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Bottom-Up Risk Regulation? How Nanotechnology Risk Knowledge Gaps Challenge Federal and State Environmental Agencies

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Abstract Nanotechnologies have been called the "Next Industrial Revolution." At the same time, scientists are raising concerns about the potential health and environmental risks related to the nano-sized materials used in nanotechnologies. Analyses suggest that current U.S. federal regulatory structures are not likely to adequately address these risks in a proactive manner. Given these trends, the premise of this paper is that state and local-level agencies will likely deal with many "end-of-pipe" issues as nanomaterials enter environmental media without prior toxicity testing, federal standards, or emissions controls. In this paper we (1) briefly describe potential environmental risks and benefits related to emerging nanotechnologies; (2) outline the capacities of the Toxic Substances Control Act, the Clean Air Act, the Clean Water Act, and the Resources Conservation and Recovery Act to address potential nanotechnology risks, and how risk data gaps challenge these regulations; (3) outline some of the key data gaps that challenge state-level regulatory capacities to address nanotechnologies' potential risks, using Wisconsin as a case study; and (4) discuss advantages and disadvantages of state versus federal approaches to nanotechnology risk regulation. In summary, we suggest some ways government agencies can be better prepared to address nanotechnology risk knowledge gaps and risk management.

Keywords Nanotechnology · Risk assessment · Government regulation · Data gaps

Introduction

Nanotechnologies, among the fastest-growing areas of scientific research and technology development worldwide, are often called the "Next Industrial Revolution" (Roco 2005). Currently, there are an estimated 580 consumer products on the market that claim to utilize nanotechnologies in some way, and some analysts predict that nanotechnology will be a nearly $3 trillion industry by 2018 (Global Industry Analysts 2008; Project on Emerging Nanotechnologies 2008). The production of nanomaterials is currently estimated to be in the millions of tons worldwide and is expected to increase dramatically in the near future (BCC Research 2007). Along with the excitement about nanotechnology development, however, scientists are raising concerns about the potential health and environmental risks related to the nano-sized materials used in nanotechnologies and the significant data gaps about these risks (Nel and others 2006; Oberdorster and others 2007).

Unfortunately, analyses of U.S. environmental regulatory statutes conclude that existing federal regulations are inadequate to address these potential risks in proactive ways (Davies 2006). Lacking timely federal-level regulations, state- and local-level agencies are likely to deal with many "end-of-pipe" challenges as nanomaterials enter environmental media without controls or monitoring. We describe how risk knowledge gaps create significant

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barriers to utilizing existing federal regulations—particularly how current lack of capacities to monitor and control nanomaterial emissions (typically state and local responsibilities) create numerous “Catch-22” situations for federal and state regulators. Rather than taking a theoretical approach, we outline how critical risk knowledge gaps are likely to challenge state and local government agency risk management capacities “on the ground” in practical, technical, political, and financial ways. Outlining and understanding these concrete challenges will help government policymakers, risk researchers, and risk managers better prioritize nanotechnology risk research and develop more proactive risk management strategies and policies.

In this paper, we explore several broad issues. Which federal and state level regulations *could* address potential environmental risks related to nanomaterials, and how do risk data gaps affect their capacities to do so? The focus is on environmental risks (versus occupational or consumer-product-related risks) and four of the key U.S. regulations directly related to environmental issues—the Toxic Substances Control Act (TSCA), the Clean Air Act (CAA), the Clean Water Act (CWA), and the Resources Conservation and Recovery Act (RCRA). In sum, this analysis (1) briefly describes potential environmental risks and benefits related to emerging nanotechnologies; (2) outlines the capacities of four key U.S. federal environmental statutes to address potential environmental risks related to nanotechnologies, and how risk data gaps challenge these regulations; (3) outlines some of the key data gaps that challenge state-level regulatory capacities to address nanotechnologies’ potential risks, using Wisconsin as a case study; and (4) discusses advantages and disadvantages of state versus federal approaches to nanotechnology risk regulations. In conclusion, we discuss what government agencies might do to be better prepared to address key nanotechnology data gaps and manage risks proactively.

A Brief Review of Potential Risks and Benefits of Emerging Nanotechnologies

What are nanotechnologies and nanomaterials? Although there is still considerable confusion about these terms, in December 2006, *nanotechnology* was defined by ASTM International (2006, p. 2) as “a term referring to a wide range of technologies that measure, manipulate, or incorporate materials and/or features with at least one dimension between approximately 1 and 100 nanometers (nm). Such applications exploit the properties, distinct from bulk-macroscopic systems, of nanoscale components.” In this paper, the term “nanomaterials” is used generally to describe *purposely engineered* materials that have at least one dimension between 1 and 100 nm.

Why all the excitement about nanotechnologies and the nanomaterials associated with them? At the nanoscale, some materials have properties that make them useful for a variety of applications including enhanced conductivity, strength, durability, and reactivity. The physical and chemical characteristics of nano-sized materials can differ substantially from those of bulk materials (Aitken 2004; Preining 1998). One reason nano-sized materials can behave differently is that they have high surface-to-volume ratios, so a large proportion of their atoms is on the surface, allowing them to more readily react with adjacent atoms (Jefferson 2000).

Unfortunately, many of the properties that make nano-sized materials so useful can also make them more likely to react with tissues in the body and cause cellular and tissue damage. A large body of research associates existing nano-sized materials in our environment, such as fine (micron-sized) and ultrafine (nano-sized) particulates produced incidentally via fossil fuel combustion, with adverse public health effects such as respiratory problems, cardiovascular diseases, and/or increased mortality (Nel and others 2006; Oberdorster and others 2007).

A growing number of studies on engineered nanomaterials show that some of these materials can have detrimental biological effects (see Appendix 1). For example, nanoscale titanium dioxides used in sunscreens and cosmetics have been associated with pulmonary effects such as lung inflammation, pulmonary damage, and fibrosis in animal studies and related effects in vitro (Bermudez and others 2002, 2004; Grassian and others 2007; Long and others 2007). Many different types of carbon nanotubes, which have fibrous structures similar to that of asbestos, are used in electronics, pharmaceuticals, and a variety of other applications; some forms of carbon nanotubes have been associated with oxidative stress, cytotoxicity, inflammation, granuloma formation, and fibrogenesis in in vitro and in vivo studies (Donaldson and others 2006; Muller and others 2006). Fullerenes, or “buckyballs,” are soccer-shaped balls of carbon used in catalysts, copolymers and composites, lubricants, drugs and drug delivery systems, cosmetics, health care products, and sporting goods. Due to their anti-oxidant properties, they show promise as treatments for cancer, AIDS, and bacterial infections, but some studies suggest that they can cause DNA damage, lipid peroxidation, and leaky cell membranes (Oberdorster 2004; Sayes 2005). Quantum dots, nano-sized particles used or being developed for use in electronics, biomedical imaging, and surveillance, are typically made of cadmium or lead, well-known toxins. Toxicological and pharmaceutical studies suggest that protective coatings of quantum dots can degrade in light and oxidative conditions, releasing these metals into cells and organisms and causing toxic effects (Hardman 2005). There are numerous other types of nanomaterials currently in production, most of which have not been studied for toxicity.

Nanotechnology for Pollution Remediation, Detection, and Prevention

Nanomaterials also show great promise for environmental improvement and energy efficiency. Due to their novel properties, some are able to react with pollutants and either transform them into harmless compounds or enhance removal efforts (Savage and others 2007; Zhang 2003). Metal-based or composite nanomaterials, for example, show promise for contaminant reduction or elimination in groundwater and drinking water (Kanel and others 2005; Nutt and others 2005; Schrick and others 2002). Studies also suggest that they could be useful for soil remediation of toxic contaminants (Gardner and others 2004; Mikszewski 2004; Tungittiplakorn and others 2004) and for removal of contaminants from wastewater and other types of effluent (Kofinas and Kioussis 2003; Nagappa and Chandrappa 2007; Wu 2005). Nanotechnologies are being used to create chemical sensors that can rapidly detect pollutants and microbes in air and water. Because of their size, integration of nanosensors into devices and sensor networks enable the detection of biological and chemical agents at very low concentrations (Cui and others 2001; Kong and others 2000; Manzoor and others 2007; Shih and others 2004). These chemical sensors will cost less per measurement, require less energy, and allow for greater versatility when creating remote, in-the-field, continuous monitoring devices, as well as sensor arrays for environmental monitoring.

