it has the same "particular molecular identity" of an existing substance. If it does, they contend that the EPA must consider it an existing substance regardless of its nanoscale size. The real issue, then, is how the EPA defines "molecular identity" for TSCA purposes. It is on this subject that the EPA issued guidance on July 12, 2007.

Molecular identity

In its recent guidance, the EPA reaffirms its policy not to use particle size to distinguish, for Inventory purposes, substances that are known to have the same molecular identity. The EPA states that molecular identity is "based on such structural and compositional features," including 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 a molecule. Chemical substances that "differ" in any of these structural or compositional features, according to the EPA, have different molecular identities. Importantly, the EPA states that substances have different molecular identities when they

- Have different molecular formulas;
- Have the same molecular formulas but different atom connectivities;
- Have the same molecular formulas and atom connectivities but different spatial arrangements of atoms;
- Have the same types of atoms but different crystal lattices;
- Are different allotropes of the same element; or
- Have different isotopes of the same elements.

In its guidance, the EPA encourages nanoscale material manufacturers to arrange a pre-notice consultation with the EPA to address these issues, or to submit a request for an Inventory search (called a bona fide intent to manufacture submission). The EPA also notes that it may need additional information, including data, to determine whether a material requires new chemical notification.

The EPA's guidance is a must-read for nanoscale material manufacturers, as it can assist in determining how to proceed with newly developed materials-and how to avoid trouble.

Lynn L. Bergeson is managing director of Bergeson & Campbell PC, a law firm focused on specialty chemical product approval and regulation, health and safety law, chemical product litigation, and associated business issues. Ms. Bergeson was chair of the American Bar Association (ABA) Section of Environment, Energy, and Resources (SEER) in 2006 and managed the Section's Nanotechnology Project (www.abanet.org/environ/nanotech).