

The New Business of Nanotechnology: Exploring Commercial Opportunities and Risks

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There is an Alice-in-Wonderland awe associated with nanotechnology. While the technology is both exciting and hopeful for many good reasons, for businesses, and the lawyers who counsel them, the lack of certainty in areas involving potential risk is unsettling. The U.S. Environmental Protection Agency (EPA) is only now beginning to think through how best to apply the authority it has under the traditional environmental statutes, and to adopt regulatory programs and policies to address the potential risks and regulatory challenges nanotechnology invites. While research is progressing briskly on key hazard and exposure nanotechnology issues, much remains to be done leaving commercial applications of nanotechnology in new, unsettled waters. This article identifies some of these challenges and the non-conventional, innovative ways that lawyers, business managers, risk assessors, and others must embrace to manage risk and avoid liability effectively.

INTRODUCTION

Much has been written about the business potential of nanotechnology. This article discusses the new and rapidly expanding field of diverse applied sciences known broadly as “nanotechnology,” outlines key potential business risks, and reviews governance and risk management mechanisms intended to address these potential business risks.

PRODUCTS OF NANOTECHNOLOGY IN COMMERCE

Nanotechnology has many definitions. It is the “understanding and control of matter at dimensions of roughly one to one hundred nanometers, where

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unique phenomena enable novel applications,” according to the National Nanotechnology Initiative (NNI).¹ The U.S. Environmental Protection Agency (EPA) defines nanotechnology as “research and technology development at the atomic, molecular, or macromolecular levels using a length scale of approximately one to one hundred nanometers in any dimension; the creation and use of structures, devices and systems that have novel properties and functions because of their small size; and the ability to control or manipulate matter on an atomic scale.”² Nanotechnology is viewed broadly as many technologies over time are expected to generate numerous new products and applications. Lux Research, Inc., the New York-based nanotechnology research and advocacy firm, predicts that by 2014 products that incorporate nanotechnology will constitute 15 percent of global manufacturing output and will total \$2.6 trillion.³

One of the key reasons governments, business groups, public interest groups, and others around the world are focusing on nanotechnology is the lack of understanding in all cases regarding the environmental, health, and safety (EHS) effects of exposure to engineered nanoscale materials. Some believe sufficient information exists to suggest caution is needed. The small size of certain nanoparticles and structures facilitate their uptake into cells and their movement through the body more readily than is the case with their macro counterparts.⁴

In addition to size, other factors contribute to a general sense of uncertainty as to the biological, ecological, and environmental effects of exposure to engineered nanoscale materials. Given the inherent uniqueness and complexity of engineered nanomaterials, their potential impact on human health and the environment will depend on more than size alone. Shape, surface chemistry, and surface coating, for example, are but a few of the many factors that can influence how these materials function and behave in biological and ecological settings. In some cases, size alone may have no significant impact on biological functioning. In other instances, however, size may impact functionality and increase the potential for risk.

In the United States, many federal agencies are engaged in the active review of applications of nanotechnologies and their EHS implications. These include the EPA,⁵ the Food and Drug Administration (FDA),⁶ the National

¹ National Nanotechnology Initiative, “What is Nanotechnology?.” <http://www.nano.gov/html/facts/whatIsNano.html> (accessed February 22, 2008).

² EPA, *Nanotechnology White Paper* (February 2007), 5. <http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf> (accessed February 22, 2008).

³ See Lux Research, *The Nanotech Report*TM, 4th Ed. (2006), iii.

⁴ Toxicology studies of certain ultrafine particles demonstrate that smaller particles have potential to induce oxidative stress and inflammation in the respiratory tract and cardiovascular systems. See G. Oberdörster, E. Oberdörster, and J. Oberdörster. Nanotechnology: An emerging discipline evolving from studies of ultrafine particles. *Environ. Health Perspect.* 113(7) (July 2005):823.

⁵ See EPA, “Nanotechnology under the Toxic Substances Control Act.” <http://www.epa.gov/oppt/nano/> (last updated February 22, 2008).

⁶ See FDA, “Nanotechnology.” <http://www.fda.gov/nanotechnology> (accessed February 22, 2008).