Nanomaterials also show promise for the design of more environmentally friendly products that use less energy and generate less waste throughout the production life cycle. Stronger, lighter nanomaterials such as composite wood/nonwood nanoscale biomaterials being developed by the U.S. Forest Service Forest Products Laboratory (Berglund and others 2004) could decrease fuel and material use. Nanotechnology promises to make current wastewater treatment processes more energy efficient by utilizing single-stage treatment methods that can remove biological and chemical contaminants in treated wastewater (Kamat and others 2002). Treatment processes incorporating nanotechnologies could be less toxic by negating the need to use chemical compounds like chlorine and ozone and improving the quality of treated wastewater increases the potential for beneficial reuse.

Environmental Fate and Environmental Effects of Engineered Nanomaterials

Engineered nanomaterials used widely for environmental applications will end up in the environment. Moreover, the increasing number of nanomaterials used in consumer products and construction materials are likely to eventually find their way into air, water, and soil through waste streams when these products are discarded and/or through wear and tear (Blaser et al. 2007; Boxall and others 2007; Nowack and Bucheli 2007).

A small but growing number of studies have been done to date to assess fate and transport of engineered nanomaterials (Baun and others 2008; Cheng and others 2005, 2007; Duncan and others 2008; Gimbert and others 2007; Hyung and others 2007; Terashima and Nagao 2007). Brumfiel (2003) reported that fullerenes dispersed in water are poorly absorbed by soils (Tomson and others 2005), which may allow absorption by terrestrial invertebrates, and a more recent study suggests that negatively charged aggregates of C60 fullerenes may be stable in aqueous environments (Duncan and others 2008). Similarly, a recent study on multiwalled carbon nanotubes shows that they can remain stable in water for up to a month (Hyung and others 2007). These studies and others raise concerns about potential transport of these materials downstream from their emissions.

A scattering of recent studies also raises concerns about potential effects wildlife and ecosystems of nanomaterials released into the environment. For example, Fortner and others (2005) and Brayner and others (2006) showed that when micro-organisms are exposed to varying concentrations of nanomaterials (e.g., zinc oxide, buckyballs), their growth and metabolism are inhibited. Moving up the evolutionary ladder, studies have shown nanomaterial uptake and effects on *Daphnia* (Lovern and Klaper 2006; Luo 2007; Roberts and others 2007). Others have shown that some nanomaterials can cause hatching delays, deformities, and acute toxicity in zebrafish and/or zebrafish embryos (Cheng and others 2007; Griffitt and others 2007; Lee and others 2007; Zhu and others 2006) and respiratory distress, organ pathologies, and other physiological effects in rainbow trout (Federici and others 2007; Smith and others 2007). A unique study on plants suggests that some nanomaterials may inhibit seed germination and root growth (Lin and Xing 2007). In one of the only food-chain studies to date, Luo (2007) showed that nano-sized zinc oxide and fullerenes are more toxic to algae than larger particles and can be transferred to *Daphnia* when they eat algae containing these nanomaterials.

Nanotechnology Risk Data Gaps and Existing Federal Environmental Regulations

Adequate risk assessments for emerging nanotechnologies and nanomaterials are extremely difficult because of significant data gaps and unknowns. Relatively few toxicological studies have been done to date, there are many methodological uncertainties and inconsistencies among these studies, and it is difficult to extrapolate study results done primarily in controlled settings in labs to human beings and wildlife within complex ecosystems. Little to nothing is known about actual human exposures to engineered nanomaterials in real workplaces or the environment, or what levels of exposures are likely to be harmful (Nowack and Bucheli 2007).

Data gaps about nanotechnologies notwithstanding, discussions about regulating engineered nanomaterials are increasing as more scientific studies indicate that some of these materials may have negative and possibly irreversible health and environmental effects. These data gaps challenge regulatory agencies' authority to enforce existing statutes as well as their abilities to anticipate or address potential risks. In the following sections, we describe how these and other data gaps and unknowns are likely to challenge federal regulators' authority to enact and enforce the TSCA, CAA, CWA, and RCRA.

How Nano Risk Data Gaps Challenge the Toxic Substances Control Act

Analysts agree that the TSCA, in theory, is more suited than other statutes to *preventing* potential environmental and health problems related to emerging nanomaterials rather than *reacting* to them downstream (Bell and others 2006). It is a broad, holistic statute, making it appropriate for engineered nanomaterials, which are likely to be found in all media eventually because of their widespread applications (Davies 2006).

A recent American Bar Association analysis of the TSCA concludes generally that the U.S. Environmental Protection Agency (EPA) could regulate nanomaterials under the TSCA, primarily under Section 5, because they "fall within the broad sweep of … 'chemical substances'" (Bell and others 2006, p. 5). However, definitional problems regarding the "newness" of nanomaterials create substantial confusion about the TSCA's applicability to nanomaterials. If nanomaterials are defined as "new" under Section 5(a)(1), TSCA Section 8(b)(1) would require the EPA to compile and publish lists of each chemical substance which is manufactured or processed in the United States. Manufacturers of substances defined as "new" are then required to submit "premanufacture notices" (PMNs) at least 90 days before producing the chemical, submit required health and safety studies to the EPA, report adverse health reactions in production, and provide the EPA any information that suggests that a chemical represents a previously undetected significant risk (Rosenbaum 2005, p. 232).

Bell and others (2006) argue that the EPA *could* in theory designate some nanomaterials as new, and that even if nanomaterials are not designated as new, the EPA has flexible authority to regulate them as "existing" chemicals under Section 5(a)(2) or Significant New Use Rules (SNURs). The statutory factors that the EPA must consider in issuing a SNUR include (a) the projected volume of manufacturing of a chemical substance; (b) the extent to which a use changes the type or form of exposure to human beings or the environment; (c) the extent to which a use increases the magnitude and duration of exposure; and (d) the reasonably anticipated manner and methods of manufacturing, processing, distribution, and disposal of a chemical substance.

The report does not note, however, that current and projected volumes of nanomaterials, and anticipated methods of manufacturing, disposing, etc., are not publicly available because they are not systematically tracked and, in many cases, are confidential business information. Moreover, adequate information about the uses of nanomaterials in production—and exposures that might be associated with these uses—is also not available. Ironically, the TSCA was intended to give the government the authority to track this kind of information, but this authority is rarely used. For example, the TSCA provides the EPA with the authority to gather production and health data for existing chemicals as well as new chemicals. If a SNUR is promulgated for an existing chemical, the provisions triggered by 5(a)(2) are very similar to those triggered by Section 5(a)(1), which provides authority for the EPA to gather the information about production necessary to fill key data gaps. Under SNURs, the EPA can require premarket notification procedures essentially identical to those required for new chemicals. Further, under Section 26(c), the EPA could issue SNURs for categories of nanomaterials, in which case it could then "conduct its risk assessments, impose risk management controls, on individual nanomaterials in the same manner as it does through the PMN process" (Bell and others 2006, p. 16).

Most analyses are markedly less optimistic than the American Bar Association (ABA) analyses of the TSCA's adequacy and authority to address nanomaterials. For example, Davies (2006) agrees that the TSCA *in theory* would be the most appropriate statute to address nanomaterials. He argues that issuing SNURs for nanomaterials is highly unlikely to happen given current political and economic contexts, because it would require "an unrealistically large amount of time and money" (Davies 2006, p. 10). Another significant problem with the TSCA is that it exempts several categories of chemicals, including those produced in volumes of 10,000 kg or less per year and chemicals used in research and development or for purposes of test marketing. This would effectively exclude much of the nanomaterial production to date, other than that of very large industries (Wardak and Gorman 2006). Moreover, the TSCA and other environmental statutes are based on mass/volume measurements, even though many scientists have proposed that mass is not an appropriate metric by which to assess the toxicity of nanomaterials (Brown and others 2001).

Perhaps most problematically, the TSCA assumes that "no knowledge equals no risk," and several key parts of the act are based on legal "Catch-22" situations. For example, Section 5(e) says that the EPA can delay or prohibit manufacture of a chemical if it does not have enough information to "permit a reasoned evaluation of the health and environmental effects" only if it can show that the chemical "may present an unreasonable risk"—which is, as Davies (2006, p. 12) points out, exactly what it cannot show. Similarly, the statute says that the EPA can take action if a chemical will be produced in "substantial quantities" and when there will be "significant environmental or human exposure." Of course, most new chemicals are initially produced in low volumes, and it is not possible to predict the likelihood of significant exposure in the future without knowing production volumes or how they are likely to grow. Further, the information that would be required by certain TSCA statutes (e.g., chemical production volumes and emissions information) is the very criterion needed in the first place in order to have authority under these statutes and others.

