

Nanotechnology: An Update on Business Opportunities and Regulatory Challenges

Barry M. Hartman and B. David Naidu

ABSTRACT

Nanotechnology—the deliberate engineering of particles that are too small for the eye to see in order to create matter that has different properties than those at the conventional scale—has come of age. There are reportedly over 300 consumer products world-wide that contain some nanomaterials.¹ According to some experts, the global sales of nanoscale materials could exceed \$1 trillion by the year 2015.² Not surprisingly, over the last year, significant debate has begun, and action is being undertaken—to decide how this technology should be regulated. Businesses already involved in nanotechnology products and those interested in getting involved, need to be aware of regulatory developments and should be willing to educate regulators to ensure that new and changing rules do not undermine the promise of this technology.

Inevitably, concerns over the potential impacts of this new and largely unseen technology on human health and the environment have arisen. As with other scientific advances, this one may not fit neatly into current regulatory regimes designed to address these concerns. This Alert gives a snapshot of how agencies and the public are responding to this—and how nanotechnology is and may be regulated.

BACKGROUND: NANOTECHNOLOGY COMES OF AGE

“Nanoscale” means that the *materials* are at one billionth of a meter (or one ten-thousandth the diameter of human hair). Engineering nanoscale materials has the potential to revolutionize every aspect of business including pharmaceuticals, semi-conductor manufacturing, communication technology, chemical production, consumer products (such as cosmetics) and pollution remediation. Scientists predict that utilization of nanomaterials will give rise to cancer therapies, pollution-neutralizing compounds, advanced detectors for biohazards, and higher-efficiency fuel cells.³

There is a great deal of optimism for the promise of this technology. Federal funding of nanotechnology research and development has gone from \$464 million in 2001 to a requested \$1.2 billion in fiscal year 2007.⁴ More importantly, as noted above, it has moved into the commercial production phase.

WHY MIGHT A PRODUCT THAT CONTAINED A NANOMATERIAL NEED TO BE REGULATED DIFFERENTLY BECAUSE SIZE (OR LACK OF IT) MATTERS.

There is limited empirical data on nanomaterials’ toxicity.⁵ However, some limited studies have raised concerns. For

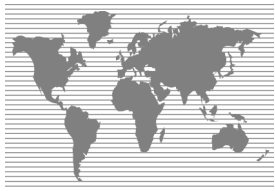
example, one study has indicated that due to their size, nanoscale materials have the potential to enter the blood and lymph circulation to reach potentially sensitive target sites such as bone marrow, lymph nodes, spleen and heart.⁶ Based on these concerns, some argue that the introduction of nanomaterials into consumer products may turn what has been a safe product into one that is unsafe. Others have posited that because of their high surface-area-to-mass ratios and enhanced surface activity, nanomaterials are likely to prove more potent at lower concentrations levels than the regulatory thresholds currently provide.⁷

These observations are directly at odds with many current regulatory standards that are based on mass and mass concentration,⁸ and that operate on the logical assumption that toxicity is diminished at these lower levels.

THE REGULATION OF NANOTECHNOLOGY IS STUDIED—TWICE

These concerns have led to the question of whether and how nanomaterials should be regulated. Two recent major papers—one by the United States Environmental Protection Agency (“EPA”) and the other by the Woodrow Wilson School Project for Emerging Nanotechnologies at Princeton University address the current regulatory structure and what may be needed for the regulation of nanotechnology.

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In a December 2005 White Paper, the EPA Nanotechnology Workgroup,⁹ recognized that nanotechnology posed a challenge to the current statutory and regulatory structure, as current testing procedures, instrumentation, and risk assessment tools might have limited applicability to nanomaterials. Recognizing how new this technology is, EPA suggested an approach under which it would review nanotechnology products and processes as they are introduced and evaluate them under already existing statutes to determine if particular protections (or new legislation or regulation) is necessary.¹⁰

In the second study, the Woodrow Wilson Center's Project on Emerging Nanotechnologies concluded that there are sufficiently known and significant shortcomings in the current regulatory regime to justify regulatory action now. For example, the paper noted that with respect to occupational health and safety regulations, the currently permissible levels for certain air contaminants may not be sufficient to address the toxicity of those same substances at the nano scale. Moreover, even if appropriate standards were in place, due to budgetary issues and inappropriate or unavailable equipment, there would be difficulties in enforcing these standards.

