Nanotechnology and the Environment: Will Emerging Environmental Regulations Stifle the Promise?

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INTRODUCTION

The United States and the European Union, in a manner that is consistent with the approach taken by each in the past with respect to emerging high technologies, are again taking divergent approaches to developing environmental regulatory programs for nanomaterials and nanoproducts. Because the market for nanomaterials and nanoproducts is global, it is not clear whether the potential inconsistencies that exist in these approaches could stifle the development and distribution of those materials and products. At the same time, however, independent voluntary standards-setting entities, such as the American National Standards Institute (ANSI) and the International Standards Organization (ISO), propose to develop standards for measuring and evaluating toxicity effects, environmental impact, risk assessment, metrology, and methods of analysis for nanomaterials. Because these "voluntary" standards will form the basis of any regulatory programs that are developed for nanomaterials, they could significantly influence the environmental regulatory programs that ultimately are developed in the United States and the European Union.

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1. ENVIRONMENTAL REGULATION OF NANOMATERIALS IN THE UNITED STATES

In the United States, the manufacture, use, transport and disposal of engineered nanomaterials currently is unregulated. Despite the novelty and unique features of these materials, the development of new environmental regulatory programs specifically tailored to nanomaterials is unlikely. Instead, existing regulatory programs such as the Toxic Substances Control Act (TSCA) and the Occupational Health and Safety Act (OSHA) likely will be applied, or adapted to apply, to the regulation of nanomaterials. However, environmental and health-based regulation of nanomaterials is unlikely to progress significantly until a standardized nomenclature for nanomaterials is developed.

1.1 The ANSI Nanotechnology Standards Panel (NSP)

At the end of last year, the ANSI NSP released its "priority recommendations" with respect to the need for nanotechnology standardization. Among the "broad standardization topics" identified by the ANSI NSP, the need for standardization was classified as "most urgent" in the following four areas: (i) general terminology for nanoscience and technology; (ii) systematic terminology for materials composition and features; (iii) toxicity effects/environmental impact/risk assessment; and (iv) metrology/methods of analysis/standard test methods. The ANSI NSP has recommended that standards be achieved in these areas within the next year.

Standards developed by voluntary standards-developing entities such as ANSI and the American Society for Testing and Materials International (ASTM) are quasi-regulatory in nature, and readily are incorporated into regulatory programs. This pattern is not uncommon in the United States, especially in the context of environmental regulatory programs. For example, after the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) was passed in 1980, ASTM developed standards for performing environmental site assessments to assess the potential presence and level of contaminants at commercial properties. Until recently, those standards provided the basis at both the federal and state level for determining whether a prospective purchaser of property had performed all appropriate inquiry in order to qualify as an innocent purchaser. ASTM, which is accredited by ANSI, is a member of the ANSI NSP, and announced in January of this year its likely involvement in developing standardized nomenclature for nanomaterials. It should be assumed that any ANSI NSP and ASTM standards that are developed for the purpose of measuring the toxicity effects of nanomaterials, as well as assessing the potential environmental impacts and risks associated with the manufacture, use, and disposal of nanomaterials, will be used in a similar manner.

ANSI also is the only U.S. representative to the ISO and the International Electrotechnical Commission (IEC), key international standards-developing bodies. ANSI promotes the use of U.S. standards internationally, and advocates for the adoption of those standards at the international level via ISO and IEC. Similarly, the British Standards Organization

already has proposed that ISO develop nanotechnology standards that would provide suitable instruments for the evaluation of risk and the protection of health and the environment. Once an ISO standard is developed (as evidenced by the prior issuance of the ISO 14000 International Environmental Management Standards), it frequently takes on a quasi-regulatory effect and forms the basis for determining the adequacy of environmental-related activities on a world-wide basis.

The standards being developed by ANSI NSP, and ultimately by ISO, will have a tremendous impact on the future direction of nanotechnology development both in the US and internationally, especially in the area of environmental regulation. For this reason, entities interested in the development of nanomaterials should actively monitor and participate in the standards-development process for nanomaterials that is currently underway.

1.2 TSCA: New or SNU?

One of the most intriguing legal questions concerning the environmental regulation of nanomaterials in the United States is whether the Environmental Protection Agency (EPA) will treat nanomaterials as "new" chemical substances under existing environmental laws that regulate the manufacture and use of chemical substances, such as TSCA. The two key aims of TSCA are to ensure that adequate risk assessment data are developed with respect to a given substance, and appropriate actions are taken, using regulations based on those data, to mitigate human and environmental exposure to any unreasonable risk. Prior to manufacturing or using a "new chemical substance," TSCA requires chemical manufacturers and importers to submit a pre-manufacture notification (PMN) and risk assessment information to the EPA.

