The uncertainties surrounding nanotechnology may lead to potential product liabilities in the future.

New on the Horizon: Nanotechnology

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Managing any business is tough. Managing a nanotechnology (nanotech) business is tougher than most. This article briefly discusses this new and rapidly expanding field of applied science, outlines key risk management issues that companies engaged in the manufacture of nanoscale materials and nanotechnology-enabled products confront, and reviews existing and proposed governance and risk management mechanisms intended to address potential nanotechnology risks.

Products of Nanotechnology in Commerce

Nanotechnology is defined as the "understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications," according to the National Nanotechnology Initiative (NNI).[1] Nanotechnologies, over time, are expected to generate many new products and applications. Lux Research, Inc., the New York-based nanotechnology research and advocacy firm, predicts that products that incorporate nanotechnology will constitute 15 percent of global manufacturing output by 2014 and will represent $2.6 trillion in value.[2]

One of the key reasons that governments around the world are focusing on nanotechnology is the lack of understanding regarding the environmental, health,

and safety (EHS) effects of exposure to engineered nanoscale materials. Some believe that sufficient information exists to suggest a need for caution.

The small size of nanoparticles facilitates their uptake into cells and their movement through the body more readily than is the case with their macro counterparts.[3] In addition to size, however, other factors contribute to a general sense of uncertainty as to the biological and environmental effects of exposure to engineered nanoscale materials. The complexity of engineered nanomaterials means that their impact will depend on more than chemistry alone. Size, shape, surface chemistry, and surface coating, for example, can all influence how these materials behave. In some cases, their tiny size alone might allow nanoparticles to more easily enter and affect living organisms. In other instances, the fact that nanoscale materials can have unusual properties — properties that do not conform to "conventional" physics and chemistry — may increase the potential for risk.

Many federal agencies are engaged in the active review of nanotechnology applications and their EHS implications. These include the U.S. Environmental Protection Agency (EPA),[4] the Food and Drug Administration (FDA),[5] the Occupational Safety and Health Administration (OSHA),[6] the National Institute for Occupational Safety and Health (NIOSH),[7] the National Toxicology Program (NTP),[8] and the Department of Defense (DOD),[9] among others. Regulatory and health agencies globally are similarly engaged. EPA is most prominently involved in reviewing the EHS implications of nanotechnologies and in identifying and funding research initiatives regarding the beneficial environmental applications of nanotechnologies in a wide variety of areas.[10]

Products of nanotechnology are diverse and growing exponentially. According to NNI, nanoparticles and nanoscale materials are used in many industries, including electronics, pharmaceuticals, chemicals, energy, and biomedical. Reportedly, areas producing the greatest revenue using nanoparticles are chemical/mechanical polishing, magnetic recording tapes, sunscreens, automotive catalyst supports, biolabeling, and electroconductive coatings and optical fibers. According to at least one source, there are many nano-enabled products in commerce today, including paints, sporting goods, cosmetics, stain-resistant clothing, electronics, and surface coatings.[11]

A wide range of businesses are engaged in the production, distribution, and use of nanotechnologies. Currently, more than 1600 nanotech companies are operating in the United States. These companies include Fortune 50 companies, start-ups, and companies of all shapes and sizes between these two extremes.[12]

The uncertainty of nanotechnology, its health and safety implications, its commercial applications, the public's receptivity to this technology, and the global governance mechanisms that may be brought to bear to manage risk potentially arising from nanoscale materials do not play well to investors, insurers, regulators, or the public. The hope is that prudent business practices will prevail, the promise of nanotechnology will materialize, and the science will unfold in ways that support its continued commercialization. In the interim, business people will be challenged to address an increasingly complex constellation of legal, commercial, regulatory, and public relations issues.

Potential Liabilities and Governance Mechanisms

Nanotech companies face a range of potential liabilities. Assessing and quantifying these potential liabilities is difficult, given the relative infancy of the field, the lack of clear legal precedent and regulatory standards, the developing industry standards and practices, and the fast-evolving science. Nonetheless, several areas of potential liability warrant note.