Institute for Occupational Safety and Health (NIOSH),⁷ the National Toxicology Program (NTP),⁸ and the Department of Defense,⁹ among others. Regulatory and health agencies globally are similarly engaged, as well as international groups such as the Organization for Economic Cooperation and Development (OECD), the World Health Organization, and others. The EPA is most prominently involved in the review of 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 the NNI, nanoparticles and nanoscale materials are used in many industries, including electronics, pharmaceuticals, chemicals, energy, and biomedical, among others. Reportedly, areas producing the greatest revenue for 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. These products include paints, cosmetics, stain-resistant clothing, electronics, surface coatings, and sporting goods, among other applications.¹¹

Businesses engaged in the production, distribution, and use of nanotechnologies are diverse. One survey found that in 2005 there were approximately 1,645 nanotech companies 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 This number is likely even higher today.

Nanotechnology's promise is matched by its uncertainty in the area of health and safety implications. The global regulatory/governance/legal mechanisms that may be brought to bear to manage risks potentially arising from nanoscale materials are only just evolving. Uncertainty is not a welcome term to investors, insurers, regulators, or the public, and the hope is that prudent business practices will evolve at the same pace as nanotechnology. In the interim, business men and women will be challenged to address an increasingly complex constellation of legal, commercial, regulatory, and public relations issues, as briefly summarized below.

⁷ See NIOSH, "NIOSH Safety and Health Topic: Nanotechnology." <http://www.cdc.gov/niosh/topics/nanotech/> (accessed February 22, 2008).

⁸ See NTP, "NTP Nanotechnology Safety Initiative." <http://ntp.niehs.nih.gov/go/nanotech> (last updated February 28, 2006).

⁹ See United States Naval Research Lab, "Nanoscience and Technology." <http://www.nanosra.nrl.navy.mil/> (accessed February 22, 2008).

¹⁰ See EPA, "Nanotechnology: Research Projects." <http://es.epa.gov/ncer/nano/research/index.html> (last updated February 12, 2008).

¹¹ Project on Emerging Nanotechnologies, Woodrow Wilson Center for International Scholars, "Consumer Products: An Inventory of Nanotechnology-Based Consumer Products Currently on the Market." <http://www.nanotechproject.org/inventories/consumer/> (accessed February 22, 2008).

¹² *Small Times Magazine* (March 2005).

POTENTIAL LIABILITIES AND REGULATORY GOVERNANCE MECHANISMS

Nanotech companies face many challenges and a range of potential liabilities. Assessing these liabilities is difficult given the embryonic stage of development, the lack of clear legal precedent and regulatory standards, evolving industry standards and practices, and the fast-evolving science. Nonetheless, several areas of potential liability warrant note.

PRODUCT LIABILITY ISSUES

Despite the promise of new technologies, the specter of product liability casts a shadow over nanotechnology innovations just as it does with other products of technological innovation. The bad publicity following the Magic Nano product recall in Germany in 2006 has become the poster child for nanotech product liability concerns. That the product contained no nanoparticles is irrelevant. 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 specific case appears to have been brought to date involving nanotechnology or a nano-enabled product per se, many believe this is expected to change sooner rather than later. Nano businesses must monitor fast-evolving science developments, evolving industry standards and “best” practices, emerging regulatory standards, and disclosure practices, and developing risk management strategies in response to new information. The full range of protective measures to minimize product liability must be considered, including contractual protections with upstream suppliers and downstream customers; implementation of best management practices; contractual representations and warranties; indemnification agreements; appropriate warnings, labeling, and related disclosure strategies; and insurance coverage. Additionally, businesses need to track postsale consumer product complaint and incident reports, analyze these data, and respond quickly and thoroughly.

Businesses also must be keenly sensitive to the need for transparency, communication, and public relations. Workers, community residents, downstream formulators, upstream suppliers, vendors, and customers can be anticipated to want to know what a nano-enabled product contains, the health and safety implications from exposure to the product and its nano components, and related product safety information that stakeholders have come to expect under right-to-know laws and the assumptions they invite.

