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Nanotechnology Regulation: A Small Reminder to Look before You Leap

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Tiny materials that are becoming commonplace in consumer products are raising big questions about how they should be regulated. They are called "nanomaterials," and are defined as particles that have at least one dimension of 100 nanometers or less.[1] A nanometer, one billionth of a meter, is approximately 1/100,000 the width of a human hair.[2]

While small in size, nanomaterials are a fast-growing industry. According to recent reports, over 1,000 manufacturer-identified products or product lines on the global market are made with nanotechnology, including consumer products such as sunscreen, cosmetics, paint and sports equipment.[3] Although many applications of nanotechnology are not yet commercially available, many experts predict the technology will become a "general purpose technology" that, like the Internet, will significantly impact a wide range of industry sectors and products.[4] If the introduction of new products continues at the present rate, it is estimated that by 2014 nanoproducts will account for 15 percent of total global manufacturing.[5]

The expansion of nanotechnology is expected to provide benefits in multiple areas, including environmental, energy, and health care. Expected environmental benefits include improvements in environmental remediation, monitoring, and green manufacturing. The application of nanotechnology to manufacturing is particularly promising because it allows for building from the bottom up, using only those molecules that are needed, and thereby eliminating the large amount of wastes generated by traditional manufacturing.[6] In the energy sector, leading nanotechnology researchers are creating cleaner, more efficient ways of delivering electrical power. Some of the nanotech energy devices already developed today include nano-enhanced lithium ion batteries that perform better and are safer than their predecessors.[7]

Some consumer groups and other organizations, however, have expressed concern that exposure to engineered nanomaterials poses unique and unknown risks to human health and the environment. The basis for the concern is the proposition that knowledge of the

chemical properties of a substance when in bulk may not predict how that substance will behave at the nanoscale. Due to their structure and miniscule size, some carbon nanotubes, for example, are under scrutiny as possibly having asbestos-like qualities, even though the carbon nanotubes have the same molecular identity as graphite. Some animal studies on the exposure of nanomaterials have also suggested that inhaled nanoparticles accumulate in the nasal passage, lungs and brain. At this time, however, there is only minimal information on the effects of exposure to nanomaterials on human health and the environment. All that is clear so far is that research is just beginning to address the risks of exposure to engineered nanomaterials.

Because of the current lack of information on the effects of nanomaterials, government agencies have been uncertain of how to respond to the "nano-revolution" that is taking place. The biggest question facing the potential regulators of the nano-world is whether current federal safeguards are sufficient, or whether a new nano-specific regulatory system needs to be created. Without adequate scientific information on the risks the materials pose, federal agencies have, appropriately, been tentative to create nano-specific regulations. In 2007, a U.S. Food and Drug Administration ("FDA") Nanotechnology Task Force recommended that the agency issue guidance regarding nanotechnology issues, but did not recommend new regulations. And although the Occupational Health and Safety Administration ("OSHA") points out that existing law imposes a "general duty" on employers to protect employees from recognized hazards in the workplace—including hazards posed by nanotechnology—the agency declined to advance specific nanotechnology regulation in 2008. Instead, OSHA elected to work with the National Institute of Occupational Safety and Health ("NIOSH") to better understand the potential hazards. There are currently no federal rules specifically governing the growing nanotech industry.

Of federal agencies, the Environmental Protection Agency ("EPA") may be said to have taken the most initiative, yet its early attempts at understanding and regulating nanotechnology's potential risks, while instructive, have not shown much promise. In January of 2008, EPA launched the Nanoscale Materials Stewardship Program ("NMSP"). The NMSP asked companies to voluntarily submit basic information about nanoscale materials they use, including their chemical and physical properties, hazard information, worker and other human exposure, whether the company releases the materials to the environment, and the company's risk-management measures. By January 2009, only 29 companies or trade associations had submitted information to EPA under the basic program, and seven additional firms had pledged to provide basic information. Because of this limited participation, EPA announced in January 2009 that it would consider ways to regulate nanoscale materials.