Product Liability

Despite the promise of important new technologies, the specter of product liability casts a long shadow over nanotechnology innovations, just as it does with other product and technological innovations. The relentless stream of bad publicity following the Magic Nano product recall in Germany in 2006 has become the quintessential poster child for nanotech product liability concerns. Magic Nano, a household glass and ceramic tile sealant in an aerosol can, was first sold in supermarkets and discount stores in March 2006 in Germany. According to the German federal Institute for Risk Assessment (BfR), between March 27 and March 30, 2006, almost 100 people who used the product claimed to experience breathing problems requiring hospital treatment. It was ultimately determined that the product contained

no nanoparticles.

That the product contained no nanoparticles, and even less magic, is irrelevant in the court of public opinion, and the incident was widely regarded as a wake-up call to industry as to the mischief "nano" can inspire. Strict liability, negligence, and breach of warranty, and claims made in connection with these legal principles (e.g., design defect, manufacturer defect, and failure to warn), arguably could be asserted against manufacturers or suppliers of nano-enabled consumer products, given the right facts. Claims for damages could include personal injury, medical monitoring, fear of future injury, deceptive trade practices (inviting treble damages), and punitive damages.

While no reported litigation appears to have been brought to date involving nanotechnology or a nano-enabled product, many believe this will change sooner rather than later. Nanobusinesses need to stay abreast of fast-changing scientific developments, rapidly evolving industry standards and practices, regulatory developments and disclosure practices, and emerging risk management strategies to be well positioned to respond effectively to new information and shifting liability standards.

The full range of protective measures to minimize product liability must be considered, including contractual protections with upstream and downstream suppliers; implementation of best management practices; contractual representations and warranties; indemnification agreements; and appropriate and legally sound warnings, labeling, and related disclosure strategies. Additionally, businesses need to track post-sale consumer product complaints and incident reports and respond quickly and thoroughly.

Businesses also must be sensitive to the need for transparency, communication, and effective public relations. Workers, community residents, downstream formulators and vendors, and customers can be expected to want and to need to know what a nano-enabled product contains, the health implications from exposure to the product and its nano components, the considerations for proper disposal of nano-enabled products at the end of their useful life, and related product safety information that stakeholders have come to expect under right-to-know laws and the expectations they invite.

A related concern is the Consumer Product Safety Commission's (CPSC) expanded role as consumer product watchdog. Following a series of high-profile toy recalls, the Senate, in early 2008, reached a compromise on a bill to overhaul and strengthen CPSC. The Consumer Product Safety Improvement Act of 2008 (CPSIA),[13] which became law on August 14, 2008, provided CPSC greater resources to remove consumer products from the market, would raise fines for safety violations to $15 million from the current $1.825 million, and would require CPSC to create a database containing reports of injuries, illnesses, and deaths from consumer products based on information submitted by the public.

Importantly for present purposes, the CPSIA provides state attorneys general authority to file lawsuits to stop sales of "dangerous" products and require third-party safety certifications of children's products. With this new authority, it is not much of a leap to believe that nano product producers would be concerned about the potential for enhanced CPSC scrutiny of nano-enabled consumer products, given a newly emboldened CPSC, and depending on the regulatory climate engendered by national leadership.

Securities Law Reporting

For domestic companies, the issues of accountability and transparency raised by the Magic Nano recall serve as a reminder that nanotech businesses need to be scrupulous in complying with corporate disclosure reporting requirements and with the Sarbanes-Oxley Act of 2002, where it applies. Sarbanes-Oxley requires, among other things, that the chief executive officer (CEO) and chief financial officer (CFO) of a corporation certify the accuracy of each U.S. Securities and Exchange Commission (SEC) filing the company makes.

For publicly traded nanotech companies, three sections of Regulation S-K, which predates Sarbanes-Oxley and specifies the disclosure requirements for periodic reports filed with the SEC, require the disclosure of environmental liabilities. First, S-K 101 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. Signing off on a description of the "material effects of compliance" with environmental laws under S-K 101 is more challenging when it is uncertain whether and when some of those laws will affect a nanotechnology product or

a consumer product enabled by nanotechnology.

Second, S-K 103 requires a description of "any material pending legal proceedings, other than ordinary routine litigation incidental to the business to which the registrant or any of its subsidiaries is a party." Environmental litigation is not considered "ordinary" or "routine." The projected impacts of environmental litigation inspired by nanotechnology similarly are complicated in the absence of a litigation history.