A related thought is the Consumer Product Safety Commission's (CPSC) soon to be 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 the CPSC. The bill, which passed the Senate on March 6, 2008, would give the CPSC greater resources to remove consumer products from the market, would raise fines for safety violations to \$20 million from the current \$1.8 million, restore the CPSC to five members (from three), and require the CPSC to create a database containing reports of injuries, illnesses, and death from consumer products based on information submitted from the public. Importantly for present purposes, the Senate version of the bill would allow state attorneys general to file lawsuits to stop sales of "dangerous" products and require third-party safety certifications of children's products. If enacted, it is not much of a leap to believe nano product producers could be a bit concerned about the potential for enhanced CPSC scrutiny of nano-enabled consumer products given a newly emboldened CPSC, particularly if the November elections bring new leadership that is decidedly more cautious about potential nano risks.

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 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 if 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 impacts of environmental

litigation inspired by nanotechnology, reported under S-K 103, similarly are complicated and difficult to predict 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 Interpretative Release that emphasizes that this requirement applies to environmental trends and uncertainties, including anticipated new regulations and Superfund liabilities. 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.

Related uncertainties for public and privately-held companies involve disclosure required by the General Accepted Accounting Principles (GAAP).¹³ In the environmental area, the most notable GAAP is Financial Accounting Standard No. 5, Accounting for Loss Contingencies. A more recent accounting standard, the Financial Accounting Standard No. 143, Accounting for Asset Retirement Obligations, and the follow-on interpretation, Financial Interpretation No. 47 (FIN 47), issued in March 2005, are also relevant. Under FIN 47, the Financial Accounting Standards Board clarified when and how companies must estimate and recognize costs that they expect to incur in the future when they retire fixed assets. Prior to FIN 47, companies were not required to report such obligations absent a pending or “probable” future legal action. Companies may now be required to disclose environmental legal obligations associated with tangible assets even without threatened or pending legal action. The implications of FIN 47 on nanotech companies are unclear, but care should be taken to ensure that they are carefully reviewed.

INSURANCE

The business uncertainties noted above help explain the challenges insurance coverage presents—both in terms of providing coverage (from the insurer’s perspective) and obtaining it. The key issue in insuring against liabilities where nanotechnology is involved is the relative lack of certainty regarding potential EHS risks. Swiss Re’s much cited report, *Small Matter*,

¹³ These are accounting rules used to prepare and report on financial statements for public and private companies.

Many Unknowns,¹⁴ noted bluntly that in the case of nanotechnology the uncertainties prevail, since “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 reliant upon nanotechnology. One interpretation of this is that some risks will simply be excluded from coverage because some essential element in the risk calculus is too speculative. Alternatively, coverage may be capped at one end or the other, and insurers will either pay claims only up to a specified ceiling, or they will pay the excess only after the insured shoulders (i.e., self-insures) a large deductible. Other types of risk-pooling and limitation, in the form of bond sales/purchases, for instance, may be employed. This is an emerging area and no hard and fast rules yet apply.

In an article in *Insurance Networking News*, Dr. Robert Blaunstein notes that the position of insurers and reinsurers is best viewed in terms of a continuum.¹⁵ We are now in the “early study period” and potential risks and uncertainties will be addressed under existing policies and by efforts by the insurance industry to become better aware of potential risks and insurable events. The “apprehensive phase” may inspire insurers and reinsurers to become more cautious and “nanotechnology risk may be higher than earlier estimated. Insurers and reinsurers begin to look at reducing cover, and pressure develops to contain risk transfer by the use of sub-limits and ‘claims made’ covers.” The final phase, a number of years off, is the “mature phase” where “customized solutions” are developed and become available at reasonable rates. The business community can expect to achieve the comfort this stage offers down the road, but for the time being, a level of discomfort will prevail.¹⁶

ACQUISITIONS

The duties and challenges posed by environmental licensing, permitting, and compliance issues are well-known for a seller/transferor and, especially, for a prospective purchaser/transferee of a business or a commercial property. If a business uses or produces chemical substances, or if the property has been used for the manufacture, storage, treatment, and/or disposal of these substances, it becomes all the more critical to ensure the requisite level of environmental due diligence was completed thoroughly and to negotiate the

¹⁴ Swiss Re, *Nanotechnology—Small Matter, Many Unknowns* (2004), 48. http://www.swissre.com/resources/31598080455c7a3fb154bb80a45d76a0-Pub104_Nano_en.pdf (accessed February 22, 2008).

