Nano Disclosures: Too Small to Matter or Too Big to Ignore?

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Determining whether the presence of nanoscale materials in chemical substances, mixtures, and articles triggers a disclosure obligation is complicated. The decision turns on a calculus that includes what law applies, what is known about the presence of nanoscale components, what knowledge standard applies, whether and how a nanoscale material is defined, and an entity's interpretation of disclosure obligations. This article outlines the state of domestic environmental and securities law and regulatory policy regarding disclosure obligations pertinent to nanoscale materials. The article concludes that there are a growing number of potential disclosure obligations of which commercial entities should be aware, but that the nature of these requirements continues to be fluid and ill-defined.

By now, most lawyers and environmental professionals have a general understanding of what nanotechnology is. According to the U.S. Environmental Protection Agency (EPA), nanotechnology is "the understanding and control of matter at dimensions of roughly one to 100 nanometers, where unique phenomena enable novel applications." The tiny engines driving nanotechnology are nanoscale materials, defined generally by EPA as materials having structures with dimensions in the nanoscale and that may have properties different than the same chemical substances with structures at a larger scale.

An important caveat is there is no one definition embraced by EPA or the federal government at large. The definitional void has frustrated nanomaterial stakeholders as the lack of definitional clarity invites commercial, legal, and compliance uncertainties. Similarly, the lack of a regulatory definition has created uncertainty and possibly complexities for regulators as well.

The commercial promise that nanotechnologies generally elicit is matched by the palpable apprehension of many, based on the relative paucity of available information regarding the health and environmental implications of exposure to or release of nanoscale materials. We have all heard or read the views that the novel properties that make nanoscale materials commercially valuable are also potentially capable of posing hazards and risks to human health and the environment.

For example, nanoscale zero-valent iron (nZVI), when used as a contamination clean-up technology, has been demonstrated to be less costly and potentially more effective than macroscale ZVI. EPA has noted, however, that there are many "unanswered questions regarding nanotechnology" and that research is needed to understand if nanoscale materials have "toxicological effects on various biological systems."

The current state of play creates opportunities for increased legal and governance disarray regarding whether enforceable obligations to disclose the presence of nanoscale materials exist and under what circumstances. This discussion focuses on obligations to disclose the presence of nanoscale materials in several settings under U.S. environmental laws and securities law.

EPA has focused its attention on deploying its authority to regulate nanoscale materials under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These statutes are substance- or product-oriented rather than facility-oriented.

EPA Disclosure Requirements under TSCA

After several years of public debate, in October 2008 EPA issued its *TSCA Inventory Status of Nanoscale Substances—General Approach*. The document describes how EPA determines whether a nanoscale substance is "new" for purposes of the TSCA Inventory and clarifies whether a disclosure obligation exists under TSCA. The TSCA Inventory consists of substances that are defined under TSCA as "existing" in U.S. commerce and thus need not be the subject of a Premanufacture Notice (PMN). For substances considered new, a PMN must be submitted to EPA and, once reviewed and upon receipt of a Notice of Commencement of Manufacture or Import, a chemical substance is added to the Inventory and becomes an "existing" chemical substance subject to any controls imposed by EPA. Entities proposing to manufacture/import a new chemical, including new chemical nanoscale materials, must submit the information required by PMN reporting regulations. The reporting standard includes information in the possession of the submitter, parent company, or affiliates, and a description of existing data "known to or reasonably ascertainable" by the submitter. Submitters are also

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required to meet any regulatory requirements imposed by EPA in its review of the new chemical nanoscale materials; these typically consist of controls on exposures and releases, use limitations, and requirements to conduct and submit test data.

Under TSCA, a chemical substance is defined to mean "any organic or inorganic substance of a particular molecular identity.…" TSCA § 3(2), 15 U.S.C. § 2602(2). To classify a chemical substance as new or existing, EPA determines whether the chemical substance has the same molecular identity as a substance already listed on the Inventory. In other words, a chemical substance that has the same molecular identity as a substance listed on the TSCA Inventory is considered existing.

