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Engineering at the Atomic Scale

Nanotechnology presents novel environmental, health and safety issues

By James Stewart and
Michael J. Caffrey

Nanotechnology is essentially engineering at the atomic scale. At this scale, materials begin to exhibit distinct properties that affect their physical, chemical and biological behavior. Many believe that these distinct properties provide unlimited possibilities for products and applications. Government, industry and academia have invested heavily in research and development of nanoscale materials with many products and applications already in use and thousands more to be introduced over the next decade. Recognizing that little is known about the potential risks to human health and the environment from nanoscale materials, federal agencies are now contemplating how best to evaluate the risks associated with nanoscale materials and how to manage those risks.

The term “nanotechnology” comes from the Greek word “nanos,” meaning dwarf. A nanometer is one thousand millionth — one billionth — of a meter. Nanotechnology generally does not

Stewart is shareholder of Lowenstein Sandler of Roseland and a member of its environmental department. Caffrey is counsel and a member of the firm’s environmental department.

refer to a specific technology at all. Nanotechnology frequently refers to items that have a length scale of one to one-hundred nanometers.

At this scale, materials begin to exhibit distinct properties that affect their physical, chemical and biological behavior — such behavior may be different than the behavior of the same materials at larger scales. Particles less than 50 nanometers are no longer subject to the laws of classical physics, but those of quantum physics. Such nanomaterials also have an increased surface area compared to their mass. The relatively greater surface area of nanomaterials makes them more reactive. Nanomaterials can exhibit surprising changes in behavior. For example, electrically insulating substances may become conductive and insoluble substances at larger scales may become soluble at the nanoscale.

Nanomaterials are not entirely creations of man. There are nanomaterials that exist in nature. They tend, however, to agglomerate and thereby increase their size beyond the nanoscale. When they agglomerate and increase in size, they become subject to the normal rules of physics and operate on terms that can be dealt with immunologically through the body’s immune system and other protective mechanisms and environmentally through regular filtration and

treatment systems.

Manmade nanomaterials are specially coated to prevent their agglomeration. These coatings allow the beneficial characteristics of the nanomaterials to continue unimpeded by the natural tendency to agglomerate. At the same time, however, the risks presented by nanomaterials remain.

On a nanoscale, the mobility of materials can change. Coated nanoparticles can be very mobile in the environment. Once airborne, they can drift endlessly; largely unaffected by gravity, they no longer settle on surfaces and become an inhalation risk. If they cease to be airborne, they can move through soil particles and in water. Their small size makes them very difficult to filter out of water.

The mobility of nanoparticles makes them a unique exposure risk. Inhalation of nanoparticles and the subsequent movement of those particles into the blood stream is highly likely. Ultra-fine particles, including nanotechnology materials, cause significant damage to lung tissue because they penetrate deeply into the lungs. Most inhaled particles are exhaled, but particles that penetrate the lungs more deeply remain in the lung tissue without being exhaled. As the lungs exchange oxygen with blood, the nanoparticles enter the blood stream and become absorbed by blood cells.

Some nanoparticles may get into the body through the digestive tract. If nanoparticles are ingested through drinking or eating, these particles can then be absorbed in the intestinal tissue.

Once in the blood stream, they move freely throughout the entire body. There is currently concern that nanoparticles may have the ability to pass through the blood/brain barrier and present additional unique health risks.

Nanotechnology is not some development in the far-off future. Nanomaterials are being used now by industry in electronic, magnetic, biomedical, pharmaceutical, cosmetic, energy, catalytic and materials applications. Commercially available products include nanoscale powders, metal cutting tools, paints and coatings to protect against corrosion, stain-free clothing, inks, and burn and wound dressings. Nanotechnology products are currently being applied to human skin and used in medical materials. Nanoscale titanium dioxide is used in cosmetics and sun block creams. Nanoscale silica is being used as a filler in a range of products, including dental fillings.

The United States government is a strong proponent of nanotechnology and through the National Nanotechnology Initiative (NNI) has made nanoscale science, engineering and technology one of its top research priorities. Government, industry and academia in New Jersey are also at the forefront of nanotechnology research and commercial development. For example, the New Jersey Nanotechnology Consortium, LLC, headquartered at Bell Labs in Murray Hill, is one of the first U.S. companies to focus on developing and commercializing nanotechnology products, bridging the gap between nanotechnology research and manufacturable products.

Consumers of these products may be unknowingly exposed to special risks of these nanomaterials. In addition to consumers, workers involved in manufacturing of nanomaterials or products using nanomaterials can suffer workplace exposure. Up to two million U.S. workers are currently exposed to ultra-fine materials and OSHA estimates that one million more Americans could be exposed through work in nanotechnology-based industries in the next decade.

No federal agencies currently regulate nanomaterials per se. Several federal agencies are evaluating potential risks of exposure to nanomaterials. These agencies include the National Toxicology Program under the lead of the National Institute for Health, the National Institute for Occupational Safety and Health, the Environmental Protection Agency and the Department of Defense. The National Toxicology Program is focusing its study on the potential toxicity of nanomaterials. It is evaluating the distribution and uptake through the skin of titanium dioxide and certain other nanomaterials. NIOSH is in the process of a five-year program to access the toxicity of ultra-fine and nanoparticles. USEPA is examining the toxicity of manufactured nanomaterials. The FDA recognizes that nanomaterials are used in cosmetics and drugs currently on the market, but it currently has no special process for dealing with nanomaterials.