¹⁵ Robert Blaunstein, PhD. Unfamiliar exposure, *Insurance Networking News* 10(4) (Nov. 2006):13–14. <http://www.insurancenetworking.com/issues/20061101/4372-1.html> (accessed February 22, 2008).

¹⁶ For another review of emerging risk from the insurer’s perspective, see Lloyd’s *Nanotechnology: Recent Developments, Risks and Opportunities* (2007). http://www.lloyds.com/NR/rdonlyres/7C1D8222-A3E8-4781-8C80-7FFABFC3F59E/0/Nanotechnology_Report.pdf (accessed February 22, 2008).

appropriate contractual representations, warranties, and indemnities in the contract for the 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 the 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 somehow be treated differently than their conventionally-sized counterparts. Even with significant research actively underway, it likely will be some time before sufficiently robust 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 as it stands today is only a snapshot of the regulatory and best practices landscape that necessarily will evolve significantly as nanomaterials are better identified, characterized, and understood from a risk assessment and risk management perspective. From a purchaser’s point of view, the purchase/sales agreement could be fashioned to insulate itself against exposure to hypothetical future liabilities of this kind. In reality, a seller will likely refuse to go beyond a certain point in consenting to bear the costs of long-term contingent liabilities, particularly those as ill-defined as “nano risks,” 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, governance mechanisms become all the more important. As the EPA, other federal and state regulatory bodies, and stakeholders increasingly have the benefit of better data and information about the EHS impacts of nanoscale materials, the regulatory pathway forward will be more informed and, from a stakeholder’s perspective, less uncertain. While a more developed regulatory governance framework is still years away, businesses also need to be mindful of potential citizen action suits under federal and state laws seeking the imposition of liability for cleanup of hazardous substances and/or natural resource damages. Even if such actions are unsuccessful, their nuisance value and potential for inviting unwanted media attention cannot be dismissed.

GOVERNANCE MECHANISMS

Traditional governance mechanisms such as statutory enactments and/or standard Administrative Procedure Act notice and comment rulemakings are thought by some to be challenging and possibly ill-suited tools for addressing

potential EHS risks posed by the fast pace of evolving nanotechnologies. 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 potential hazards and risks of nanoscale materials, and it may take years, not months, to obtain needed data. In the interim, the EPA, and regulatory bodies globally, are pursuing more innovative governance strategies to assist in addressing potential risks arising in connection with nanotechnology.

Key among the EPA's governance responses to nanotechnology is the Office of Pollution Prevention and Toxics' (OPPT) voluntary Nanoscale Materials Stewardship Program (NMSP),¹⁷ which OPPT rolled-out in January 2008. First announced by the EPA's OPPT in 2005, the NMSP reflects the EPA's keen interest in obtaining quickly much-needed information on existing engineered nanoscale materials to facilitate the EPA's ongoing review of potential risks posed by these materials.¹⁸

After some initial public discussions about the concept of a voluntary program, on October 18, 2006, EPA Assistant Administrator James Gulliford sent a letter to stakeholders formally announcing the development of the NMSP and inviting their participation.¹⁹ Several months later, the EPA simultaneously published three *Federal Register* notices related to the NMSP.²⁰

The EPA's January 2008 notice reveals that it will implement the NMSP in two parts: (1) a basic program, where participants report all known or

¹⁷ 73 *Federal Register* 4861 (January 28, 2008).

¹⁸ See 70 *Federal Register* 24574 (May 10, 2005). The EPA convened a public meeting to discuss various options in June 2005. The discussion at the public meeting yielded a consensus that a voluntary program on existing engineered nanoscale materials would have significant value. Shortly thereafter, the 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 tasked with advising 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 outlined a framework for a 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. NPPTAC, *Overview Document on Nanoscale Materials* (November 22, 2005). <http://www.epa.gov/opptintr/npptac/pubs/nanowgovoverviewdocument20051125.pdf> (accessed February 22, 2008).

