

Nanotechnology Enforcement: The Future Is Now

The U.S. Environmental Protection Agency, the regulated community, scientists, non-governmental organizations and other stakeholders currently are embroiled in debate over how best to identify and manage potential risks to human health and environment from the exponentially growing field of nanotechnology. Ideas for industry guidelines, standards of care, new legislation and novel uses of existing regulatory authorities are being exchanged at a terrific pace.

Getting somewhat overshadowed in the midst of this debate, however, is the important point that several current laws already apply to nanoscale materials and that failure to comply with those laws can have profound, if not catastrophic, effects on the business of the violator. A discussion of all the potential laws applicable to nanoscale materials is beyond the scope of this article, but in particular, the Toxic Substances Control Act (TSCA) bears emphasis.

Among the plethora of environmental laws passed in the 1970s, TSCA historically has been the statute most often overlooked by media and at times by the regulated community. The media has long focused on statutes addressing issues of most concern to the general public, namely those addressing chemicals in air, water, and groundwater, feeding a misplaced perception that TSCA -- almost completely a reporting and recordkeeping statute -- holds lesser significance. With respect to nanotechnology this is not the case because EPA is charged with responsibility for reviewing and if appropriate controlling the risks of each new chemical substance -- nanoscale or otherwise -- entering the marketplace. Furthermore, civil penalties under TSCA are significant, (originally up to \$25,000 per violation, since raised to \$32,500), and because each calendar day that a violation continues is a separately chargeable violation, in theory a prolonged violation could lead to astronomical fines. Perhaps even more significant is that some violations of TSCA can result in a complete shut-down of the violator's business for weeks or even months -- even in the absence of any actual risk from the chemical in question and without any administrative order from EPA.

Broad Scope of TSCA

One key to understanding TSCA's potential to affect and even shut down a nanomaterial-related business is the almost limitless scope of the statute. TSCA applies to any "chemical substance," which the statute defines broadly as:

Any organic or inorganic substance of a particular identity, including ... any combination of such substances occurring in whole or in part as a result of a chemical reaction. . . .

TSCA Section 2(2)(A). The statute excludes from the definition of "chemical substance" -- and therefore from TSCA requirements -- any pesticide or food, food additive, drug, or cosmetic, but only when these substances are being manufactured, processed, or distributed in commerce solely for such use. In other words, a substance that ordinarily is a pesticide or food additive immediately becomes a "chemical substance" subject to TSCA if it is manufactured for any other purpose. As a result,

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companies that have been manufacturing nanoscale materials exclusively for use in, for example, cosmetics without regulatory incident must be mindful of the immediately applicable TSCA compliance obligations if their research and development departments begin to commercialize non-cosmetic uses.

“New” Versus “Existing” Chemicals

The second key to understanding TSCA’s potential impact is the distinction that the Act draws between “new” and “existing” chemicals. The latter generally can be manufactured without regulatory obligation or delay, but the former cannot, and the distinction between the two can be blurred in the emerging field of nanotechnology.

Section 8(b) of TSCA directs EPA to “compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States.” EPA originally compiled the list -- officially called the “Chemical Substance Inventory” but usually referred to simply as “the Inventory” -- in the late 1970s and “keeps it current” by adding hundreds of additional chemicals each year through the premanufacture notification process discussed below. TSCA Section 2(9) defines any chemical substance not listed on the Inventory as a “new chemical substance.” Over time, Inventory-listed chemicals have come to be referred to as “existing” chemicals to distinguish them from “new” chemicals.

Absent some chemical-specific regulation aimed at a particular “existing” chemical, it can be manufactured or imported by anyone, anytime, without premanufacture TSCA regulatory obligations. TSCA Sections 5(a)(1) and 5(b) and EPA’s implementing regulations, however, state that no person may manufacture a “new” chemical substance unless such person submits to EPA, at least 90 days before such manufacture, a notice, together with all of the test data and other relevant data in the person’s possession or control. EPA can unilaterally extend the PMN review period to 180 days, can issue Section 5(e) orders barring or limiting manufacture of the new chemical, and can and often does negotiate even longer voluntary extensions of the review period to develop with the PMN submitter a consent order setting conditions under which the new substance will be manufactured. Unlike the European Union scheme, however, there is no minimum data set that must be submitted with the PMN under TSCA.

PMNs for traditional new chemicals often are submitted to EPA without substantial toxicity test results and other data, but when conducting premanufacture review of the PMN chemical’s potential risks, the Agency can consult its extensive database, using data from chemically similar materials to assess the risk. Often use of such readily available data on structurally analogous substances permits EPA to meet the 90-day review deadline without extension or any demand that the submitter develop additional data. At present, however, EPA does not have such an extensive database on nanoscale materials and the EPA traditional structure-activity analysis may suffer as a consequence. As a result, a nanomaterial PMN submitted without certain test data may be more likely to require an extended review period and/or development of a consent order.

