

February 14, 2006

MEMORANDUM**Nanotechnology Regulatory Developments**

As companies press forward in the development and commercialization of ever more innovative nanomaterials, uncertainty over the United States Environmental Protection Agency's (EPA's) regulation of nanotechnology continues to grow. In December 2005, EPA's Nanotechnology Workgroup (NWG) issued a Nanotechnology White Paper (External Review Draft) as part of its efforts to describe the issues EPA must address to better understand any potential risks from exposure to nanomaterials in the environment. Although the document, summarized below, provides some key recommendations for further research by EPA and identifies the Agency's current regulatory framework, the regulatory uncertainty confronting industry remains largely unresolved.

Currently, companies involved in nanotechnology must make regulatory decisions about their products under EPA's existing environmental statutes, with very little official guidance. In light of these concerns, and to ensure that consumers of nanotechnology products will not be exposed to unacceptable risks, the Woodrow Wilson International Center for Scholars, a public-private research institution, in January called for Congress to enact a new federal statute governing the regulation of nanotechnology. Beveridge & Diamond, P.C. is actively monitoring EPA's management of nanotechnology and will continue to provide updates regarding developments in this area.

I. WHAT IS NANOTECHNOLOGY?

A nanometer is one billionth of a meter (10^{-9} m), about one ten-thousandth the diameter of a human hair, a thousand times smaller than a red blood cell, or about half the size of the diameter of DNA. Unfortunately, there is not yet any widely accepted standard definition for nanotechnology. However, for purposes of the White Paper, the NWG defines nanotechnology as:

research and technology development at the atomic, molecular, or macromolecular levels using a length of scale of approximately one to one hundred nanometers in any dimension; the creation and use of structures, devices and systems that have novel properties and functions because of their small size; and the ability to control or manipulate matter on an atomic scale.¹

¹ EPA, White Paper at 4. The United States Department of Energy's (DOE's) National Nanotechnology Initiative website provides a diagram illustrating the relative scale of nanomaterials, at http://www.nano.gov/html/facts/The_scale_of_things.html.

This definition excludes unintentionally produced nanomaterials like diesel exhaust particulates, or naturally occurring nanomaterials such as viruses and volcanic ash. Nanotechnology can be used to change a molecule's size; to arrange the atoms of a chemical to change its molecular shape, surface area, and its ability to conduct electricity; and to adjust other properties that might alter the chemical's effect on the human body or the environment.

II. IMPLICATIONS OF NANOTECHNOLOGY

A. Commercial Applications of Nanotechnology

Many products containing nanomaterials are already available in U.S. markets. These products include coatings, computers, clothing, cosmetics, sports equipment, and medical devices. About \$2 billion in annual research and development is currently spent by non-governmental U.S. sectors, including states, academia and private industry, while global nanotechnology research and development spending is estimated at around \$9 billion.² The NWG estimates that global sales of nanomaterials could exceed \$1 trillion by 2015.

The NWG also notes that the convergence of nanotechnology and biotechnology (defined generally as the use of microorganisms or bacterial "factories" to produce molecules like amino acids) is expected to rapidly accelerate in the coming decades. For example, researchers have extracted photosynthetic proteins from spinach and coated them with nanofilms to convert sunlight to electrical current, which one day may lead to energy generating films and coatings. Most dramatically, the potential exists in the next two decades to see the invention and production of nano-sized robotic devices with self-assembly capabilities and integrated with advanced information, biological, and cognitive technologies.

The NWG recognizes that nanotechnology has the potential to affect many sectors of American industry, including consumer products, health care, transportation, energy, defense, homeland security, and agriculture, while simultaneously presenting new opportunities to improve how environmental pollution is measured, monitored, managed, and minimized. EPA has spearheaded research in the development of the use of nanomaterials for environmental clean-up -- including the development of nanometer-sized biological sensor devices that can detect specific biological and chemical contaminants within the natural environment, process the accumulated data, determine the import of that data, and provide a specific response such as the release of a certain amount of biological or chemical compound or the removal or transformation of a compound -- and in understanding the disposition of nanomaterials in biological systems.³

² International organizations involved in nanotechnology issues include the Asian-Pacific Economic Cooperation (APEC), the British Standards Institute (BSI), the National Institute of Standards and Technology (NIST), the American Society of Testing Materials (ASTM), and the Organization for Economic Cooperation and Development (OECD) (under the auspices of the Joint Meeting of the Chemicals Committee and Working Party of Chemicals, Pesticides and Biotechnology).

³ For example, chloro-organics are a major class of contaminants at U.S. waste sites and several nanomaterials, such as zero-valent iron, have been applied to aid in their remediation.