Until these studies are completed, the current regulations must suffice to deal with the risks to human health and the environment of nanomaterials. Workers must rely, for example, on the existing OSHA regulations for protection while working with nanomaterials. There are questions whether these existing standards adequately address the risks that nanomaterials pose.

OSHA has a variety of standards that currently apply to nanotechnology. For example, employers who manufacture nanomaterials and market them as raw materials are required under the hazard communication standard, 29 CFR 1910.1200, to develop material safety data sheets (MSDSs) describing any known hazards, "safe handling" practices and likely "routes of exposure." Given the current uncertainty regarding the true hazards of nanomaterials, hazard determinations under section 1910.1200(d) may require substantial testing. There is an issue whether the MSDS for a substance should be substantially different when the material is marketed in nanoscale.

Employers using nanomaterials may also be required either to provide

engineering controls on exposure or respirators pursuant to OSHA's respiratory protection standard, 29 CFR 1910.134. Many nanotechnology applications are performed under vacuum, which would likely eliminate the need for respirators. If, however, respirators were required in some situations, novel techniques may be needed in order to determine whether they are effective and compliant with Section 1910.134 in light of nanomaterial sizes.

Finally, the General Duty Clause, 29 USC 654(a)(1), could be used to address nanotechnology hazards. The general duty clause requires employers to maintain a workplace "free from recognized hazards." OSHA often relies upon voluntary consensus standards, including standards developed by the American National Standards Institute, to prove that a hazard is "recognized." Given the current paucity of information regarding the hazards of nanomaterials, it is uncertain whether the General Duty Clause requires special measures for nanomaterials.

USEPA is evaluating how to address potential risks posed by nanoscale chemicals, utilizing its authority under the Toxic Substances Control Act (TSCA). TSCA was intended as a regulatory gap filler, providing USEPA with regulatory and information collection authority lacking in other environmental statutes. TSCA authorizes USEPA to regulate chemical substances that may present an unreasonable risk of injury to health or the environment. To accomplish this, USEPA was required to establish an "inventory" of all chemical substances manufactured or processed in the United States. Chemical substances placed on the inventory are considered "existing chemicals" and those not on the inventory are "new chemicals."

For new chemicals, TSCA §5 provides USEPA the authority to consider potential health and environmental risks before a chemical substance is manufactured for commercial purposes (under TSCA "manufacture" includes importation). TSCA §5 requires manufactures to give USEPA 90-day advance

notice of their intent to manufacture a new chemical substance. For existing chemicals, TSCA §6 provides USEPA with the authority to regulate existing chemicals when there is a reasonable basis to conclude that the chemical substance presents or will present an unreasonable risk of injury to health or the environment. TSCA §4 provides the USEPA with the authority to require manufacturers of chemical substances to develop new data on health and environmental effects needed to assess potential chemical risks.

Currently, USEPA lacks sufficient information about nanoscale chemicals and the necessary procedures to evaluate the health and environmental effects of such substances to establish an effective regulatory program. For example, conventional modeling used by the agency for predictions of toxicity and fact may not be appropriate because of the unique properties of nanoscale chemicals. USEPA also does not have standardized testing procedures to determine the human health and environmental impacts posed by nanoscale chemicals or even procedures to determine whether a substance is present on a nanoscale. Moreover, the agency has

not yet established a definition of or terminology for nanoscale chemicals.

At this time, USEPA has indicated that it will follow its new chemicals program for new nanoscale chemicals and establish a voluntary pilot information collection program for existing chemicals. The agency acknowledges that at times it may be unclear whether a nanoscale chemical is a new or existing chemical. While USEPA has developed policies regarding the identification of chemical substances for the purpose of assigning a unique description of each substance on the TSCA inventory, current nomenclature conventions are inadequate to describe nanoscale chemicals.

For existing chemicals, USEPA intends to establish a voluntary pilot program to obtain the information needed to determine how best to evaluate the risks associated with nanoscale chemicals and how best to manage those risks. USEPA has established an Interim Ad Hoc Nanotechnology Work Group within the National Pollution Prevention and Toxics Advisory Committee (NPP-TAC) to provide input on (1) possible elements of a voluntary program and approaches that may be appropriate

for putting such a program in place for existing chemicals; and (2) consideration of issues that may be relevant to the review of new nanoscale chemicals under TSCA. The Work Group will provide such input to the NPPTAC for consideration at NPPTAC's October 2005 meeting for forwarding to the USEPA.

USEPA intends to announce by the end of this year its voluntary pilot program on nanoscale chemicals that are or have been sold in the United States. It is anticipated that the voluntary program will include the voluntary collection of detailed information on physical characterization, hazard, exposure and use of nanoscale chemicals in the United States. USEPA will use the information obtained through its voluntary pilot program to determine whether modifications are needed to its existing regulatory framework to address nanomaterials.

Ultimately, the regulatory approach taken by the various federal agencies must ensure that the environmental, health and safety concerns of nanomaterials are adequately addressed to assure the public that nanotechnology products are safe. ■