EPA states in its policy statement that because it generally has "not considered units of matter beyond molecules, such as physical aggregates, to be reportable to the TSCA Inventory, EPA has not used particle size" to distinguish two substances that are known to have the same molecular identity. EPA, TSCA Inventory Status of Nanoscale Substances—General Approach (Jan. 23, 2008) at 4, *available at* www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf. In short, particle size is immaterial for TSCA Inventory purposes. Molecular identity is the single most significant factor in determining whether a chemical substance is new, and therefore subject to PMN requirements.

In its policy statement, EPA clarified that it generally considers carbon nanotubes (CNTs), a particular category of nanoscale materials, to be chemical substances distinct from other substances included on the Inventory and that as such manufacturers or importers of CNTs are required to submit a PMN prior to engaging in commercial activities. After a short grace period ended, EPA stated that it would initiate enforcement efforts to ensure compliance with TSCA.

While EPA's Inventory interpretation is believed to be legally well-grounded, it is not without controversy. EPA's view that nanoscale versions of existing substances are themselves existing substances if they share the same molecular identity as their macro counterpart regardless of whether they possess properties that influence the substance's risk profile has contributed to the current debate as to TSCA's core adequacy.

Perhaps this is why pending legislative measures to amend TSCA focus both on molecular identity and substance characteristics. Under S. 3209, the Safe Chemicals Act of 2010 introduced on April 15, 2010, by Senator Lautenberg, EPA would be authorized to decide when a substance is new based on molecular identity and the presence of "special substance characteristics." S. 3209 at section 6. The bill defines special substance characteristics as "such physical, chemical, or biological characteristics, other than molecular identity" that "may significantly affect the risks posed by substances exhibiting those characteristics." S. 3209 at section 4. Under S. 3209, EPA may consider such characteristics as size or size distribution, shape and surface structure, reactivity, and other properties that may significantly affect the risks posed. A similar provision is included in a House bill, the Toxic Chemicals Safety Act of 2010, H.R. 5820, introduced by Reps. Waxman and Rush on July 22, 2010, which focuses on "different forms" of a chemical substance with a particular molecular identity, and states that such different forms may be different chemical substances based on "variations in the substance characteristics." H.R. 5280 at section 3.

An often overlooked TSCA statutory provision that bears directly on the subject of disclosure is TSCA section 8(e). Manufacturers, processors, and distributors of chemical substances must immediately inform EPA if they obtain information that supports the conclusion that a chemical substance, including nanoscale substances, presents a substantial risk of injury to health or the environment.

Other TSCA disclosure provisions that apply to nanoscale materials include section 8(c) allegations of significant adverse reactions to health or the environment. Section 13 also requires disclosure regarding import certifications, particularly with regard to imported mixtures (e.g., fluids that contain nanoscale materials) and manufactured articles (where the nanoscale material is intended for release). If new chemical nanoscale materials are involved, such importation will also trigger notification requirements under TSCA section 5.

EPA recently announced plans to develop testing and disclosure requirements concerning nanoscale materials. These include a section 4 test rule to obtain health and environmental data, a categorical Significant New Use Rule under TSCA section 5(a)(2) requiring notification to EPA concerning existing chemical nanoscale materials, and an information gathering rule under TSCA section 8(a).

Several disclosure requirements under TSCA are thus clear. First, EPA believes that chemical substances consisting of "new" nanoscale materials must be submitted to EPA for premanufacture review if they are not otherwise exempt under TSCA. Chemicals manufactured at the nanoscale that are considered existing are not required to be disclosed to EPA unless new "substantial risk" information on the substance causes them to be reportable under TSCA section 8(e) or are required to be reported to EPA under TSCA sections 8(c) or 13. What constitutes an existing chemical substance is based on the molecular identity of the substance and, while distinguishing an existing chemical may not always be clear, EPA has stated CNTs are *per se* new chemical substances. Finally, pending TSCA reauthorization legislation would, if enacted, potentially treat all nanoscale chemical substances as "new" chemicals and require that they be submitted to EPA for review based on any "special substance characteristics" that EPA determines may significantly affect the material's risk/toxicological profile.

EPA Disclosure Requirements under FIFRA

EPA has been less active under FIFRA in clarifying how existing obligations apply to nanoscale materials used as ingredients in pesticide products. Regulatory activity is picking up as EPA's Office of Pesticide Programs (OPP) has indicated that it intends soon to issue regulatory guidance on nanopesticides.