While EPA has made small moves to extend the current regulatory regime to cover certain nanomaterials, some groups have been unsatisfied by the pace of EPA's progress. EPA's announcement that the NMSP was not working came at the same time as a petition calling on the agency to classify nanosilver as a pesticide, which would trigger certain regulatory and legal obligations.[8] "Nanoscale silver," an antimicrobial agent, and "carbon-based" nanomaterials, such as carbon nanotubes and fullerenes, are the two most widely used nanomaterials in consumer products. EPA has already enforced nanosilver as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") last year and settled with a company that allegedly violated FIFRA by marketing computer keyboards and mice coated with nanosilver as having antibacterial qualities without registering them as "pesticides."[9]

EPA has also struggled with the proper way to apply the Toxic Substances Control Act ("TSCA") to nanomaterials. Last year EPA announced that it considers carbon nanotubes new chemical substances requiring full Pre-Manufacture Notice ("PMN"), registration, and approval under TSCA, even though the chemical composition of the carbon-based materials is the same as graphite, an existing chemical under TSCA. EPA has initiated at least one recent enforcement action against a carbon nanotube manufacturer that has failed to properly register its products. In June of 2009, EPA issued two proposed Significant New Use Rules ("SNURs") under the TSCA for multi-walled and single-walled carbon nanotubes.[10] The SNURs require that manufacturers, importers and processors of certain substances notify EPA at least 90 days before beginning any activity that EPA has designated as a "significant new use." EPA subsequently withdrew the proposed SNURs because it received adverse comments, but it announced its intention to resubmit the rules for the two substances to notice and comment rulemaking in a future *Federal Register*.[11] On September 29, 2009, EPA Administrator Lisa Jackson announced the administration's principles to guide Congress as it writes a new law that would modernize TSCA.[12] In a speech in which Administrator Jackson called the current law "outdated," Ms. Jackson stated that "EPA is reviewing how nanoscale materials are managed under TSCA." The open questions associated with the classification of nanosilver, EPA's plans for the NMSP, and its future use of TSCA to regulate nanomaterials reflect the uncertain state of regulation of nanotechnology in general, leaving companies already active in this area in a state of limbo about the future of these products.

While regulation of nanomaterials may be justified, the critical question is how to regulate when so little is known about the risks associated with nanomaterials. While the unknown risks to human health and the environment will take center stage in that debate, there are other important questions that should also be considered. First, how would precautionary

restrictions—*i.e.*, those based on the absence of information instead of proven risks to human health or the environment—impact the development of this industry, which offers wide-ranging public and private benefits? Second, should federal laws and regulations preempt states and local governments from enacting their own restrictions? If the federal government is slow to act, then that may lead to a patchwork of local efforts that could leave regulatory gaps, confuse consumers, and impose conflicting restrictions that stunt the industry's continuing development. Some local governments have already launched their own ordinances seeking information on the use of nanomaterials. In 2006, Berkeley, California passed what appears to be the world's first nanotechnology ordinance, requiring nanotech firms within the city limits to detail what they are producing and what they know about its risks. Cambridge, Massachusetts, which is one of the country's nanotech "hot spots," opted to take a voluntary approach, but is leaving the door open to regulating nanotechnology at the local level.

On September 29, 2009, EPA announced its preference to act based on scientific information when it issued its new Nanomaterial Research Strategy to proactively examine the impacts of manufactured nanomaterials on human health and the environment.[13] While recognizing that the use of nanomaterials in consumer products and industrial applications is expected to increase, EPA's goal is to minimize any human health and ecological risks. According to EPA, the new strategy focuses on locating the path of the nanomaterials from source to exposure, understanding the effects of exposure, developing risk assessments, and creating risk reduction and elimination methods.

Under EPA's new plan, the agency is initially focusing its research on certain manufactured nanomaterial types: single-walled carbon nanotubes, multi-walled carbon nanotubes, fullerenes, cerium oxide, silver, titanium dioxide, and zero-valent iron. Over time, EPA expects to extend its efforts to other types. Different applications of nanotechnology need to be approached differently according to Andrew Maynard, Chief Science Advisor for the Project on Emerging Nanotechnologies. "Nanotechnology is going to be in your iPod, but it's also in your sunscreen," says Maynard. "And to treat iPods as you would treat sunscreen is clearly nonsensical."[14]

EPA's renewed research strategy indicates its commitment to making clear and transparent regulatory decisions based on science and evidence. Lack of funding for nanomaterial research, however, is a challenge that could hinder the implementation of EPA's plan. Whether EPA will receive funding for the resources it needs is still an unknown. If EPA cannot move forward with its plan in a timely manner, there will likely be increasing pressure to fill the legal void with precautionary laws and regulations, as has been done in

the past in other areas. While such action quiets the critics, there is potentially no benefit to human health or the environment, while significant costs would be imposed on a fledgling industry that may be significantly restricted as a result.

The immersion of engineered nanomaterials into industry and products is not only another milestone in scientific advancement, it presents an important opportunity to learn from past experiences and to explore innovative ways to implement environmental laws and regulations to emerging technologies. To do this effectively, a high priority must be placed on first answering the scientific and policy questions central to creating an effective governance approach. Without prudent action based on science, nanotechnology could fail to realize its tremendous potential to benefit human health, the environment, and many sectors of our economy. That risk cannot be ignored in the future debate over what actions our lawmakers should take.

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