The Clean Air Act and the Clean Water Act

The CAA and the CWA, unlike the TSCA, are "end-of-pipe" statutes. They do not aim to prevent potentially harmful materials from being produced but, instead, to prevent and/or control discharges or emissions of toxins into water and air during or after production. Both the CAA and the CWA use similar mechanisms: they (1) set standards and (2) enforce them through permits issued to pollution sources, usually via state regulatory agencies (Davies 2006). Unfortunately, their abilities to address the potential releases of engineered nanomaterials into air and waterways are limited at this point, in part because of significant data gaps that create Catch-22 situations similar to those inherent in the TSCA.

Nanotechnology Risk Gaps and the Clean Air Act

The CAA is one of the most complex and detailed federal environmental regulatory programs in the United States (Rosenbaum 2005). Originally enacted in 1970, the CAA is more relevant to nanomaterials, especially nanoparticles, than any other existing federal regulations, because its key statutes already address particulate matter. Among other things, the original CAA and its 1977 amendments directed the EPA to determine "maximum permissible ambient air concentrations for pollutants found to be harmful to human health or the environment," including small particulate matter (Rosenbaum 2005, p. 181). By the 1970s, scientists had known for some time that particulates were associated with health hazards, which is why they were included as criteria pollutants in the original CAA. Although initial regulations did not specify particular size ranges, as scientific evidence grew about the health effects of small particulates, scientists and some regulators pushed for the regulation of increasingly smaller particulate sizes. In 1987, new regulations were created specifically for particulates smaller than 10 μm, and in 1997, based on growing scientific evidence, the EPA created regulations for particulates smaller than 2.5 μm. In recent years, the agency is considering regulating particulates in the nano-size range (<0.1 μm).

Legal analysts differ on the usefulness of the CAA for regulating engineered nanomaterials. The ABA analysis (Ternes 2006) concludes that "the CAA does provide the statutory framework and authority to both regulate these emissions of engineered nanoparticles, as well as to support the development of the appropriate tools to identify, monitor, and measure emissions of engineered nanoparticles and establish proper emission limitations and compliance tools" (p. 9). The analysis, however, is filled with caveats that are likely to seriously challenge this authority in practice. As with other statutes, there are significant data, monitoring, and technology gaps that will make it difficult to use the CAA to regulate nanomaterial air emissions. The ABA report states that before the CAA can be clearly used to regulate nanomaterials, the EPA must "distinguish between types of nanoparticles, identifying nanoparticles posing actionable risk and determining appropriate regulatory approaches for each type of nanoparticle requiring regulatory control; develop appropriate methods of sampling, analysis, and control sufficiently effective for nanoparticles; and recognize and adapt to a new form of 'quantification' as number, rather than mass" (Ternes 2006, p. 21).

Interestingly, the fourth challenge the ABA analysis states is that "to avoid creating unnecessary delay in developing strategies to address nanoparticle emissions, which could result in overregulation stifling this new industry," the EPA should "*recognize that the current CAA program already contains sufficient authority to adequately address each of the issues discussed in this paper*" (Ternes 2006, p. 21, emphasis added).

The subsequent text is filled with further contradictions, many of which again hinge on gaps related to monitoring and control techniques. After noting that the "application of conventional methods to identify, monitor, and measure, and control nanoparticles is, for the most part, inappropriate" (Ternes 2006, p. 9), the ABA report argues that the act has the authority to take several actions that could both regulate these emissions and support the development of appropriate tools to identify, monitor, and measure them, as well as creating appropriate emission limitations and compliance tools. Indeed, because the EPA has been dealing with small particulates in ambient air for decades, there is a substantial infrastructure under the CAA that could deal with measurement and monitoring issues related to engineered nanoparticles—including several centers such as the Support Center for Regulatory Air Models (SCRAM), the EPA Regional Modeling Center, and the Emission Measurement Center (Ternes 2006). The EPA is already involved in trying to capture nanoparticulate emissions through its $PM_{2.5}$ rules, and there are several ultrafine monitoring devices available that assess number of particles in air.

However, after describing at some length the extensive EPA infrastructure that could address engineered nanomaterial air emissions, the ABA report concludes:

> Because nanoparticles are neither steady state, nor properly regulated as mass, these models simply cannot be used for purposes of modeling nanoparticles. Thus, until measurement and modeling methods are developed for nanoparticles that take into account the unique nature of these pollutants, nanoparticulate emissions cannot be reliably measured, and their fate and transport in the atmosphere cannot be predicted. (Ternes, 2006, p. 8)

The EPA could revise the NAAQS to include nanoparticles, or could "simply revise the tools used to monitor the current $PM_{2.5}$ NAAQS so that nanoparticles are included in the $PM_{2.5}$ compliance requirements" under Section 108(b) (Ternes 2006, p. 12). However, emission levels for new air pollution sources (and most water sources) are set based on the performance of available pollution control technologies. The ABA report first states, "A wide variety of air pollution control equipment is currently utilized to control types of emissions from stationary sources that may contain nanoparticulates" (p. 13), but then later states that nanoparticulates "do not behave as larger particles do, rendering these conventional control device techniques ineffective" (p. 14). However, after describing several currently available but more sophisticated and expensive nanoparticle filtration devices, it concludes: "It is clear that air pollution control technologies exist upon which EPA can rely in implementing specific air emission standards pursuant to the various sections of the CAA" (p. 15).

Without production volume information, it is very difficult to predict whether emissions from nanotechnology industries and processes are likely to add significantly to ambient levels of incidentally produced nanomaterials, or whether monitoring techniques will be able distinguish between incidental and purposely produced nanomaterials. Currently, the EPA does not monitor or regulate incidental nanoparticle emissions from mobile sources or power plants because existing monitors do not capture them. It is not clear whether EPA should create a general nanoparticle $PM_{2.5}$ category (1–100 nm) and regulate all nanoparticulate ambient concentrations, or single out engineered nanoparticles as $PM_{2.5}$ or as VOC precursors (Ternes 2006). Nanoparticles could be listed as new-criteria pollutants under CAA Section 109, because they "may very well be $PM_{2.5}$, behave like VOC ozone precursors, or they may contain lead" (p. 16). Section 111 could also be used, if the EPA decides to regulate nanoparticles as criteria pollutants, in which case it would have authority to limit emissions from new stationary sources. Similarly, if the EPA listed nanomaterials as "hazardous air pollutants" (HAPs) under Section 112, it could then adopt MACT standards.

To add a pollutant to the HAP list, however, again the EPA must demonstrate that a substance presents a threat of "adverse human health effects." Given that there is no monitoring or exposure information for engineered nanomaterials, and few toxicological data, it would be difficult for the EPA to demonstrate adverse health effects. Moreover, again these regulations are based on mass, as are the exemptions; sources that emit less than10 tons a year of HAPs are exempted.

Mobile sources (cars, trucks, lawn mowers, etc.) also emit combustion-related nanoparticles, and the increasing use of nanoparticles-based fuel additives and emissions technologies may add to this. Sections 202 and 211 of the CAA may have some authority to require basic information about these types of nanomaterial uses, to require toxicity tests, and to regulate emissions (Simms 2007). The CAA also has general provisions (302, 303, 304) that provide the EPA with broad authority to "protect public health and welfare from air pollutant emissions" and to regulate "any air pollution agent or combination of such agents including their precursors" (Ternes 2006, p. 20). Section 303 allows the EPA to take emergency regulatory actions if it has evidence that a nanomaterial emission "is presenting an imminent and substantial endangerment to public health or welfare, or to the environment" (p. 20). According to this section, the EPA has "cease and desist" powers to order emissions to stop if it has such evidence. Citizens, further, can file suit against the EPA according to Section 304 if the EPA fails to perform any "nondiscretionary duty or act under the CAA" (p. 20).