Third, S-K 303 sets out a general requirement to disclose "any known trends or any known demands, commitments, events or uncertainties" that are reasonably likely to have a material effect on a company's "financial condition and results of operation" — this requires companies to assess, for example, the likely future consequences of new environmental costs or liabilities. In 1989, the SEC issued an Interpretive Release emphasizing that this requirement applies to environmental trends and uncertainties, including anticipated new regulations and Superfund liabilities.[14] While not explicit in its application to nanotechnology, the scope of this release is sufficiently broad to include potential regulatory measures pertinent to nanotechnology.

Sections 302 and 906 are also relevant. These sections require CEOs and CFOs to certify that a company's financial statements fairly present the company's financial status. Section 404 requires that an independent financial auditor review and attest to the adequacy of the company's internal controls.

A related bundle of uncertainties for public and privately held companies involves disclosure required by the Generally Accepted Accounting Principles (GAAP).[15] In the environmental area, the most notable GAAP is Financial Accounting Standard No. 5, Accounting for Loss Contingencies (FAS 5).

In addition to compliance with these disclosure obligations, shareholder rights activists can be expected to continue to demand enhanced transparency and disclosure with regard to a wide array of issues, particularly environmental and product toxicity issues. On December 11, 2008, a coalition of activists wrote then President-Elect Obama asking that investors be afforded a right to propose and vote on resolutions directing a company to evaluate how specific risks may affect the company's business. Among the types of risks the coalition specifically identified were "climate change and product toxicity."[16]

Similarly, the advocacy group As You Sow Foundation's Corporate Social Responsibility Program noted, in early 2009, 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.[17] According to the Investor Environmental Health Network, shareholders filed or refiled 46 resolutions at 28 companies for consideration at shareholder meetings between 2006 and 2008. Many of these specifically requested information on nanomaterials.[18]

Insurance

The uncertainties noted above help explain the formidable challenges that insurance coverage presents — both in providing coverage and in obtaining it. The key issue in insuring against nanotechnology liabilities is the relative lack of certainty regarding potential EHS risks. Swiss Re's much-cited report, "Small Matter — Many Unknowns," bluntly states that, in the case of nanotechnology, uncertainties prevail, because "neither the probability nor the extent of the potential losses are precisely calculable," and businesses can expect to see creative approaches by the insurance industry as it tries to address a growing need among an expanding client base that relies on nanotechnology.[19] This may mean that some risks will be explicitly excluded from coverage, because some essential element in the calculus is too speculative.

This prediction morphed into fact on September 24, 2008, when Continental Western Insurance Group announced to its policyholders a coverage change in the form of an endorsement to its general liability policy. Under the terms of endorsement CW 33 69 06 08, Nanotubes and Nanotechnology Exclusion, bodily injury, property damage, or personal and advertising injury related to the actual, alleged, or threatened presence of or exposure to "'nanotubes' or 'nanotechnology' in any form, or to harmful substances emanating from 'nanotubes' or 'nanotechnology'" are excluded from insurance coverage. "Nanotubes" are defined as "hollow cylinders of carbon atoms or carbon fibers or any type or form of 'nanotechnology.'" "Nanotechnology" is defined to mean "engineering at a molecular or atomic level."

According to a "Background on Nanotubes" document prepared by and posted on Continental's Web site (but since removed), Continental's intent in adding the exclusion is to remove coverage for

"as yet unknown and unknowable risks created by products and processes that involve nanotubes. The exclusion is being added to make you and your customers explicitly aware of our intent not to cover injury and/or damage arising from nanotubes, as used in products and processes …." The exclusion took effect on November 15, 2008.

The announcement caused significant concern for several reasons. The terms "nanotubes" and "nanotechnology" as used in the exclusion are vague and ill-defined. As written, the exclusion could exclude from commercial liability insurance coverage losses incurred by manufacturing activites undertaken by entire sectors of the economy. As noted in one media account, a hollow-carbon-fiber fishing rod that makes no claim to be a product of nanotechnology or to contain carbon nanotubes could be considered within the scope of the exclusion, because it is a hollow cylinder made of carbon atoms.