B. Potential Hazards Related to Nanotechnology

Of course, the same properties that make nanomaterials useful may also raise issues regarding potential hazards to humans and the environment. For example, the NWG notes that some nanomaterials that enter animal tissues may be able to pass through cell membranes or cross the blood-brain barrier; inhaled nanomaterials may become lodged in the lung; and the high durability and reactivity of some nanomaterials may raise issues of their environmental fate.

As the use of nanomaterials in society increases, it is reasonable to assume that their presence in the environment will also increase, with consequences for human and environmental exposure. The NWG acknowledges that there is currently not enough information to assess environmental exposure for most nanomaterials, but the White Paper indicates that the overall risk assessment approach used by EPA for conventional chemicals is thought to be generally applicable to nanomaterials. The challenge of detecting nanomaterials in the environment, however, is compounded both by the extremely small size of the particles and their unique physical and chemical characteristics. The NWG states that there is a “significant gap” in knowledge of the environmental, health, and ecological implications associated with nanotechnology.⁴

III. CURRENT EPA NANOTECHNOLOGY ACTIVITIES

Currently, EPA is:

- participating in DOE’s National Nanotechnology Initiative (NNI), which coordinates research and development across 24 federal agencies (including the National Institutes of Health (NIH), the National Institute of Occupational Health and Safety (NIOSH));
- funding nanotechnology research through the Agency’s Science To Achieve Results (STAR) grant program and Small Business Innovative Research (SBIR) program;
- collaborating with scientists internationally to share information;
- initiating the development of a voluntary pilot program for the evaluation of nanomaterials and reviewing new chemical submissions (premanufacture notifications) under the Toxic Substances Control Act (TSCA) in the Office of Pollution Prevention and Toxics (OPPT) with a decision expected on implementation by this fall; and

⁴ Section 4 of the White Paper provides a detailed assessment of the current thinking regarding potential risks of nanomaterials.

- reviewing the potential health effects of nanomaterial components of new gasoline, diesel fuel, and fuel additives registered by the Office of Air and Radiation/Office of Transportation and Air Quality (OAR/OTAQ).

Since 2001, EPA has providing funding for the development of: (1) low-cost, rapid, and simplified methods of removing toxic contaminants from surface water; (2) new sensors that are more sensitive for measuring pollutants; (3) “green manufacturing” (improving manufacturing processes by increasing material and energy efficiency, reducing the need for solvents, and reducing waste products); and (4) more efficient, selective catalysts. EPA intends to review nanomaterial products and processes as they are introduced, pursuant to its authorities under TSCA, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the Clean Air Act (CAA), working with producers and users of nanotechnology to prescribe protocols and approaches that limit exposure and address any potential risks.

IV. REGULATORY FRAMEWORK

The White Paper outlines the environmental statutes relevant to EPA’s evaluation and management of nanotechnology’s risks and benefits, noting that some current EPA policies and regulations may require modifications to address nanotechnology and that until adequate nomenclature conventions are developed, it will be difficult to determine if reporting to EPA is required. For example, there are unresolved questions regarding whether nanomaterials are covered by current chemical substance listings on the TSCA inventory (which determines whether premanufacture notifications are required), or whether use of a nanomaterial may result in a change to a pesticide product already registered under FIFRA (which could result in the need for further EPA review and approval).

A. TSCA

Under TSCA § 5(a), Premanufacture Notices (PMNs) must be submitted to EPA by a person intending to manufacture or import “new” chemical substances, *i.e.* those not on the TSCA Inventory of Chemical Substances. Nanomaterials that are “chemical substances” under TSCA and not on the TSCA Inventory must be reported to EPA. Use restrictions, occupational exposure limits/controls, limits on releases to the environment, and limits on manufacture may be required until toxicity and fate data are developed to better inform a risk assessment of the chemical. If EPA determines by regulation that use of a chemical substance is a “significant new use” under TSCA § 5(a)(2), companies must submit notice to EPA at least 90 days before they manufacture, import, or process the substance for that use.

Voluntary and regulatory measures for evaluating nanomaterials are being developed and implemented by EPA under TSCA. For example, the Agency is currently developing a Nanoscale Materials Voluntary Program (“NVP”), which is intended to encompass engineered nanomaterials now in or soon to enter commerce, regardless of whether those materials would otherwise qualify for existing TSCA exemptions or fall below TSCA reporting thresholds. The NVP would help EPA develop the capacity and process needed to identify and assess potential risks of nanomaterials and determine what information the Agency will need to develop a comprehensive regulatory approach to nanomaterials under TSCA. Although OPPT is already

reviewing new chemical submissions for nanomaterials under TSCA, in light of the above nomenclature issues, companies are currently determining on their own whether current inventory listings are sufficient to cover their nanomaterials and their approaches may not be consistent with each other or with EPA policies that may ultimately be developed to address the issue.