Subject to certain exemptions, manufacturers of nanomaterials will be required to comply with TSCA's PMN requirement in the event that EPA determines that nanomaterials constitute "new chemical substances." Alternatively, EPA may determine that certain nanomaterials are Significant New Uses (SNU) of existing chemical substances. For example, the same Material Safety Data Sheet (MSDS) for graphite potentially could be used for carbon nanotubes (CNTs), fullerenes, and carbon black. In fact, a review of MSDSs for various CNTs currently available for sale indicates that manufacturers have used a range of Chemical Abstract Registry (CAS) numbers, including those of graphite and carbon. However, because common elements like carbon behave very differently at the nano-scale, EPA could find that the manufacture of CNTs, for example, constitutes a SNU; and last year EPA staff indicated that the Agency is likely to do so. Such a determination would require manufacturers to file, subject to certain exemptions, a PMN with the EPA.

Recently, a CNT manufacturer applied to EPA for a low-volume exemption (LVE) to manufacture single walled CNTs under TSCA. If EPA determines that the CNTs are covered by an existing TSCA Inventory listing (*e.g.*, for carbon), the LVE application would be denied as unnecessary. If, however, EPA grants the application, its decision may signal the Agency's determination that such CNTs do not fall within the definition of Inventory-listed substances, or constitute a significant new use of listed substance(s). EPA's decision on that filing is expected soon.

Under TSCA, the manufacturer or importer of a substance that has been determined to be a SNU must file a PMN at least 90 days before it plans to begin manufacturing or importation. Along with the PMN, the entity must provide data that it believes will show that the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment. There are very far-reaching requirements concerning the test data that must be provided. In essence, all data related to health and environmental effects in the possession, custody or control—defined broadly to include several categories of related corporate entities if they are associated with the research, development, and marketing of the substance—of the company must be submitted to EPA. Additionally, any other data known to the Company concerning health and environmental effects must be described in the PMN, as far as "reasonably ascertainable." Further, EPA may require testing where it determines unreasonable risk may exist and existing data on health and environmental effects are insufficient. These data submission requirements highlight the need for businesses to think carefully about the designs for any studies, engage qualified experts to assist, consult with counsel early on, and maintain records of data developed to ensure full TSCA compliance.

2. ENVIRONMENTAL REGULATION OF NANOMATERIALS IN THE EUROPEAN UNION

Similar to the situation in the United States, the manufacture, use, transport and disposal of engineered nanomaterials currently is unregulated in the European Union. Unlike the United States, however, the novelty and unique features of these materials make it likely that the European Union will develop new environmental regulatory directives that are specifically tailored to nanomaterials. In the meantime, member states with existing environmental regulatory programs that apply to chemical substances, such as the United Kingdom, likely will apply those programs (either directly or after adaptation) to regulate nanomaterials as new chemical substances.

2.1 The Precautionary Principle

The European Union (EU) was created in its current form in 1993, and currently has 25 member states (with the applications of four additional states pending). Within the EU, the European Commission (EC) is responsible for proposing

legislation (in the form of "directives"), as well as the administration and enforcement of enacted legislation.

The so-called "precautionary principle" forms the basis for all environmental directives that are under consideration or have been issued by the EC. The approach envisioned by the precautionary principle stands in direct contrast to that under TSCA, in that under the precautionary principle a manufacturer may be restrained from manufacturing and distributing a material unless it can conclusively demonstrate that the material is "safe."

According to the EC, the precautionary principle acts to ensure a high level of protection of the environment and of human, animal and plant health whenever the available scientific data do not permit a complete evaluation of the potential risk. The precautionary principle may be invoked when the potentially dangerous effects of a new product or process – such as those related to the development of nanomaterials and nanoproducts – have been identified through a scientific evaluation that does not allow the level of risk to be determined with a sufficient degree of certainty. In such a case, the burden of proving that a material is "safe" is shifted to the manufacturer, and distribution of the material can be halted unless the manufacturer can "prove the negative" and meet this burden of proof.