Of course, data gaps make it highly unlikely that EPA CAA actions will be viewed as "nondiscretionary," so citizens would have little grounds for filing suit and little chance to succeed in such a legal effort. Further, many of the regulatory options under the CAA require health risk data for engineered nanomaterials, monitoring technologies, and methods for modeling life cycle impacts. None of the CAA regulations will be triggered without this information (Simms 2007). Perhaps more importantly, Simms

(2007) notes that historically the EPA has not been proactive, particularly when actions are discretionary—and in numerous cases when the actions are mandatory. The past track record of the EPA suggests that the agency is not likely to take *timely* actions; it is not likely to utilize or enforce CAA provisions regarding nanomaterials until a documented problem has already occurred (Simms 2007). Air pollution problems related to engineered nanomaterials are likely to be detected downstream by state and local agencies charged with detection and monitoring of particles and enforcement of air pollution regulations.

Nanotechnology Risk Data Gaps and the Clean Water Act

Compared to the CAA, which already regulates small particles and has at least some capacity to monitor and control them, the CWA has a much more limited capacity to address nanomaterials because it has never addressed small particles per se. Gaps in CAA statutes will also eventually affect waterways, since some (if not most) of the air emissions from production of engineered nanomaterials or products will enter water via air deposition.

Barker and others (2006) argue that the CWA generally provides the EPA with authority to regulate the discharge of nanoparticles as "pollutants." Again, several data gaps will make it difficult for CWA to regulate nanoparticles. The EPA would have to demonstrate that nanoparticles have "potential adverse effects on human health or the environment" before they could be regulated under the CWA. Before the EPA is required to create water quality standards, it must assemble a database covering "all known effects of specified nanoparticles in water bodies" (p. 5). Water quality effluent limitations in the CWA, similarly, require the EPA to demonstrate that the "water is adversely affected by the addition of nanoparticles to the water body" (p. 4). This information is not available currently and is not likely to be available for many years given current research funding levels and the time needed for such studies.

Limitations of current technologies for monitoring nanoparticles in water, just as in air, create significant barriers to implementing and enforcing various CWA statutes. For example, the ABA analysis notes that CWA Section 308 may be the best tool presently to gather information about nanoparticles that may be discharged to water from point sources (Barker and others 2006, p. 6). More specifically, it states, "If a facility that uses or manufactures nanoparticles is discharging to waters of the United States, EPA could utilize Section 308 to inspect the facility, obtain records, require discharge monitoring, and make reports to gain more information on the nature of nanoparticle discharges" (p. 7). It then goes on to note, however, that lack of appropriate monitoring technologies for nanoparticles could render the section "meaningless." Similarly, effluent guidelines could be developed under the CWA, but they must be "technology-based," so again, appropriate and economically feasible technologies to control nanoparticle releases into water have to be developed first.

Dealing with potential *nonpoint* sources of nanoparticles into water under the CWA involves a set of additional challenges, which are important because many of the current and anticipated uses for nanomaterials (e.g., consumer products and construction materials) have the potential to produce significant sources of nanoparticles into waterways through various waste streams, product wear, air deposition, and numerous other sources. The CWA charges the states with most of the responsibilities for investigating, identifying, and developing best management practices for nonpoint sources. Again, though, effective measurement technologies and identification of potential sources of nanoparticle diffusion must be developed before the states are required and able to do this. Further, in order to create and enforce adequate best management practices, states must have a certain amount of knowledge about nanoparticle sources, environmental fate, and transport.

Finally, CWA Section 402 (National Pollutant Discharge Elimination System; NPDES) requires the issuance of point source discharge permits based on effluent limitations for specific pollutants. These limitations, in turn, are based on technology-forcing standards and/or water quality protection standards. The NPDES requires routine monitoring of effluents to make sure they meet these limitations and routine reporting of these measurements for regulators and the public. Without reliable monitoring technologies for nanoparticles and technology to treat nanoparticles, these requirements cannot be met. Moreover, when there are no effluent limitations—as is the case with nanoparticles—source-specific "best management practices" are often prescribed in addition to or in place of numeric effluent limitations (Barker and others 2006, p. 10). Adequate best management practices cannot be developed without some knowledge about specific point sources of nanoparticles, where they are, what kinds of nanoparticles are being emitted, their behaviors in the environment, and available treatment technologies.

Given all of these factors, Barker and coworkers conclude that the CWA best management approaches are likely to be developed reactively rather than proactively. They admit that "the establishment of water quality-based effluent limitations may lag in time pending the performance of research on effects of the nanoparticle on various surface water receptors and designated uses" (Barker and others 2006, p. 10). Until field research is done and water quality standards are developed, NPDES permits for nanomaterials will likely be based on the “best professional judgments” of the permit writers at the state level.

How Nanotechnology Risk Data Gaps Challenge the Resources Conservation and Recovery Act

The RCRA was designed to “regulate the generation, transportation, management, and disposal of secondary materials that become solid or hazardous wastes” (Hester 2006). The statute is intended to assure that waste materials do not enter the environment in ways that will be detrimental to human or environmental health, by establishing a “cradle-to-grave” reporting system for hazardous wastes and setting technology-based standards for waste disposal sites (Davies 2006). This statute may already be relevant to nanotechnology, because nanomaterials that include known toxic substances (e.g., cadmium, lead, silver) are currently in production and in consumer products.

Although Hester (2006) concludes that the EPA could regulate discarded wastes that might include nanoscale materials under the RCRA, she notes several significant caveats to this authority. Nanomaterials would fall under the RCRA only if they meet the definition of hazardous wastes, but to date, no federal or state statutes have defined them as such. Nanomaterials also must be shown to pose “novel” environmental risks to fall under the RCRA.

Without knowing how companies plan to use and store recycled or nonrecycled nanomaterials, and what kinds of processes are being used to produce nanomaterials wastes, it will be difficult to assess the applicability of RCRA statutes. The EPA now relies on the “toxicity characteristic leaching procedure” to determine whether a waste is toxic, which is designed to model the releases that might occur in an unlined municipal solid waste landfill (Hester 2006). The EPA sets levels of constituents allowed to leach from the waste so that they will not exceed limits for drinking water. However, because there are so few data on whether nanomaterials’ movements and behaviors in soils and groundwater are different from larger materials’, the “EPA’s current assumptions for the toxicity characteristic may not fully assess how characteristically toxic wastes with nanomaterials might affect groundwater” (p. 8).

The RCRA also contains many potentially problematic exemptions from the “solid waste” and “hazardous waste” definitions, including several types of “secondary wastes” such as household hazardous wastes. Small-quantity generators (<100 kg) of nanomaterials would also be exempted from reporting their activities and waste storage plans, or only have to meet some of the requirements. Little is known about the amounts of wastes nanomaterial producers are generating at this point, but it is likely that a significant proportion of them would be considered small-quantity generators. Further, current RCRA exemptions for on-site storage (which many nanomaterial wastes are likely to meet) may also be problematic areas for nanomaterials if they do indeed pose unique hazards even in small amounts.

The RCRA also includes rules for facilities that treat, store, and dispose of hazardous wastes. Hester (2006) states that the “EPA should have the ability to promulgate regulations as needed to address novel environmental risks posed by the disposal of hazardous wastes containing nanoscale materials,” although the agency may want to make sure regulations are adequate for nanomaterials that might pose “unexpected or qualitatively different properties in groundwater, soils, or waste waters (p. 14). Of course, little is known about whether or not the nanomaterials that might end up in wastes exhibit qualitatively different properties, or about the efficacy of incineration or combustion as control strategies for nanoscale versions of hazardous constituents in incinerators, boilers, or industrial furnaces.

How Will Data Gaps Affect State and Local Agencies’ Abilities to Address Nanomaterials?

The ABA analyses notwithstanding, given current political realities, existing federal statutes are unlikely to address the potential environmental risks related to emerging nanotechnologies in proactive and preventive ways (Davies 2006). Although federal statutes provide some legal authority to address these risks, all of them are challenged by significant data gaps that will take years, if not decades, to fill and will make enacting mostly discretionary statutes unlikely. Further, the TSCA, which is intended to prevent toxic substances from being produced and going on the market in the first place, is rarely enforced and severely underfunded. Given this context, the CAA and CWA, which are “end-of-pipe” statutes to begin with, are likely to be used only if/when problems have already occurred.

Meanwhile, some of the engineered nanomaterials in production are likely to be in the environment now via emissions from production facilities and consumer products, and other engineered nanomaterials are likely to end up in the environment at some point in the future as production ramps up. In the following sections, we briefly review state- and local-level environmental regulatory responsibilities related to the CAA, CWA, and RCRA and then use Wisconsin as a case study to illustrate some of the specific data gaps and challenges that state regulatory agencies may face in addressing potential risks from nanotechnologies.