Similarly, because "nanotechnology" is a loosely defined term that is intended more to capture an emerging technology than a particular material or process, it is by its very nature ill-defined and exceedingly open-ended. The exclusion could be interpreted to include any "engineering at a molecular or atomic level," whatever this means. Given the inherent lack of clarity in the terms of the exclusion and the nearly limitless breadth of these terms, the exclusion was found to result in significant confusion as to coverage. In the potential worst case, widespread use of an endorsement like this could result in an immediate halt in many businesses' ability to obtain insurance coverage. Continental Western Group was urged by at least one prominent trade association, Nanotechnologies Industries Association (NIA), to clarify or retract the endorsement.[20] Continenal Western declined to do either, and the endorsement is still in effect in June 2009.

Other options that insurers may consider pursuing include capping coverage at one end or the other (either insurers will pay claims only up to a specified ceiling, or they will pay the excess only after the insured shoulders a large deductible), other types of risk-pooling agreements, and limitations and exclusions narrowly defined. This is an emerging area, and no hard and fast rules yet apply.

Acquisitions

In these early years of the 21st century, the duties and challenges posed by environmental licensing and compliance issues for a seller/transferor and, especially, for a prospective purchaser/transferee of a business or a commercial property, are well-known. If the business uses or produces chemical substances or if the property has been used for the manufacture, storage, treatment, or disposal of these substances, it becomes all the more critical to ensure that the environmental due diligence is completed thoroughly and to negotiate the appropriate representations, warranties, and indemnities in the contract for purchase, merger, or other acquisition, as well as any associated lending arrangement. If the business being acquired processes, manufactures, discharges, or emits nanomaterials, the goals of the due diligence do not change, but this context adds challenging scientific, risk-identification, and risk-allocation wrinkles for the parties to consider in their negotiation.

No nanomaterial has been explicitly listed as "hazardous" under the Comprehensive Environmental Response, Compensation, and Liability Act or any of the other federal statutory environmental authorities, and no such listing seems to be on the near-term horizon. That is not to say, however, that engineered nanoscale versions of listed hazardous substances would not somehow be treated differently from their conventionally sized counterparts. Even with significant research actively underway, it likely will be some time before sufficient information is available about how nanomaterials act if they are "released into the environment," a challenge enhanced by the unique properties of many such materials.

The picture presented here is only a snapshot of the regulatory and best-practices landscape, which necessarily will evolve as nanomaterials become better identified, characterized, and understood from a risk assessment and risk management perspective. In an ideal world, from a purchaser's perspective, the purchase/sales agreement could be fashioned to insulate the purchaser against exposure to hypothetical future liabilities of this kind. In reality, a seller will refuse to go beyond a certain point in consenting to bear the costs of long-term contingent liabilities, in most cases drawing the line at what has occurred or what is, or should be, known as of the transaction's closing date.

Against this backdrop of potential liabilities, regulatory initiatives and governance mechanisms become all the more important. As EPA, other federal

and state regulatory bodies, and stakeholders alike have the benefit of better information about the EHS impacts of nanoscale materials, the regulatory pathway forward will be more informed and, from a stakeholder's perspective, less obscure. While a more developed regulatory framework is still years away, businesses also need to be mindful of the potential for citizen action suits to be filed under federal and state laws, seeking the imposition of liability for cleanup of hazardous substances and natural resource damages. Even if such actions are unsuccessful, their nuisance value and potential for inviting unwanted media attention should not be underestimated.

Government Mechanisms

Traditional government mechanisms, such as statutory enactments and standard Administrative Procedure Act (APA) notice and comment rulemakings, are thought by some to be challenging and possibly ill-suited tools for addressing potential EHS risks posed by the lightning-fast pace of evolving nanotechnology. Even if these tools are believed suitable, most government agencies are of the view that they now lack sufficient data and information to make informed judgments on the specific types of potential hazards and risks posed by some nanoscale materials. It may take years, not months, to obtain needed data. In the interim, EPA — and regulatory bodies globally — are pursuing more innovative regulatory strategies to assist in addressing potential risks associated with nanotechnology.