2.2 REACH

In 2003, the EC proposed a comprehensive system, known as REACH (for Registration, Evaluation, and Authorisation of Chemicals), that would impose greater responsibility on industry to identify and manage the risks associated with chemical substances and ensure that safety information concerning these substances is provided to regulatory agencies and the public. At its core, REACH would reverse the burden of proof from public agencies to industry for ensuring the safety of any chemicals that are introduced into the EU market. As such, REACH would replace over 40 existing Directives and Regulations, and would fully implement the precautionary principle with respect to both existing and new chemical substances. Direct costs to industry that are associated with the implementation of REACH have been estimated to total 2.3 billion euros over an 11 year initial period. Over a 50 year period, it has been estimated that the costs of REACH to both industry and end-users could total 50 billion euros over a 30-year period.

Numerous concerns have been raised – by EU member states, industry, and even the United States government – concerning the high regulatory costs and burdens associated with implementing the REACH proposal. In response to those concerns, the EC has signaled that it is prepared to make major changes in the proposed legislation. Key changes under consideration include prioritizing the testing process for more than 50,000 chemicals, based on volume and toxicity considerations, as well as implementing a "one substance, one registration" system for all chemicals. At this time, it is not known whether formal amendments to the REACH proposal to implement these revisions will be made after the first reading of the legislation in the second half of 2005, or if the first reading will be postponed so that the revisions can first be made.

2.3 The EU's Proposed Environmental Approach to Nanotechnology

Environmental issues concerning the EU fall within the jurisdiction of the European Environmental Agency (EEA). The EEA recently developed its Sixth Action Programme for the Environment, which establishes the environmental priorities for the EU for the period from 2001 through 2010. These priorities include the management of natural resources and waste, and the development of an integrated product policy. In the context of nanomaterials and nanoproducts, the management of waste materials generated and the development of "end-of-life" vehicles is of primary importance.

In December 2004, the EC released a formal communication entitled "Towards a European Strategy for Nanotechnology." In that communication, the EC stressed that nanotechnology must be developed in a safe and responsible manner. As such, the EC urged that any potential public health, safety, environmental and consumer risks be addressed up front by generating the data needed for risk assessment, integrating risk assessment into every step of the lifecycle of nanotechnology-based products, and adapting existing methodologies (and, as necessary, developing new ones) for the regulation of nanomaterials and nanoproducts. Until that strategy is implemented, the EC has advised member states to make maximum use of their existing regulatory programs to address public health, worker and consumer safety, and environmental protection issues that may arise as a result of the manufacture and use of nanomaterials and nanoproducts.

2.4 Independent Observations

Concerns regarding potential environmental and health-related impacts associated with the widespread manufacturing and use of nanomaterials is not limited to the EC or its member states.

In July 2004, The Royal Society and The Royal Academy of Engineering released a comprehensive report on the opportunities and uncertainties associated with nanoscience and nanotechnologies (the "Royal Report"). The Royal Report noted that there is virtually no information available about: the effect of nanoparticles on species other than humans; how nanoparticles would behave in the air, water, or soil; or their ability to bioaccumulate in the food chain. As a result, the Royal Report recommended that, as a precautionary measure, entities producing nanoparticles and nanotubes should treat those materials as if they were hazardous and remove them from their waste streams. In addition, the Report recommended that the use of free nanoparticles in environmental applications (such as the remediation of groundwater) be prohibited. Finally, the Royal

Report concluded that chemicals produced in the form of nanoparticles and nanotubes should be classified as new chemical substances under both the existing and proposed regulatory frameworks present in the UK and the EU.

In 2004, Swiss Re, the world's second largest insurer, released a report that highlighted numerous questions related to the opportunities and potential hazards associated with nanotechnology. While Swiss Re was careful not to sound an alarmist cry, it nevertheless questioned whether nanotechnology would, despite its potential to be used in innovative and beneficial applications, suffer the same fate as did asbestos. As a result, Swiss Re concluded that, in the absence of an existing regulatory scheme that applied to nanotechnology, a new nano-specific framework of regulation is needed, along with an internationally valid system of standardization of nanomaterials.

3. CONCLUSION

A large degree of uncertainty remains regarding the shape of the environmental regulatory programs that will be developed and implemented in the United States and the European Union with respect to nanotechnology. Whether those programs will restrict, either by design or through inconsistencies, the manufacture and use of nanomaterials on a global basis is an open question. Current events indicate, however, that the development or refinement of those programs will be based, in substantial part, on the nomenclature and risk assessment standards that independently are being developed by organizations such as ANSI, ASTM, and ISO. At a minimum, those standards could lead to nanomaterials being regulated as either new chemical substances or significant new uses of existing chemical substances.

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