First, EPA intends to confirm that nanoscale versions of existing registered active ingredients are "new" pesticides that require registration under FIFRA section 3. This is because unlike TSCA, under FIFRA section 3(c)(5)(D) registration decisions

depend in part on EPA's determination that a pesticide will not generally cause unreasonable adverse effects on the environment. Central to this determination is whether the benefits of a pesticide outweigh its risks. Since some would assert that the balancing between risks and benefits of a nanopesticide can be expected to be different from that of its bulk counterpart, it follows that they would support EPA's position that nanoscale versions of bulk active and/or inert ingredients would require a new or amended FIFRA pesticide registration.

The current state of play creates opportunities for increased legal and governance disarray regarding whether enforceable obligations to disclose the presence of nanoscale materials exist and under what circumstances.

This is exactly what EPA confirmed in April 2010. In a public presentation on April 29, 2010, an EPA representative stated that an active or inert ingredient would be considered "new" if it is a nanoscale material regardless of whether a non-nanoscale form of the same active or inert ingredient is already formulated in a product registered under FIFRA. EPA offered this example: "Nanosilver would be considered new even though silver is a registered pesticide." William Jordan Presentation, Nanotechnology and Pesticides (Apr. 29, 2010) at Slide 18, *available at* www.epa.gov/pesticides/ppdc/2010/april2010/session1-nanotec.pdf.

EPA also announced a more controversial interpretation of its unreasonable adverse effects disclosure requirement under FIFRA section 6(a)(2). This section requires that a registrant submit to EPA any additional factual information regarding unreasonable adverse effects of the pesticide on the environment. Unreasonable adverse effects on the environment is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" or "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with" certain set standards. FIFRA § 2(bb), 7 U.S.C. § 136(bb).

Under the draft section 6(a)(2) policy, any pesticide registrant that is aware of or knows that some constituent of a registered pesticide product contains any amount of a nanoscale material, must submit the information to EPA pursuant to FIFRA section 6(a)(2). Under OPP's "working definition," a nanoscale material is "[a]n ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers." Jordan Presentation at Slide 5. Since EPA regulations generally limit the obligation of a FIFRA registrant to report information pursuant to FIFRA section 6(a)(2) to information that concerns "adverse effects," the approach announced by EPA has the effect of making the mere presence of any nanoscale material to be an "unreasonable adverse effect."

Detractors of the policy fear that one probable consequence of it will be to stigmatize all uses of nanotechnology in pesticides and possibly in other commercial applications. Even with attempts by EPA to state clearly that submission of such information *per se* is no indication of risk, such information will be described by some, and particularly in litigation contexts, as adverse effect reports that will be used against registrants and others. Some have also expressed concern with the apparent expansion of the section 6(a)(2) reporting requirement to include factual information that is merely informational and, by EPA's own admission, not necessarily related to potential or actual risks.

Some also contend that although EPA's rationale might be consistent with its current interpretation of the statutory language of FIFRA section 6(a)(2), it is not consistent with the more measured approach EPA adopted in fashioning implementing regulations that focus on only those categories of information that would call into question whether a product continues to satisfy the statutory standard for registration, nor does it fall within any category deemed reportable under other current EPA FIFRA regulations. Even the provision outlined in 40 C.F.R. § 159.195(a), which EPA cites as the basis for its interpretation, applies only if EPA might regard the information as raising concerns about the "continued registration of a product or about the appropriate terms and conditions of registration of a product." 40 C.F.R. § 159.195(a). If EPA believes that a policy requiring reporting of all information concerning nanoscale materials is necessary, this change should arguably be the subject of a proposed modification to one or more of the current reporting requirements rather than implemented through an ad hoc change in reporting procedures under FIFRA section 6(a)(2).

EPA's stated goal in making this policy change is to obtain information on nanopesticides to assess the environmental impacts of exposure to engineered nanomaterials. Because EPA is using its authority under section 6(a)(2) to gather a new category of information without regard to its risk implications, and without formally modifying its reporting regulations, some assert that this could cause registrants to submit other types of information based on the premise that it falls within a broad category that may be of interest to EPA. Thus this interpretation of section 6(a)(2) also could result in a deluge of information, much of it of little to no interest to EPA.