A Brief Review of State Responsibilities Under the Clean Water Act, Clean Air Act, and Resources Conservation and Recovery Act

Many key federal environmental regulations give substantial responsibilities to the states. Under the CAA, for example, once standards are set by the federal agencies, states are required to "calculate total emissions of that pollutant within an airshed and then to assign emission controls to each source of that pollutant sufficient to ensure that total emissions will meet air-quality standards" (Rosenbaum 2005, p. 158). States are asked to calculate how much each polluter contributes to the pollution load in the airshed area, and what level of emission control the polluter much achieve, to prescribe proper control technologies, and to enforce emission restraints on specific sources (Rosenbaum 2005). States have quite a bit of leeway on specific standards, emission levels, and how they are enforced.

Under the CWA, the EPA is authorized to delegate responsibility for enforcing most regulatory provisions to "qualified states that would issue permits to all polluters specifying the conditions for their effluent discharges" (p. 196). Currently, each state is required to have a plan for controlling nonpoint pollution, including "best management practices," which can be required or voluntary, depending on the state. The 1972 amendments to the CWA allowed states to decide on "designated uses" for water bodies that would permit "moderate to heavy pollution" (p. 197). Thirty-five states issue and enforce permits for effluent dischargers and initiate federal grants for building new local waste treatment facilities. In addition to dealing with point source emissions of pollutants to waterways, states are also responsible for the bulk of the responsibility for addressing nonpoint sources.

As far as nanoscale wastes, the EPA has delegated responsibility to 45 states to implement their own hazardous waste programs through the RCRA. States have the ability to impose more stringent hazardous waste management requirements than the EPA's, and "states may choose at a future date to regulate nanoscale wastes as listed hazardous wastes even if EPA has chosen not to impose such a listing," while other states "may wish to allow the use of nanoscale materials in a dispersive fashion into the environment" (Hester 2006, p. 15).

In sum, state and local agencies and their staff will deal with many of the most difficult and critical "on-the-ground" challenges related to emerging nanotechnologies, whether or not this is the most ideal regulatory strategy. State responsibilities will include identifying and monitoring actual emissions of nanomaterials into the environment, developing strategies for controlling emissions, and cleaning up pollution spills. Understanding the states' capacities to address these data gaps and responsibilities is critical to developing strategies to fill them.

How Data Gaps Challenge State Capacities to Address Risks: Wisconsin as a Case Study

Although many of the key nanotechnology risk data gaps facing state agencies are conceptually similar to those facing federal agencies, several of the most pressing practical and monitoring challenges that are key to enacting and enforcing federal and state regulations are state responsibilities, so they are likely to be more acutely felt at the state and local levels. To illustrate this, we briefly describe how data gaps challenge several key Wisconsin Department of Natural Resources (WDNR) programs and statutes.

Wisconsin Air and Water Management Programs

The Wisconsin Air Management Program (AM) works to maintain and improve Wisconsin's air quality in order to protect public health and the environment by monitoring the air for pollutants, inspecting emission sources, providing compliance assistance to industry, and operating a permit program. Data gaps that make it difficult to use state statutes parallel those that challenge federal agencies—lack of nanoparticles standards, as well as toxicity, monitoring, and exposure data. Wisconsin Act 118, for example, stipulates that in order to add a new air quality rule, one must show that there are *actual emissions* of the pollutant *and* that those emissions pose a human health risk. Even if monitoring techniques were available, there are no systematic data on where facilities that use and/or handle engineered nanomaterials are located—information that is necessary to know where to monitor in the first place.

The Wisconsin Watershed Management Program (WT) regulates municipal and industrial operations discharging wastewater to surface or groundwater through the Wisconsin Pollutant Discharge Elimination System (WPDES) permit program. The permit program is responsible for assessing the toxicity of wastewater effluent discharges, including the land application of industrial and municipal wastewater treatment sludge and by-product solids. For point source discharges, the WPDES program could require whole effluent toxicity (WET) testing for emissions of manufactured nanoparticles, along with proper treatment of such discharges. Nanotechnologies may also be used for in situ treatment of wastewater, but these uses are not covered by the WPDES. *Local* (city, county) governments have primary oversight of discharges to municipal wastewater treatment facilities.

Chapter NR 110, Wisconsin Adminstrative Code, provides the WDNR with the authority to review treatment processes for proposed *new* facilities and assure that they utilize appropriate treatment processes as needed to meet effluent standards. However, without the ability to detect and routinely monitor nanomaterials in wastewaters, it would not be possible to say whether or not effluents contain engineered nanomaterials, effluent toxicity (if found) is due to nanomaterials, or control and treatment processes are effective. Also, it is not known where nanotechnologies are being used or proposed for wastewater treatment or which Wisconsin industries are using nanomaterials that could be released in wastewater, so as with air emissions, agencies would not know where to monitor discharges for potential problems.

Wisconsin DNR Remediation and Redevelopment Program

Part of the responsibility of the Remediation and Redevelopment (RR) Program is to oversee the investigation and cleanup of environmental contamination. Within this program the use of nanotechnology could be covered under four main laws: s. 292.11, Wis. Stats (also known as the "spills law"), ch. 160, Wis. Stats, ch. NR 700 series, and ch. NR 140. The spills law outlines the regulatory process for the report and cleanup of a hazardous discharge. Again, data and regulatory gaps make it difficult to know whether or how this state law might apply to emerging nanomaterials. Do any nanomaterials fall under the definition of hazardous discharge? If certain nanoparticles are considered hazardous, in the event of a spill involving these nanoparticles, will current methods for cleanup be sufficient or will the cleanup process be different? These questions can only be answered once the toxicities, permeability, solubility, etc., of specific nanoparticles are determined.

Environmental cleanup activities involving the intended use of nanomaterials may also be overseen by the RR Program. Chapter NR 700, Wisconsin Administrative Code, provides general applicability and definitions for environmental cleanups in soil and water. Moreover, potential environmental remediation strategies, including the use of nanomaterials, could be covered under ch. NR 722. Chapter NR 140, Wisconsin Administrative Code, provides groundwater quality standards and specifies a range of acceptable responses when those standards have been exceeded, but does not describe or prescribe specific remedial methods. Some applications that use nanoparticles for remediation involve the use of injection wells, and this method of delivery needs both RR Program and Drinking and Groundwater (DG) Program approval under ch. NR 140. It is not clear whether ch. NR 140 covers the delivery of nanomaterials, but delivery of nanomaterials to groundwater could potentially be regulated under ch. 160, Wis. Stats. In addition, commercial treatment of contaminated soil needs both RR Program and Waste and Materials Management (WA) Program approval.

However, again, numerous data and regulatory gaps make it challenging to know how some of these sections apply. The auger/disking and air stripper methods for remediation do not require approvals from the WDNR, and it is not known whether any of these methods involve nanomaterials now or whether they might involve nanotechnologies in the future.

Waste and Materials Management Program

The Wisconsin WA Program focuses on waste minimization, pollution prevention, and proper management of solid and hazardous wastes, and encourages beneficial reuse of materials. The regulatory aspects of the program cover landfills, solid and hazardous waste storage and treatment facilities, waste transfer stations, and recycling. For example, ch. NR 500 and ch. NR 600 series require applicants for new waste facilities to identify and characterize waste types that are going to be accepted at the facility, and approvals limit the waste types that may be accepted. The ch. NR 600 series outlines what is considered hazardous waste for landfill purposes based on federal hazardous waste regulations, listing the characteristics of a material that categorize it as hazardous waste. Chapter NR 518, which deals with landspreading of wastes, requires most waste types to be physically and chemically characterized and approved.

Again, of course, data gaps make it difficult or impossible to apply these statutes. There are no agreed-upon identification and characterization standards for engineered nanomaterials, and monitoring technologies are not available, so we do not know where engineered nanotechnology waste materials might be, and at what levels. Moreover, political and economic factors are likely to create barriers to getting this information. Facility owners, for example, can challenge a WA Program decision to require identification of nanomaterials in a municipal waste stream, creating a disincentive for the agency to move in this direction.