Government-Sponsored Voluntary Initiatives

Key among EPA's governance responses to nanotechnology is the Office of Pollution Prevention and Toxics' (OPPT) voluntary Nanoscale Materials Stewardship Program (NMSP). OPPT announced its interest in considering how best to obtain much-needed information on existing engineered nanoscale materials and convened a public meeting to discuss various options in June 2005.[21] The discussion at the public meeting yielded a consensus that a voluntary research program on existing engineered nanoscale materials would have significant value.

Shortly thereafter, EPA created an Interim *Ad Hoc* Work Group on Nanoscale Materials (Work Group) as part of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), a federal advisory group assigned to advise OPPT on TSCA and pollution prevention matters. On November 22, 2005, after the Work Group had met several times, NPPTAC submitted to the EPA Administrator its "Overview Document on Nanoscale Materials," which framed an EPA approach to a voluntary program for engineered nanoscale materials and a complementary approach to new chemical nanoscale requirements under TSCA and addressed various other issues pertinent to engineered nanoscale materials.[22]

On October 18, 2006, then EPA Assistant Administrator James Gulliford sent a letter to stakeholders formally announcing the development of NMSP and inviting stakeholder participation.[23] Several months later, EPA simultaneously published three Federal Register notices related to NMSP.[24] The first notice solicited public comment on EPA's proposed Information Collection Request under the Paperwork Reduction Act, including a draft form that NMSP participants could use to submit data to EPA; the second announced a public meeting on NMSP; and the third solicited 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 draft NMSP Concept Paper outlined EPA's "initial thinking on the design and development" of NMSP and explained, among other matters, that the program, consistent with the Work Group's recommendations, would consist of two parts — a "Basic Program" and an "In-Depth Program."[25] The draft TSCA Inventory Paper "inform[ed] the public of the approach EPA has historically taken under TSCA in evaluating whether chemical substances are new, and further inform[ed] the public of EPA's intention to follow [the same] approach for nanomaterials that are chemical substances."[26] EPA explained that if a particular engineered nanoscale material has the same molecular identity as a nonnanoscale (i.e., macro) substance that is listed on the TSCA Inventory, then the engineered nanoscale material is an existing chemical, regardless of its particle size and physical/chemical properties.

After reviewing comments on the NMSP documents, EPA formally launched NMSP on January 28, 2008. Under the Basic Program of NMSP, participants are invited to voluntarily report available information

on the engineered nanoscale materials they manufacture, import, process, or use. Under the In-Depth Program, participants voluntarily develop data over a longer period of time, alone or in consortia, for a particular nanoscale material.

On January 12, 2009, EPA released its interim report on NMSP.[27] EPA states that, based on the current interim results, "the NMSP can be considered successful." EPA notes that a number of environmental health and safety data gaps still exist, however, and "EPA is considering how to best use testing and information gathering authorities under the Toxic Substances Control Act [(TSCA)] to help address those gaps." According to EPA, it will continue to review new chemical nanoscale materials submitted under TSCA Sections 5(a) and 5(h)(4) and apply, as appropriate, testing requirements and exposure controls under Section 5(e) and significant new use rules (SNUR) under Section 5(a)(2). EPA continues to welcome new participants and information submissions for NMSP, which will continue until January 2010. EPA intends to publish a final evaluation of NMSP, including next steps, in April 2010.

OPPT also continues to work extensively with international organizations on voluntary initiatives to understand and address the environmental applications and implications of nanotechnology. The Organization for Economic Cooperation and Development (OECD) established a Working Party on Manufactured Nanomaterials (WPMN), and EPA is actively participating in WPMN and contributes to all of these projects. Of particular relevance to the in-depth component of EPA's NMSP is the project on Safety Testing of a Representative Set of Manufactured Nanomaterials. WPMN has identified a representative list of manufactured nanoscale materials for EHS testing. WPMN has also published a list of testing endpoints in the following areas: nanomaterial information/identification, physical/chemical properties, material characterization, environmental fate, environmental toxicology, mammalian toxicology, and material safety.

In 2008, WPMN also launched a Sponsorship Program for Testing Manufactured Nanomaterials. OECD will act as a clearinghouse for the sponsorship program and will prepare a guidance manual for sponsors. EPA is sponsoring environmental affects and fate testing of fullerenes, single-walled CNTs, multi-walled CNTs, and cerium oxide.