Based on the foregoing, and as of the date of this writing, there is no explicit EPA policy with regard to the disclosure

of nanoscale materials in pesticide products. EPA has stated that it intends to confirm soon that the use of any nanoscale material in a pesticide product requires a new FIFRA registration application regardless of whether the nanoscale material is a nano version of a registered active ingredient or approved inert. Further, EPA intends to require the disclosure of the presence of any nanoscale material in an existing registered pesticide product as unreasonable adverse effect information under FIFRA section 6(a)(2), but the precise parameters of this disclosure obligation are not yet known. Apart from any forthcoming policy change, FIFRA section 6(a)(2) reporting requirements plainly apply to nanopesticides.

SEC Reporting Requirements

For publicly traded nanotech companies, Security and Exchange Commission (SEC) disclosure obligations under Regulation S-K appear to be the most relevant to this discussion. First, Item 101 (Description of Business) requires a company to disclose material effects that compliance with environmental laws will have on earnings, including effects on estimated material capital expenditures for environmental control facilities for the current fiscal year, the next fiscal year, and additional periods, if material.

Second, Item 103 (Legal Proceedings) requires a description of material pending legal proceedings in which the registrant or any of its subsidiaries is a party. Environmental litigation is not considered "ordinary" or "routine" and thus is not excluded. Since no publicly reported lawsuits based on nanotechnology claims have yet been filed, this provision is likely now of limited relevance, although this could change in the future.

Third, Item 503(c) (Risk Factors) requires a discussion of "significant factors" that make an investment speculative or risky. Registrants are specifically required to make the disclosure as specific as possible and to state how a particular risk might affect the company, and registrants "should not present risks that could apply to any issuer or any offering." Given the breadth of this obligation, it appears to be relevant for purposes of potential nano-risk disclosure.

Finally, Item 303 (Management Discussion and Analysis of Financial Condition and Results of Operations (MD&A)), requires management to discuss and analyze known trends or demands, commitments, events, or uncertainties that are reasonably likely to have a material effect on a company's financial condition. Companies are also required to disclose any other information the company believes is necessary to communicate an accurate understanding of the company's financial condition.

The application of these obligations to business operations has always invited controversy, particularly regarding environmental matters. Earlier this year, the SEC issued interpretative guidance on how these disclosure rules apply to climate change matters. The guidance imposes no new disclosure obligations. Rather, it clarifies the fact that the rules may require disclosure of matters relating to the potential effects of climate change. The guidance usefully explains how these disclosure obligations apply to climate change matters and covers other environmental matters, including disclosure obligations that may arise as a result of the use of nanotechnology.

Before discussing each of these obligations in the context of climate change, the guidance provides an overview of recent regulatory, legislative, and related climate change developments. The overview clarifies that the SEC issued the guidance in part because of calls from environmentally minded investor groups, attorneys general, and others urging companies to report in their SEC filings climate change risk information. The guidance notes that large numbers of U.S. companies participate in voluntary disclosure initiatives relating to climate change risks outside of SEC submissions. According to a 2009 Ceres survey of approximately 6,400 filings by Standard & Poor's 500 companies, the "vast majority" of the 2008 SEC filings exclude mention of climate change.

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A cursory review of SEC filings regarding nano matters suggests disclosures made by companies openly engaged in the manufacture of nanoscale materials and/or the application of nanotechnology exhibit a range of disclosure practices. In the Investor Environmental Health Network's (IEHN) 2008 report *Toxic Stock Syndrome: How Corporate Financial Reports Fail to Apprise Investors of the Risks of Product Recalls and Toxic Liabilities*, its counsel Sanford Lewis observed that "some of the specialists in the manufacture of nanotech products tended to engage in broader disclosure of potential health risks than those using nanotech as part of established consumer product lines." IEHN, *Toxic Stock Syndrome: How Corporate Financial Reports Fail to Apprise Investors of the Risks of Product Recalls and Toxic Liabilities* (Apr. 2008) at 33, *available at* http://iehn.org/documents/IEHN%20Toxic%20Stock%20Report%203-08.pdf (Last visited Aug. 10, 2010).