Gaps in Awareness, Communication, and Training

Gaps in government staff and public awareness and training related to nanotechnology issues, along with potential communication gaps between producers/users of nanomaterials and the WDNR, are likely to play critical roles in how proactively any problems with nanomaterials that might arise are handled. In the case of an accidental discharge of nanomaterials, for example, in Wisconsin, the party responsible for the discharge ("responsible party"; RP), who might or might not be aware that the discharge contains nanomaterials, or that there might be risks, determines if there was a release of a hazardous substance and, if so, reports the release to the WDNR. If the RPs, who could be members of the general public or industries, are not aware that a spill includes nanomaterials and/or not aware of potential risks related to nanomaterials, they are likely not to report a hazardous substance release. If they do report a hazardous release, the RR Program will then work with them to determine what efforts are necessary to restore the environment, assuming they too are aware of and trained to deal with nanomaterial issues. Decisions to use nanomaterials for remediation are also made by responsible parties rather than WDNR staff, although RPs are required to report these uses to the RR Program. However, RPs can report their remediation activities whenever they want (including after they are completed), so the application of nanomaterials for remediation may not be known by the RR Program until after it is employed. Unfortunately, given likely gaps in public and agency staff awareness, and communication lags between the RPs and the DNR, the WDNR is likely to respond to any problems related to nanomaterials used for remediation after they have already entered the environment, rather than making sure they are used safely and in appropriate situations in the first place.

Discussion

In sum, significant data gaps are likely to make it difficult to enact or enforce many of the key federal and state environmental statutes that could in theory address the potential environmental risks related to engineered nanomaterials. Key gaps, diagrammed spatially in Fig. 1, include lack of critical information throughout the nanomaterial product cycle, from production of nanomaterials through their emissions into air, water, and waste. Gaps fall into the following categories: (a) nanomaterial production levels and nanomaterial-based consumer products on the market; (b) point air emissions of nanomaterials; (c) nonpoint air sources of nanomaterials; (d) point sources of nanomaterials into waterways; (e) uses of nanomaterials for wastewater treatment; (f) nonpoint water sources of nanomaterials; (g) amounts and types of nanomaterials in landfills, waste storage, and waste treatment facilities; (h) accidental releases of nanomaterials, and (i) intentional uses of nanomaterials for environmental remediation and treatment. Specific risk data gaps in each of these categories, and the federal and Wisconsin state statutes affected by them, are outlined in Table 1.

In addition to data gaps about what nanomaterials are produced and where they are emitted into air, water, and soil, basic research data gaps need to be addressed to understand both upstream and downstream human and ecosystem risks related to nanotechnology development. These gaps include (1) uncertainties about how to characterize nanomaterials and which parameters are most critical to measure, (2) lack of toxicity/ecotoxicity data for many nanomaterials, (3) sparcity of environmental fate/transport data, and (4) sparcity of human or environmental exposure data. These data gaps influence the data gaps in Table 1 in numerous ways, making adequate environmental and health risk assessments for engineered nanomaterials difficult and in some cases impossible (Nowack and Bucheli 2007).

Lack of detection, monitoring, and control techniques are especially critical data gaps—perhaps the most critical—for enacting and enforcing environmental regulations in a timely fashion, particularly those that are "technology-forced." Figure 2 illustrates the ways in which key risk assessment and policy decisions hinge on detection, monitoring, and control techniques, which are primarily state responsibilities. Under several of the key federal CWA and CAA statutes, for example, standards cannot be set or enforced without monitoring, control, and treatment technologies for air, water, and soils.

Fig. 1 Key environmental data gaps

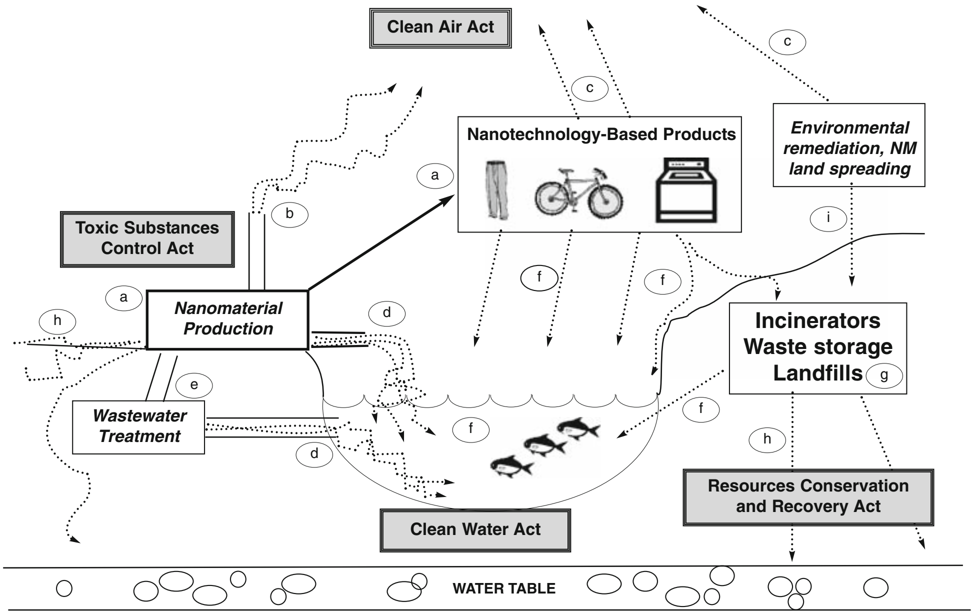

Table 1 Key risk data gaps and regulatory programs

Nanomaterial (NM) cycle (production through waste)	Key data gaps affecting federal & state regulatory programs	Federalprogram	Wis.program	Wis.statute(s) and Admin rule(s)
a. NM production	What NMs are being produced? How much? Where?	TSCA	All	S. 299.86
Air				
b. Point air sources of NMs (production facilities)	Where are NM air sources? What kinds/levels? Are they hazardous? How to identify/monitor/control?	CAA	AM	
c. Nonpoint air sources of NMs (breakdown from products, incineration, automotive uses, etc.)	What/where/how much NMs from nonpoint sources? Are they hazardous? How to identify/monitor/control?	CAA	AM	Wis. Act 118 s. 285, ch. NR 400
Water				
d. Point water sources of NMs (from production facilities, wastewater)	Where are NM wastewater sources? What kinds/levels? Are they hazardous? How to identify/monitor/control?	CAA	WT	WPDES permit program
e. Intentional uses of NMs for wastewater treatment	Are NMs being used for water treatment? Where Are NMs emitted? How to identify/monitor/control?		WT	S. 299.83, ch. NR 150
f. Nonpoint water sources of NMs (NM degradation from products, etc.)?	Where are NM water nonpoint sources? What kinds/levels? Are they hazardous? How to identify/monitor/control?	CWA	WT	Ch. NR 107
Waste				
g. NM in landfills, waste storage, waste treatment facilities	Where are NM wastes produced & stored? What//how much NMs emitted? Hazardous? How to identify/monitor/control?	RCRA	WA	Ch. NR 500, ch. NR 600
h. Accidental releases of NMs	Is NM spilled hazardous? Will existing cleanup methods be sufficient? How to identify/monitor/control?	RCRA	RR	S. 292.11, ch. NR 140
i. Intentional use of NMs for remediation and/or treatment	Are NMs being used for remediation now? What kinds? Where? Hazardous? How to identify/monitor/control?	RCRA	RR WA AM	Ch. NR 140, ch. NR 700, ch. NR 160

Note: All, all programs; TSCA, Toxic Substances Control Act; CAA, Clean Air Act; CWA, Clean Water Act; RCRA, Resources Conservation and Recovery Act; AM, Wisconsin (Wis.) Air Management Program; RR, Wis. Remediation and Redevelopment Program; WA, Wis. Waste and Materials Management Program; WT, Wis. Watershed Management Program

The data gaps diagrammed in Fig. 2, however, are intertwined and interdependent—creating tricky Catch-22 situations. Developing appropriate monitors is difficult without knowing which parameters of these materials are most critical to measure. Developing appropriate control techniques, in turn, requires the ability to monitor in order to know where controls are needed and whether the technique works. Lack of appropriate control technologies for nanomaterials is a critical barrier for regulators. As Rosenbaum (2005, p. 158) notes:

> Standards in clean air or water are only aspirations unless emission standards exist to prescribe the acceptable pollutant discharges from important sources of air or water contamination. If emission standards are to be effective, they must indicate clearly the acceptable emission levels from all important pollution sources and should be related to the pollution control standards established by policy makers.

The lack of toxicological data for many emerging nanomaterials is also a critical gap. Most environmental statutes cannot be enacted unless materials are first designated as "hazardous." Further, although the potential for human exposures to engineered nanomaterials could be significant in workplaces or via consumer products, there is little to no specific information about exposures to engineered nanomaterials. Lack of exposure data is a significant problem for statutes that are enacted based on actual or expected exposure levels (e.g., the TSCA). Again, exposure data gaps are shaped by other gaps; for example, without environmental or workplace monitors, risk assessors cannot gather human or environmental exposure data.