EPA's Office of Pesticide Programs (OPP) also is very active in nanotechnology. OPP has formed an intra-office workgroup of 20 members to develop a regulatory framework and to assist in the examination of hazard, exposure, policy, regulatory, and international issues arising in connection with nanoscale pesticides.

OPP's Nanotechnology Workgroup has the job of addressing issues pertinent to nanopesticides. The Workgroup includes individuals with expertise in chemistry, environmental law and policy, toxicology, exposure and risk assessment, and other areas. The Workgroup has particularly focused on potential exposure and hazards of nanoscale pesticides and how these concerns may or may not be addressed by traditional testing paradigms and risk assessment approaches.

OPP began receiving inquiries about registering nanoscale pesticides in 2006, particularly about those involving antimicrobial uses. Reportedly, OPP has met with companies to discuss data requirements for registration of nanoscale materials being considered for use as pesticides, but has yet to receive a formal application to register a nanoscale pesticide.

OPP has also coordinated with the OECD Working Party on Pesticides (WPP) and Task Force on Biocides (TFB) to develop a survey to gather basic information from OECD member countries on their respective involvement with pesticides/biocides and nanotechnology and to identify the various OECD member countries' regulatory approaches to nanotechnology-related pesticide and biocide issues.

On May 1, 2008, the International Center for Technology Assessment (ICTA) filed a petition for rulemaking, requesting that EPA regulate products containing nanoscale silver as pesticides. The petition requested that EPA classify nanoscale silver as a pesticide and require registration. EPA requested comment on the ICTA petition on November 19, 2008.[28] OPP expects to issue a formal response to the petition after reviewing any public comment and coordinating with EPA's Office of Enforcement and Compliance Assurance. More information about pesticide nanotechnology issues is available online.[29]

Regulatory Initiatives

On the regulatory front, EPA has received and reviewed several new chemical notices under TSCA

Section 5 for nanoscale materials, including CNTs. On November 5, 2008, EPA issued a final SNUR for 56 substances, two of which included nanoscale substances.[30] On October 31, 2008, EPA published a notice outlining the TSCA requirements potentially applicable to CNTs, and advised manufacturers of CNTs of EPA's position that CNTs must be listed on the TSCA Inventory.[31] After March 1, 2009, CNTs that are manufactured for commercial purposes and that are not listed on the TSCA Inventory or are otherwise exempt could be the subject of compliance monitoring efforts. To assist manufacturers in understanding the regulatory status of chemical nanoscale materials, EPA prepared a policy statement dated January 2008, "TSCA Inventory Status of Nanoscale Substances — General Approach."[32]

Another emerging regulatory mechanism involves the use of mandatory disclosure requirements. On December 12, 2006, the Berkeley, California, City Council unanimously approved a proposal to require businesses to report nanoparticles being used, provide available toxicological information, and outline measures for safe handling of the materials. Under the proposal, all businesses that manufacture or use nanoparticles must submit a written report of the current toxicology of the nanomaterials reported, and methods for safely handling, monitoring, containing, disposing, and tracking the inventory.[33]

Berkeley's regulations define a hazardous material as "any material that, because of its quantity, concentration, or physical or chemical characteristics, poses a significant present or potential hazard to human health and safety or to the environment if released into the workplace or the environment." The recommendation states that questions about the need to implement a nanoparticle reporting requirement arose during the design phase of the molecular foundries at the University of California and Lawrence Berkeley Lab. Both institutions, when questioned by the Toxics Management Division, "noted they had no special knowledge or tools to manage nanoparticles." After much consideration and input from staff of the Lawrence Berkeley Lab, EPA, and the Woodrow Wilson International Center for Scholars, "the recommended self-reporting was considered to be a minimum regulation for nanotechnology facilities."[34]

On January 8, 2007, the City Council of Cambridge, Massachusetts, asked the Cambridge Public Health Department (CPHD) to review the Berkeley ordinance and recommend a similar statute for Cambridge. In response to that request, the city manager made appointments to a Nanomaterials Advisory Committee (NAC). The Cambridge Chamber of Commerce solicited input from companies and organizations active in the manufacture, research, or use of nanomaterials to ensure full industry participation in the city's review of the need for regulation and the possible development of statutes to that end.