An illustration of the range of disclosures is evidenced in a few examples. In Arrowhead Research Corporation's 2009 Annual Report on Form 10-K, the company's risk factors discussion includes considerable detail regarding the state of nanotechnology. The report notes generally that nanotechnology-enabled products are new and may be viewed as being harmful to human health and/or the environment. The disclosure notes that nanostructures may present risks that are different from and greater than the risks from their bulk counterparts. Further, the disclosure notes regulatory and research efforts addressing the safety risks of nanomaterials, and the company states that the regulation and limitation of the kinds of materials used in or used to develop nanotechnology-enabled products, or the regulation of the products themselves, could delay or even stop the commercialization of nanotechnology-enabled products or substantially increase their cost, which would impair the company's ability to achieve revenue from the license of nanotechnology applications. As disclosures go, this is fairly blunt.

Other reporting entities write about the types of nanomaterials their products include, the benefits they offer, and even the awards their technology has garnered. Potential risks and regulatory uncertainties are not mentioned. Other companies presumed to be engaged in some form of nanotechnology, but not openly so, make no disclosure in this regard.

There are similarities and differences between climate change and nanotechnology. Climate change plainly impacts everyone, and certainly a far broader cross-section of companies than does nanotechnology, which some regard as a far more discrete phenomenon involving a far narrower universe of business entities. The issue of SEC disclosure of climate change matters has been swirling around for at least eight years or so, while nano issues are of much more recent origin. That said, however, that attention is already being focused on nano disclosures in connection with a company's risk factors analysis should not go unnoticed.

While the push for nano disclosures is by no means at the pitch climate change disclosure is at now and has been for a number of years, disclosure of "product toxicity" issues in SEC filings may be more of an issue than people appreciate. A broad coalition of such interests sent a letter to then President-elect Obama on December 11, 2008, urging the administration to review SEC disclosure requirements specifically with respect to climate change and "product toxicity." It does not take much of a leap to anticipate that some will try to get nanoscale material components in products to be considered under the product toxicity heading.

More recently, the advocacy group As You Sow Foundation's Corporate Social Responsibility Program noted that product safety shareholder resolutions urging companies to disclose the presence of nanomaterials in food and personal care products have greatly increased in the recent past. According to the IEHN, shareholders filed or re-filed 46 resolutions at 28 companies for consideration at shareholder meetings between 2006 and 2008. Many of these specifically requested information on nanomaterials.

How companies interpret these reporting obligations and whether and/or how exactly nanoscale materials are manufactured, used, and distributed in commerce will bear directly upon whether a company believes it has a reporting obligation under SEC regulations. Given the relatively embryonic stage of laws and regulatory measures specific to nanoscale materials, disclosures under these provisions would seem fairly speculative at this time. As more information becomes available with respect to specific nanoscale materials, and as their potential risks and benefits are more specifically defined, it is reasonable to assume more disclosure may be needed to comply with increasingly specific SEC disclosure guidance and stakeholder pressure.

When that will be is unclear. What is easier to anticipate is a growing demand from investors, investment managers, advisors, and others for more specific, detailed, and accurate information pertinent to the chemical, including nanoscale material, component of products. IEHN urges the SEC to issue guidance on product toxicity issues to improve corporate disclosure. Specifically, IEHN urges SEC guidance requiring companies to discuss and analyze "materials toxicity trends found in government regulatory databases, and their relevance to company supply chains and materials."

There are a number of current and possible future disclosure requirements under federal environmental and security laws and regulatory policies concerning manufacture or import of nanoscale materials, the presence of such materials in certain products, or their use by companies in commercial processes. While certain of these disclosure aspects are reasonably clear, others are evolving and a well-defined understanding is not currently available either to regulators or the regulated community and other stakeholders. Although much remains to be learned and disclosed about the health and environmental implications of nanoscale materials, efforts are underway by both government and industry to begin to meet these needs.

Because of the promise of this emerging technology and the innovative products and solutions that it can bring to market, it is important that commercial entities recognize and meet applicable disclosure requirements to maintain and build public confidence in products of nanotechnology. It is important that regulators proceed in a manner that provides regulatory clarity and assurance to regulated industries and other stakeholders, while avoiding the creation, or even the appearance of biases against this technology and its products lest public confidence be undermined by vague and unfounded fears.

The success of industry, regulators, and other stakeholders in meeting these challenges to develop needed understanding and provide adequate and appropriate disclosure will do much to determine the role that nanotechnology and the products which it can yield will contribute to the United States and its future national competitiveness.