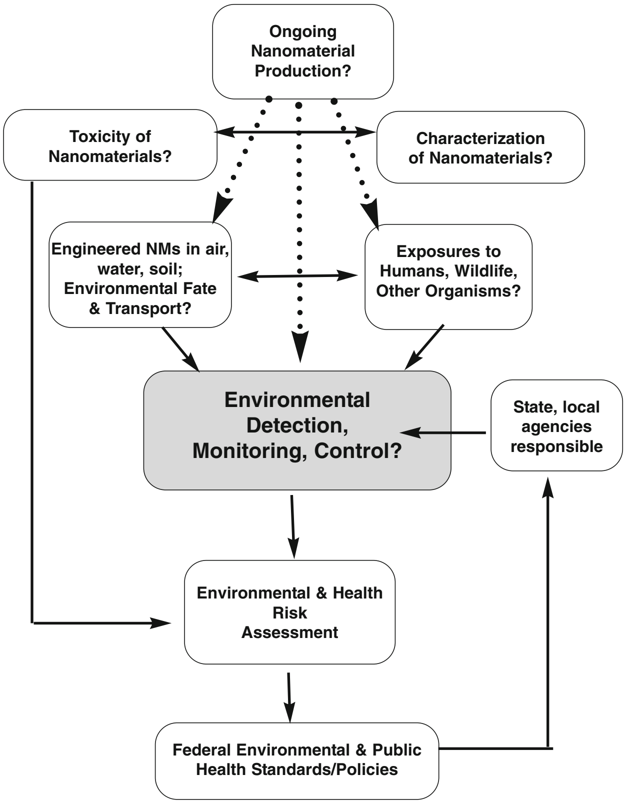

Fig. 2 Interactions between risk research gaps and regulations

Without both toxicity and exposure data, adequate risk assessments are not possible. Together, these gaps contribute to uncertainty about whether or not nanomaterials are "new" and whether or not they pose "novel" and significant risks to the environment and human health—key information for enacting preventive statutes such as the TSCA as well as many downstream federal and state regulations.

Should States and Localities Regulate Nanotechnology Risks?

Given risk data gaps and political realities, and the fact that key environmental regulatory responsibilities are delegated by federal statues to the states, state agencies are likely to face the brunt of the most difficult "on-the-ground" challenges dealing with potential environmental risks related to emerging nanotechnologies. Although federal and state regulatory agencies are dealing with similar risk and regulatory data gaps conceptually, they face different challenges in addressing these gaps in practice. Whereas federal agencies will develop models and appropriate environmental and health standards for nanomaterials based on research findings, state and local agencies need institutional and technological capacities to address monitoring and control challenges, waste management, spill cleanup, etc., on the ground. State and local agencies, moreover, will need to train people to do these tasks and write permits for nanomaterial wastes and nanotechnology applications.

To date, only a scattering of states and localities have begun efforts to regulate (or consider regulating) nanotechnologies. Berkeley, California, has developed its own reporting guidelines, and Cambridge, Massachusetts, is considering developing guidelines. Several states (California, Minnesota, New Jersey) are beginning to discuss environmental and health regulatory issues related to nanotechnology, but Wisconsin is the only state we are aware of (as of January 2008) that has an ongoing multiagency working group and white paper specifically to address the preparedness of its chief environmental agency (Department of Natural Resources) to address nanotechnology risk regulatory issues (Griffin and others 2006). The multiagency working group is developing nanotechnology risk scenarios that are likely to confront Wisconsin in upcoming years, and discussing coordinated cross-agency and policy strategies for addressing these potential risks proactively. Also, in December 2007, a Wisconsin legislator initiated an effort to work with state environmental and health agencies to develop a policy that would require a registry of what nanomaterials are being produced by industries in the state, at what levels, and other critical information necessary to address potential risks of nanotechnology developments (see Appendix 2 for more information about these efforts).

Perhaps prompted by the fact that cities and states are beginning to propose legislation to fill nanotechnology risk data gaps, in January 2008 the EPA finally released its long-awaited Nanoscale Materials Stewardship Program (NMSP), a voluntary reporting program in development for years. While some propose that federal-level nanotechnology approaches to addressing nanotechnology risks are most appropriate, and applaud the EPA voluntary reporting program, others expect the voluntary program to be ineffective—primarily because it is voluntary, provides no real incentives for industries to participate, requires only selective reporting, and includes several potentially problematic delays and loopholes (Denison 2008). Analyses of existing voluntary approaches suggest that they are not very effective unless they provide real incentives and mandatory deadlines after a certain amount of time (Hansen and Tickner 2007).

There are disadvantages and advantages to addressing nanotechnology risks at the state-level. Some argue that local- and state-level regulatory approaches to nanotechnology risks are inappropriate given substantial risk data gaps and will have a chilling effect on nanotechnology development (Monica and others 2007). Moreover, local- and state-level regulation may not make sense from a risk assessment and regulatory standpoint. Inconsistencies in how various local state agencies regulate nanotechnologies could cause a variety of cross-media problems and create incentives for companies to locate in states with more lenient regulations. Many large companies involved with nanomaterial research and development are multistate and/or international corporations. Emissions related to nanomaterial production will not be confined to a single medium (air, water, soil, etc.) or a specific locale or state.

Further, state agencies tend to be more vulnerable to pressure from regulated industries and other local interest groups than federal agencies (Rosenbaum 2005). For example, "regulated interests often are likely to press vigorously for a major state role in the administration and enforcement of water-quality standards, believing that this works to their advantage more than implementation through the EPA's regional and national offices" (p. 197). Under industry pressure, states often shape federal program implementation considerably through their own participation. For example, 35 states have assumed major implementation responsibilities for CWA statutes, often in pursuit of their own interests, "protecting the interests of the folks back home" (p. 197).

At the same time, there are some advantages to states and local agencies addressing potential nanotechnology risks and regulations. State agencies could fill in some of the most pressing nanotechnology-related environmental risk data gaps. For example, if adequate nanomaterial monitors are developed, and states and localities begin monitoring nanomaterial facility emissions and environmental media, they could help federal agencies develop standards that are based on *actual* nanomaterial emissions and exposures, rather than estimates based on general models with no empirical data. Moreover, if information about state- and local-level production facility locations and production volumes is gathered by state and local agencies, this information will be invaluable in filling key regulatory data gaps regarding current and potential human and environmental exposure levels.

Another distinct advantage to state and local agencies addressing these issues is that they know about local contexts that may affect nanomaterial production, monitoring challenges, appropriate control strategies, and which people and/or ecosystems are likely to be affected on the local and state levels. Staff at state and local agencies are familiar with their own institutional cultures and constraints, as well as various actors in their communities, geophysical settings, and the regulatory, political, economic, and cultural factors that shape the ways in which environmental issues are addressed. This contextual experience is invaluable for understanding how nanomaterial issues might be most effectively addressed and regulated within particular states or locales, and the potential barriers to addressing them effectively. Beyond compliance and voluntary programs, specific state programs, such as Wisconsin's Green Tier Program, could be valuable tools in the absence of traditional regulations. By working with industrial partners, staff at state agencies can create dialogues by which to foster communication to address data gaps and develop interim best management practices.

In practice, of course, the ways in which federal and state regulations are balanced are complex and often contentious. Regulatory approaches, emission controls, and monitoring standards for existing pollutants vary significantly among states, with some states being far more lenient than others. As Rosenbaum (2005, p. 193) notes, "States' haphazard water-quality monitoring creates massive information deficiencies that frustrate accurate national assessment." Moreover, there are intense political conflicts as a result of different state and federal viewpoints about EPA program implementation, and EPA program implementation at the state and federal levels can be continually affected by active intervention from the White House, Congress, and federal courts. The presidential administration and the makeup of Congress and the federal courts, of course, can shape federal and state regulations and funding in key ways. Ultimately, who is in the White House, and how much he or she values environmental and public health protection, will strongly influence whether or not research data gaps related to nanotechnology gaps are filled, as well as what kinds of regulations are developed (Rosenbaum 2005).