¹⁹ Letter from James B. Gulliford, Assistant Administrator for Prevention, Pesticides & Toxic Substances, to Stakeholders (October 18, 2006). According to the letter, the EPA's goal is "to implement TSCA in a way that enables responsible development of nanotechnology and realizes its potential environmental benefits, while applying sound science to assess and, where appropriate, manage potential risks to human health and the environment presented by nanoscale materials." <http://www.epa.gov/oppt/nano/nano-letter.pdf> (accessed February 22, 2008).

²⁰ See 72 *Federal Register* 38079–38085 (July 12, 2007). All the notices and accompanying documents are available at <http://www.epa.gov/opptintr/nano/nmspfr.htm> (accessed February 22, 2008). The first notice solicited public comment on the EPA's proposed Information Collection Request under the Paperwork Reduction Act, including a draft form that NMSP participants could use to submit data to the EPA; the second announced a public meeting on the NMSP; and the third solicited public comment on two draft documents: (1) the "Concept Paper for the Nanoscale Materials Stewardship Program under TSCA"; and (2) the "TSCA Inventory Status of Nanoscale Substances—General Approach."

reasonably ascertainable information regarding specific nanoscale materials, including risk management practices; and (2) an in-depth program, where participants commit to develop data. Under the basic program, participants should forward available data on nanoscale materials to the EPA within six months. The EPA will use data received within the six-month period to prepare the interim report on the NMSP. Participants in the basic program may continue to submit new data that become available on any nanoscale material reported to the EPA during the initial six-month period.

Under the in-depth program, participants would develop a plan and submit data over a longer period of time yet to be determined. The EPA states that it intends to conduct both the basic and in-depth programs for the next two years, "although it may make adjustments or decide on future steps or direction of the program at an earlier point as sufficient experience is gained." The EPA asks that entities who want to participate in the in-depth program notify the EPA. As soon as the EPA identifies potential sponsors, it will coordinate the process for in-depth data development. The EPA intends to begin to coordinate meetings for the in-depth program in ninety days. To avoid duplication of testing, the EPA states that it will coordinate the in-depth program with its research program, other federal testing and research programs, and internationally through the OECD's Working Party on Manufactured Nanomaterials (WPMN). The EPA states that it will also coordinate with the Canadian government to encourage participation of Canadian companies in the in-depth program or participation of American companies in Canadian data development activities, which will allow joint development and sharing of data by both countries.

The EPA also invites each participant in the basic program to submit available data on risk management practices for nanoscale materials it manufactures, imports, processes, or uses. The EPA invites participants who have already developed a risk management plan to include the plan as part of their submission under the basic program. The EPA encourages participants who do not have a risk management plan to "consider developing one." The EPA provides information describing risk management practices, but cautions: "EPA is not prescribing specific risk management practices that would be used for all nanoscale materials."

Another emerging governance 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 safe handling, monitoring, containing, disposing, and tracking the inventory. The proposal amends Title 15 of the Berkeley Municipal Code, Hazardous

Materials and Waste Management, which requires the filing of disclosure information for hazardous materials when certain quantities are exceeded.²¹

According to the Community Environmental Advisory Commission's recommendation, 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, the Lawrence Berkeley Lab, the EPA, and the Woodrow Wilson International Center for Scholars, "the recommended self-reporting was considered to be a minimum regulation for nanotechnology facilities."²²

On January 8, 2007, the City Council for Cambridge, Massachusetts, asked the Cambridge Public Health Department 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, which has held several meetings. The Cambridge Chamber of Commerce solicited 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 regulations. Discussions in Cambridge in this regard are ongoing.

RISK MANAGEMENT AND PRODUCT STEWARDSHIP STRATEGIES

Given the somewhat limited availability 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. These strategies are discussed below, grouped in these categories: key industry standard-setting initiatives, key government-led initiatives, and key private sector stewardship initiatives.

²¹ The amendment is available at <http://www.ci.berkeley.ca.us/citycouncil/ordinances/2006/6960.pdf> (accessed February 22, 2008).