Consequences of a PMN Violation

Each separate day that a “new” chemical substance is manufactured in violation of the PMN requirement can result in a civil penalty of up to \$32,500. Moreover, commencing or continuing to manufacture such a substance after learning that it is not covered by an Inventory listing or any exemption from the PMN requirement may be charged as a criminal act under TSCA, and EPA asserts that both the company and responsible officials can be charged. Thus, as a practical matter, a discovery that an in-production nanomaterial critical to a product line is not covered by an Inventory listing would necessitate complete cessation of manufacture until a PMN is developed and submitted and the 90-day review period has expired. Since TSCA’s language requires a 90-day wait to manufacture after a PMN is submitted, regardless of whether EPA quickly determines that the substance is innocuous, the violator faces three months of inability to resume production. If EPA has concerns about the chemical’s potential risk, the review period can be far longer.

Consequences to the business, however, do not stop there. Under TSCA Section 15(2), it is unlawful to “use for commercial purposes” any chemical that the user has reason to know was manufactured in violation of the PMN requirements. EPA asserts that “use for commercial purposes” must be construed broadly to cover virtually any use, including processing or distribution. Thus, upon discovery of a PMN violation, even already-manufactured inventories of the substance, or of finished products that contain the substance, must be quarantined to avoid further “use” violations. EPA also may assert that those unlawfully-manufactured stocks can never be used without a grant of enforcement discretion from the Agency, even after a corrective PMN has been filed and reviewed. All these profound consequences to an existing business would be completely independent of any risk – or lack thereof – posed by the nanomaterial in question, and would not require any administrative order or even an inspection by EPA. Discovery of the problem is enough to trigger the cessation of business in the new nanomaterial.

“Particular Molecular Identity”

Given the significant delay that can be caused by the time required for EPA to review a PMN, companies understandably will want to avoid the PMN process if possible, but the severe consequences of erroneously deciding that a PMN is not required raise the stakes of the decision. Certainly manufacturers will be developing their own data on potential risks and methodology to assess risk, but as noted above, the PMN requirement exists for all new chemicals, independent of their potential risk. The challenge for manufacturers of novel nanoscale materials is not only to evaluate potential risk, but also to determine whether the new nanomaterial is a “new chemical substance” or conversely is covered by an Inventory listing.

By this summer, EPA hopes to issue the first Agency guidance on how manufacturers of new nanoscale materials can determine whether a PMN is necessary. In the interim, however, such manufacturers must use existing tools and guidance.

Key language from TSCA Section 3(2)(A) is the phrase that defines a chemical substance as any organic or inorganic substance “of a particular molecular identity.” The statute and EPA regulations are silent regarding what constitutes a “particular molecular identity,” but both the statute’s language and EPA’s historical approach reflect the traditional concept that a particular substance is characterized by a definite molecular composition and that unless changes are made to that composition, the substance remains the same for TSCA regulatory purposes irrespective of its particle size. In developing the Inventory, EPA generally has taken a “one chemical, one listing” approach, relying heavily on the Chemical Abstracts Service (CAS) nomenclature rules and registration system to give a specific chemical description (name) and CAS Registry Number to each “particular molecular identity” that is listed on the Inventory.

Creation of new nanoscale materials, however, does not always involve changes to the molecular identity of the substance. As EPA’s December 2, 2005 draft Nanotechnology White Paper notes, nanotechnology encompasses development at the “atomic, molecular or macromolecular levels.” White Paper, Page 4 (emphasis added). As a result, reconfiguration of the molecules of an existing chemical into a novel nanostructure may not create a new “particular molecular identity” that would trigger PMN requirements. Many issues need to be resolved and EPA will remain at the forefront of this debate because of the Agency’s statutory obligation to review and, as a threshold matter to determine what are, “new” chemical substances. Currently EPA is wrestling with questions such as whether changes in bond angles result in a change to an existing substance’s molecular identity, and if so, how much of a change in the angles is required.

At minimum, developers of new nanoscale materials for TSCA-covered uses should create internal records of the decision logic whenever a determination is made that a PMN is or is not required. Such records could prove invaluable in the event of a later EPA inquiry or inspection. Companies desiring greater assurance of compliance can obtain second opinions by outside consultants or counsel, or even avail themselves of EPA pre-notice counseling as well. With the stakes being what they are, this is effort well spent.



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