Conclusions and Recommendations

A key premise of this paper is that state and local environmental and public health agencies will likely face the most significant "end-of-pipe" challenges in addressing nanotechnology risk issues, regardless of whether or not this is an ideal regulatory strategy. The TSCA is not likely to effectively prevent toxic nanomaterials from entering the environment because of considerable risk data gaps, lack of funding and enforcement capabilities, numerous exemptions, and a variety of other factors. Downstream federal statutes, such as the CWA, CAA, and RCRA, are challenged by similar data gaps. Consequently, states and localities will likely be *reacting* to nanotechnology-related environmental problems that may arise in the future.

What can be done by government agencies and lawmakers now to address risk data and regulatory gaps in more proactive, preventive ways? Some of the most important data gaps challenging risk assessors and regulators would be addressed if the TSCA is actually applied to engineered nanomaterials and the statutes are enforced. However, nanomaterials are not designated as new at this point, and in many cases the TSCA is not enforced because data gaps make it impossible. If nanomaterials are designated as "new" under the TSCA, as some have proposed (Natural Resources Defense Council 2006), technically producers would be required to submit at least some information about nanomaterial production levels and types of nanomaterials produced, information that is critical to risk assessors. Most agree that this is not likely to happen any time soon, if at all.

To fill these gaps, we suggest that, at the minimum, regulatory actions requiring basic information from companies producing engineered nanomaterials are critical. Voluntary programs such as the recently launched NMSP are unlikely to be sufficient to provide the comprehensive data needed to be proactive because many nanomaterial producers are likely to opt not to report. Reporting requirements should include, at minimum, the levels and nature of nanomaterials produced and emitted. Nanomaterial producers should also be required to do "in-house" toxicity tests and make them available to regulatory agencies and the public. Further, regulatory actions could require companies to develop monitoring capabilities so that they can gather needed nanomaterial production emissions data and assist in tracking the fate of these materials. Existing research funds could also be allocated to assess available emissions data, determine where additional data are necessary, and to gather these data. Beginning now to get some baseline data is critical in order to know how emissions change over time or whether environmental and/or public health effects are related to these emissions.

Since state and local agency staff play such key roles in environmental monitoring, permit writing, and enforcement, funding and resources are necessary to provide adequate training for agency staff to understand nanotechnology risk and regulatory issues and how they relate to their professional responsibilities. Beyond providing funding, this is perhaps an area in which the federal EPA can become most engaged—for example, by holding periodic workshops to inform state agency staff about emerging nanotechnology developments and their potential environmental applications and implications.

A growing number of Web sites with a variety of nanotechnology risk and regulatory resources are now available (see Appendix 1). To prepare agencies in more substantial ways, additional funding should be allocated to encourage state agencies to perform independent studies on their state-specific resource, staffing, data, and regulatory needs. Other states could organize multiagency teams similar to Wisconsin's team—perhaps leveraging resources from government-funded nanotechnology research centers and industries in their states. With agency staff input, state agencies can build nanotechnology risk assessment and regulatory capacity programs that are appropriate for and accessible to their staff and relevant to their state's environmental, economic, political, and cultural contexts, while working with other state and federal agencies to make sure efforts are coordinated and resources are leveraged efficiently. Using data from state- and local-level research, federal agencies can begin to develop more informed and appropriate standards and policies for nanotechnologies and environmental and public health.

Last but not least, addressing important risk and regulatory gaps requires significantly more resources and funding. Unfortunately, U.S. government funding to date has been grossly inadequate to address pressing nanotechnology risk data gaps (Maynard and others 2006). The estimated 2008 National Nanotechnology Initiative (NNI) budget, for example, includes $10.2 million for the EPA, about 1% of the total NNI budget of the approximately $1.5 billion (National Nanotechnology Initiative 2008). Little of this 1% or other agency funding is targeted toward nanomaterial life cycle analyses or monitoring and tracking systems for engineered nanomaterials in the environment, clearly among the most critical research needs for preventing potential problems (Davis 2007). Further, little of the EPA funding is allocated to help states or localities develop personnel and communication resources and/or technical training to address emerging nanotechnologies. Without capacities to monitor engineered nanomaterials in the environment and workplaces, regulators and scientists will not be able to assess their overall risks to humans or the environment, develop and enforce appropriate regulations, or develop appropriate controls to prevent them from entering the environment if necessary. Clearly, considerably more funding should be allotted for addressing these critical data gaps now—so that we can anticipate and prevent potential environmental problems related to nanotechnology developments upstream, rather than reacting to them downstream.

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Appendix 1: Online Resources for Nanotechnology Environmental Health and Safety Information

- International Coalition on Nanotechnology (ICON) nano EHS Virtual Journal. http://www.icon.rice.edu/virtualjournal.cfm
- NanoSafe Web site. http://www.nanosafe.org/

- National Institute of Environmental and Health Sciences (NIEHS): "Risk e Learning" seminars on nanotechnology. http://www.niehs.nih.gov/research/supported/sbrp/events/riskelearning/index.cfm
- National Institutes for Occupational Safety and Health (NIOSH) resources. http://www.cdc.gov/niosh/topics/nanotech/rsources.html
- Oregon State Nanomaterial-Biological Interactions Knowledgebase. http://www.oregonstate.edu/nbi/pages/
- Project on Emerging Nanotechnologies (PEN) Web site. http://www.nanotechproject.org/
- SafeNano Web site. http://www.safenano.org/
- University of Wisconsin's Nanoscale Science & Engineering Center Nanotechnology Risk Resource Web site. http://www.nsec.wisc.edu/NanoRisks/NS-NanoRisks.php
- U.S. Environmental Protection Agency (EPA) Web site. http://www.es.epa.gov/ncer/nano/

Appendix 2: Local, State and Federal Efforts to Address Nanotechnology Risk Regulatory Data Gaps

1. *Wisconsin Department of Natural Resources (WDNR) white paper*. Martin Griffin at the WDNR organized a team of WDNR staff to examine the agency's preparedness for nanotechnology. In 2006, this team wrote a white paper outlining the specific challenges the WDNR might face related to nanotechnologies. For more information, visit the Web site, http://www.nsec.wisc.edu/NanoRisks/Nano_WhitePaper_Draft_FINAL_SECURE.pdf.
2. *Berkeley, California, Nanotechnology Disclosure Ordinance*. In 2006, Berkeley became the first city to adopt a specific law requiring the reporting of nanomaterial use, anticipated hazards, and safety plans. The ordinance requires facilities that produce or handle manufactured nanoscale materials within city limits to report what nanoscale materials they are working with and report plans for how they will handle these materials safely. It also requires them to describe any known toxic effects. For more information, visit the Web site, http://www.ci.berkeley.ca.us/uploadedFiles/Planning_(new_site_map_walk-through)/Level_3_-_General/Manuffactured%20Nanoscale%20Materials.pdf.
3. *Cambridge, Massachusetts, considers local nanotechnology regulations.* On January 6, 2007, the Cambridge City Council asked the city's Public Health Department to consider a Cambridge nanotechnology reporting statute on nanotechnology similar to Berkeley's ordinance and to review other local regulatory options. As of November 2007, the Cambridge Health Department was reviewing local regulatory options, including registration and reporting requirements, site visits to nanotechnology facilities, and the development of a Cambridge Nanomaterials Committee that would permit nanotechnology companies and facilities and then review nanosafety best practice protocols development by permit holders. For more information, visit the Web sites, http://www.cns.ucsb.edu/storage/conf/presentations/Sam%20Lipson.pdf and http://www.boston.com/business/technology/articles/2007/01/26/cambridge_considers_nanotech_curbs/.
4. *Wisconsin legislator Terese Berceau's Nanomaterial Registry Initiative*. In December 2007, representative Berceau of Wisconsin sent a letter to officials at several state agencies asking that they work with her to craft policy to address potential environmental problems associated with nanotechnology. Berceau is proposing the creation of a registry to gather information about what types of nanomaterials are being produced and handled by industries in Wisconsin, what kinds of monitoring methods are being used or created to track them, toxicological information, disposal information, and more. The letter can be found at http://www.thedailypage.com/media/2008/01/09/Berceau%20nanotech%20letter%20120307.pdf.
5. *EPA voluntary Nanoscale Materials Stewardship Program (NMSP)*. On January 8, 2008, the EPA launched the NMSP to encourage companies that manufacture, import, process, and/or use engineered nanomaterials to voluntarily submit information about these materials and their risk management practices. For more information, visit the Web site, http://www.epa.gov/oppt/nano/stewardship.htm.

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