²² The recommendation is available at <http://www.ci.berkeley.ca.us/citycouncil/2006citycouncil/packet/120506/2006-12-05%20Item%2013%20Manufactured%20Nanoparticle%20Health%20and%20Safety%20Disclosure.pdf> (accessed February 22, 2008).

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.²³

ASTM International is working on a similar set of standards. ASTM International Committee E56 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.²⁴

Key Government-Led Initiatives

In addition to the NMSP discussed above and related voluntary initiatives sprouting up around the world, the OECD is engaged in a robust nanotechnology program. OECD includes thirty member countries, including the United States, and seventy others with OECD relationships.²⁵

Two OECD group activities are relevant. In September 2006 OECD established the WPMN, noted above. The chemicals sector is the principal focus of the WPMN, and the EPA and FDA are engaged in the WPMN.

In 2007 the WPMN initiated work on six projects, each managed by a steering group (SG). The projects are: SG1 "Development of an OECD Database on EHS Research"; SG2 "EHS Research Strategies on Manufactured Nanomaterials"; SG3 "Safety Testing of Representative Set of Manufactured Nanomaterials"; SG4 "Manufactured Nanomaterials and Test Guidelines"; SG5 "Co-operation on Voluntary Schemes and Regulatory Programmes"; and SG6 "Cooperation on Risk Assessment and Exposure Assessment." These projects have commanded the international cooperation of an unprecedented number of OECD participants and others, and are advancing the goals of each SG at a rapid pace. The output is expected to be historic at several levels, not the least of which is the international cooperation exhibited to complete the six projects.

In March 2007 the 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

²³ See ISO, "TC 229: Nanotechnologies." http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983 (accessed February 22, 2008).

²⁴ See ASTM, "Committee E56 on Nanotechnology." <http://www.astm.org/cgi-bin/SoftCart.exe/COMMIT/COMMITTEE/E56.htm?E+mystore> (accessed February 22, 2008).

²⁵ OECD, "About the OECD." http://www.oecd.org/pages/0,3417,en_36734052_36734103_1_1_1_1_1,00.html (accessed February 22, 2008).

cooperation that facilitates the research, development, and responsible commercialization of nanotechnology in member countries.

Key Private Sector Stewardship Initiatives

In June 2007 Environmental Defense (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.”²⁶

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—government, academia, public interest groups, and both large and small companies. In addition to considering the various comments, ED and DuPont conducted pilot-testing on surface-treated high-rutile phase titanium dioxide (TiO₂), single- and multi-walled carbon nanotubes (CNT), and nano-sized zero-valent iron (nano-Fe⁰) “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, will help 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 are as follows:

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

²⁶ A complete copy of the *Framework* and other related information are available at <http://nanoriskframework.com/page.cfm?tagID=1095> (accessed February 22, 2008).

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 appendix for documenting information, assumptions, and decisions.²⁷

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 consists of 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

²⁷ Completed worksheets for the three DuPont demonstration projects — TiO₂, CNTs, and nano-Fe⁰ — are available at <http://nanoriskframework.org/page.cfm?tagID=1326> (accessed February 22, 2008).

instrument to measure particle concentration in workplace ambient air in 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 is the *Responsible NanoCode*.²⁸ Britain's Royal Society, the Nanotechnology Industries Association, Insight Investment, and the United Kingdom government-sponsored Nanotechnology Knowledge Transfer Network collaborated on the proposed 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. The seven principles are:

- **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 in 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/or business partners to encourage and stimulate their adoption of the code and so assure its own ability to fulfill its code commitments.

Code proponents held a consultation period in the United States, which ended on November 12, 2007. The final code is expected to be launched in 2008.

As with the other commercial, legal, and governance issues and impacts discussed above, nanotechnology businesses must look to existing laws and

²⁸ Responsible NanoCode, "Background to the Responsible NanoCode." <http://www.responsiblenanocode.org/index.html> (accessed February 22, 2008).

rules, voluntary and stewardship initiatives, and best industry practices to manage risk effectively to avoid liability. At the same time, these entities must discover new ways to proceed in an arena where the state of knowledge is evolving quickly, and traditional legal and regulatory governance framework may not in all cases be the best or only framework to address potential risks.