On July 28, 2008, the City Council voted to accept a set of recommendations for a municipal health and safety policy on nanomaterials. The recommendations were set forth in a report prepared by CPHD and NAC.[35] Cambridge thus became the second city in the United States — Berkeley is the other — to take municipal action on nanomaterials.

The recommendations call for Cambridge to take the following steps:

- establish an inventory of facilities that manufacture, process, handle, or store engineered nanoscale materials;
- offer technical assistance to help firms and institutions evaluate their existing health and safety plans;
- offer up-to-date health information to residents on products containing nanomaterials;
- track rapidly changing developments in research;
- track the evolving status of regulations and best practices concerning engineered nanoscale materials; and
- report back to the City Council every other year on the changing regulatory and safety landscape.

Risk Management and Product Stewardship Strategies

Given the relative paucity of legal and regulatory standards specific to nano manufacturing operations, nanotech businesses and other stakeholders have devoted considerable effort to developing alternatives to traditional "command and control" regulation to identify and manage risk.

Key Industry Standard-Setting Initiatives

Several major efforts are underway to develop standards involving nanotechnology. The International Organization for Standardization (ISO) Technical Committee 229 is preparing international consensus standards on several aspects of nanotechnology, including vocabulary, terms, and definitions; measurement and metrology; and EHS.[36]

ASTM International is working on a similar set of standards.[37] ASTM International Committee E 56 on Nanotechnology is developing standards and guidelines for nanotechnology, specifically including: terminology and nomenclature; characterization, environmental, and occupational safety and health; international law and intellectual property; liaison and international cooperation; and standards of care and product stewardship.

Key Government-Led Initiatives

In addition to the NMSP and related voluntary initiatives sprouting up around the world, OECD is engaged in a robust nanotechnology program. OECD includes 30 member countries, of which the United States is one, and maintains relationships with 70 others.[38]

Two OECD group activities are relevant. In September 2006, OECD established WPMN. The chemicals sector is the principal focus of the WPMN, and EPA and FDA are engaged in the WPMN. Current projects involve generating an EHS database, developing an EHS research strategy, evaluating existing testing guidelines, safety testing a representative set of manufactured nanomaterials, cooperating and exchanging information on voluntary reporting and regulatory schemes, and performing risk assessment and exposure measurement.

In March 2007, OECD created the Committee on Scientific and Technological Policy (CSTP), which focuses on considering applications of nanotechnologies. CSTP's primary objective is to promote international cooperation that facilitates research, development, and the responsible commercialization of nanotechnology in member countries.

Key Private-Sector Stewardship Initiatives

In June 2007, Environmental Defense Fund (ED) and DuPont formally announced the release of their joint effort, the "Nano Risk Framework." The framework is rapidly becoming the standard for measuring best management practice in the nano industry. The framework defines "a systematic and disciplined process for identifying, managing, and reducing potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product's 'lifecycle' — its full life from initial sourcing through manufacture, use, disposal or recycling, and ultimate fate."[39]

ED and DuPont began their collaborative effort to develop the framework in September 2005. They released a draft version to the public on February 26, 2007, and received comments from a diverse array of stakeholders. ED and DuPont also conducted pilot-testing on surface-treated, high-rutile phase titanium dioxide (TiO_2), single- and multi-walled CNTs, and nano-sized zero-valent iron (nano-Fe^0) "to ensure that [the framework] is flexible, practical, affordable, and effective." The final document "offers guidance on the key questions an organization should consider in developing applications of nanomaterials, and on the information needed to make sound risk evaluations and risk-management decisions." The framework is intended to support ongoing regulatory initiatives, not replace them.

ED and DuPont believe that the framework, which is aimed primarily at organizations, both private and public, that are actively working with nanomaterials and developing associated products and applications, helps users organize and evaluate currently available information; assess, prioritize, and address data needs; and communicate clearly how risks are being mitigated. Ultimately, ED and DuPont "believe that the adoption of the *Framework* can promote responsible development of nanotechnology products, facilitate public acceptance, and support the formulation of a practical model for reasonable government policy on nanotechnology safety."

The framework consists of six distinct steps and is intended to be used iteratively as stages of development advance and new information becomes available. The six steps follow.