B. FIFRA

Under FIFRA §§ 3 and 12, EPA must approve all new pesticide products, as well as new uses and changes in the composition of existing pesticide products, before the products may be sold or distributed in commerce. In order to evaluate an application for registration, EPA requires the applicant to provide a complete characterization of the composition of the product, proposed labeling which describes the intended use of the product, and the results of extensive health and safety testing. Using this information, EPA determines whether the product may “cause unreasonable adverse effects on the environment,” including risks to human health. Nanomaterials added to an existing pesticide product may require renewed EPA approval.

C. CAA

The CAA contains a number of provisions that need to be considered in determining its applicability to nanotechnology: CAA § 108, which directs EPA to identify pollutants which “may reasonably be anticipated to endanger public health and welfare” and to issue air quality criteria for them, and CAA § 109, which directs EPA to promulgate National Ambient Air Quality Standards (NAAQS) for these pollutants; Title III of the 1990 CAA Amendments, which directs EPA to identify the sources of 189 pollutants and issue technology-based emissions standards for each source category; and CAA § 211, which provides EPA with the authority to designate any mobile source fuel or additive for registration.⁵

D. The Pollution Prevention Act (PPA)

Under the PPA, EPA established OPPT, which initiated two programs: the Design for the Environment (DfE Program), through which EPA works in partnership with industry sectors to improve performance of commercial processes while reducing environmental risks; the Green Chemistry Program, which promotes research to design chemical products and processes that reduce or eliminate the use and generation of toxic chemical substances; and the Green Engineering Program, which applies approaches and tools for evaluating and reducing the environmental impacts of processes and products.

E. The Clean Water Act (CWA)

If a wastewater stream of nanomaterials is produced, it will be subject to effluent guidelines under the CWA.

⁵ OAR/OTAQ has received and is reviewing an application for registration of a diesel additive containing cerium oxide, intended to decrease emissions and potentially lead to fuel economy benefits.

F. The Safe Drinking Water Act (SDWA)

The SDWA authorizes EPA to establish non-enforceable health-based Maximum Contaminant Level Goals (MCLGs) and enforceable Maximum Contaminant Levels (MCLs) or required treatment techniques. Nanotechnology has the potential to influence the setting of MCLs through improvements in analytical methodology or treatment techniques, or by nanomaterials themselves entering drinking water and qualifying for regulation as drinking water contaminants.

G. The Comprehensive Environmental Response Compensation and Liability Act (CERCLA)

CERCLA gives EPA the authority to respond to actual or threatened releases of environmental pollutants or contaminants that may present an imminent and substantial danger to public health. Nanomaterials that meet these criteria would be subject to this authority.

H. The Resource Conservation and Recovery Act (RCRA)

RCRA regulates the transportation, treatment, disposal and cleanup of hazardous wastes. Nanomaterials that meet the definition of RCRA hazardous wastes would be subject to these regulations.

I. The Emergency Planning and Community Right to Know Act (EPCRA)

EPCRA established the Toxic Release Inventory (TRI) Program, setting up a publicly available database containing information on toxic chemical releases and other waste management activities that are reported annually by facilities. Some producers of nanomaterials may be subject to reporting under the TRI Program if releases of nanomaterials are found to be toxic. Nanomaterials that are “hazardous chemicals” for which material safety data sheets (MSDSs) are required would also trigger the reporting required by EPCRA’s emergency planning provisions.

V. KEY RECOMMENDATIONS

The NWG makes several major policy recommendations in its White Paper:

- **Pollution Prevention, Stewardship, and Sustainability:** EPA should engage resources and expertise in the development of approaches that promote pollution prevention, sustainable resource use, and good product stewardship in the production and use of nanomaterials. In addition, EPA should draw on new nanotechnologies to identify ways to support “green energy” and “green manufacturing.”

- **Research:** EPA should undertake and support research to better understand and apply information regarding nanomaterials' (1) chemical identification and characterization; (2) environmental fate; (3) environmental detection and analysis; (4) potential releases and human exposures; (5) human health effects; (6) ecological effects; and (7) environmental technology applications.
- **Risk Assessment:** EPA should conduct case studies on several engineered/manufactured nanomaterials to identify unique considerations for risk assessments on nanomaterials.
- **Collaboration and Leadership:** EPA should expand its collaborations regarding nanomaterial applications and potential human health and environmental implications.
- **Cross-Agency Workgroup:** EPA should convene a standing cross-Agency workgroup to foster information sharing on science and policy issues.
- **Training:** EPA should expand its nanotechnology training activities for scientists and managers.

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