- **Step 1: Describe Material and Application.** The first step is to develop a general description of the nanomaterial and its intended uses, based on information in the possession of the developer or in the literature. The user also identifies analogous materials and applications that may help fill data gaps in this and other steps.

- **Step 2: Profile Lifecycle(s).** Step 2 defines a process to develop three sets of profiles — the nanomaterial's properties, its inherent hazards, and associated exposures throughout the lifecycle. The user considers the nanomaterial's full lifecycle, from material sourcing, through production and use, to end-of-life disposal or recycling. The user considers how the material's properties, hazards, and exposures may change during that lifecycle.

- **Step 3: Evaluate Risks.** In this step, all of the information generated in the profiles is reviewed to identify and characterize the nature, magnitude, and probability of risks presented by the nanomaterial and its anticipated application. The user considers gaps in the lifecycle profiles, prioritizes those gaps, and determines how to address them — either by generating data or by using, in place of such data, "reasonable worst case" assumptions or values.

- **Step 4: Assess Risk Management.** In the fourth step, the user evaluates the available options for managing the risks identified in Step 3 and recommends a course of action. Options include engineering controls, personal protective equipment, risk communication, and product or process modifications.

- **Step 5: Decide, Document, and Act.** In Step 5, the user consults with the appropriate review team and decides whether or in what capacity to continue development and production. Consistent with transparent decision-making, the user documents those decisions and their rationale and shares appropriate information with the relevant internal and external stakeholders. A worksheet is provided in the framework's appendix for documenting information, assumptions, and decisions.[40]

- **Step 6: Review and Adapt.** Through regularly scheduled and triggered reviews, the user updates and re-executes the risk evaluation, ensures that risk management systems are working as expected, and adapts those systems in the face of new information or new conditions. Reviews may be prompted by development milestones, changes in production or use, or new hazard or exposure data. As in Step 5, the user not only documents changes, decisions, and actions, but also shares appropriate information with relevant stakeholders.

Another significant private-sector initiative is the Nanoparticle Benchmarking Occupational Health, Safety and Environment Program. This initiative reflects the efforts of a consortium of companies that convened to address common analytical needs to measure airborne concentrations of nanoscale materials and particle sizes and to assess the effectiveness of controls. Several work products are being developed: a chamber test to define aerosols and monitor aerosol behavior as a function of time; a prototypical instrument to measure particle concentration in workplace ambient air in a discrete particle size range; and the ability to measure penetration of nanoparticles from an air stream through filters, gloves, or protective clothing.

A third initiative recently launched in the United States is the "Responsible NanoCode." Britain's Royal Society, the Nanotechnology Industries Association, Insight Investment, and the U.K.-government-sponsored Nanotechnology Knowledge Transfer Network collaborated on the code. The objective of this "principles-based" voluntary code of conduct is to encourage industries, retailers, universities, research institutes, and other public or privately funded bodies involved in developing, manufacturing, and selling products of nanotechnology to adhere to seven principles to demonstrate responsible governance.

- **Principle One** — Each organization should ensure that responsibility for guiding and managing its involvement with nanotechnologies resides with the board or governing body.

- **Principle Two** — Each organization should proactively engage with its stakeholders and be responsive to their views in its development or use of products using nanotechnologies.

- **Principle Three** — Each organization should identify and minimize sources of risk for workers handling products using nanotechnologies, at all stages in the production process or in industrial use, to ensure high standards of occupational health and safety.

- **Principle Four** — Each organization should carry out thorough risk assessments and minimize any potential public health, safety, and environmental risks relating to its products using nanotechnologies.

- **Principle Five** — Each organization should consider and respond to any social and ethical implications and impacts during the development or sale of products using nanotechnologies.

- **Principle Six** — Each organization should adopt responsible practice in the sales and marketing of products using nanotechnologies.

- **Principle Seven** — Each organization should engage with suppliers and business partners to encourage and stimulate their adoption of the code and so ensure its own ability to fulfill its code commitments.[41]

Conclusion

As with the other commercial, legal, and regulatory issues and impacts discussed in this article, nanotechnology businesses must look to existing rules, voluntary and stewardship initiatives, and best industry practices to avoid liability. At the same time, these entities must discover new ways to proceed in an arena where the state of knowledge still is catching up to entrepreneurial initiatives.

Endnotes

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