Another example is the Toxic Substances Act ("TSCA). The Wilson paper notes that under TSCA, if the EPA does not have enough information to evaluate the health and environmental effects of a chemical, the agency can only delay or prohibit the chemical's manufacture if the EPA can show that the chemical may present "unreasonable risk." This, however, creates the ultimate regulatory "Catch 22": the EPA can't demonstrate "unreasonable risk" without adequate information in the first place.¹¹

The Wilson Project paper also argued that the existing regulatory regime suffers from major shortcomings of either legal authority or lack of resources, or both¹² and that a new law may be required to address the inherent risks in nanotechnology.¹³ The paper proposed that a new law should be *product*-based instead of *environment*-based so that the regulation could target nanotechnology's unique physical properties.¹⁴

The Wilson Center suggested new legislation should place the burden on the manufacturers to demonstrate that the product is safe. As such, there would be four stages—(1) the EPA would establish testing protocols based on the type of product and the results of prior tests as well as reporting requirements placed on the manufacturer; (2) the manufacturer would submit a sustainability plan that would, among other things, indicate the label for the product, product risk, restrictions on use and life cycle analysis; (3) the EPA would review the sustainability plan

with the aim of either approving or disapproving it; and (4) there would be a set of follow-up procedures.¹⁵ The goals of this proposal is to put a system in place that provides the government with the information it needs for regulation without stifling the entrepreneurship necessary to develop this new technology.

NANOTECHNOLOGY – RECENT DEVELOPMENTS

There have been a number of recent developments since the EPA and the Wilson Center published their papers.

- "Magic Nano"—a German aerosol spray that reportedly contained nanomaterials – was taken off the market because consumers had reported respiratory problems. The distributor maintained that the product was not to blame for the problems, but Germany's Federal Institute for Risk Assessment investigated. Ultimately it was determined that the product contained no nanomaterials at all. It demonstrates, however, that even the use of the word "nanomaterials" is sparking concern

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- The first free, publicly available online database of consumer products engineered with nanotechnology was launched by the Wilson Center. Over 200 products have been listed, but there has been a general reluctance to post information on the part of companies worried about protecting trade secrets. As with the German example, it is not at all

clear which of these products really contained nanomaterials. Moreover, many are not even available in the United States.

- An ad hoc panel of experts reported to the EPA that the agency should prioritize its nanotechnology research. The panel acknowledged that EPA's draft paper as a good first step, but urged the EPA to specify what kind of information the EPA would need to begin the process of regulating nanomaterials. Also, the House Science Committee commissioned the National Academies to investigate the issues surrounding nanotechnology to see if legislation is necessary or appropriate.
- The EPA urged companies that use nanomaterials in pesticides to meet with the EPA to discuss what types of data will be needed for specific registration of the products under the Federal Insecticide, Fungicide and Rodenticide Act. The EPA suggested it may impose new and more stringent registration requirement for nanoscale pesticides.
- The International Center for Technology Assessment and seven other consumer, health, and environmental groups petitioned the Food and Drug Administration to

develop regulations for products made with nanomaterials.¹⁶ The petition asked the FDA take a number of actions, such as:

- Amending its regulations to include nanotechnology definitions;
- Conducting an environmental impact statement under the National Environmental Policy Act;
- Requiring toxicity testing immediately;
- Enacting new regulations classifying nanomaterials as new substances;
- Recalling publicly available sunscreen products that contain nanomaterials and declare those products an ‘imminent hazard’ to the public health;
- Placing a moratorium on production of consumer goods that contain nanomaterials until regulations can be developed.¹⁷

This petition marks the first formal legal request to compel a federal agency to promulgate nanospecific regulations. The Center argued that ‘nano’ does not simply mean ‘smaller,’ it means fundamentally ‘different,’ and failure to regulate it now means risking unique health and environmental hazards that cannot be properly managed after the nanomaterials are introduced wholesale into the environment or for public consumption.

Any accommodation of such a perspective could have dramatic implications upon the future introduction and public acceptance of nanotechnology as a whole. FDA has regulatory jurisdiction over the vast majority of products—foods, drugs, cosmetics, dietary supplements and medical devices—to which the consumer is directly exposed. The degree to which the safety of a given product can be assumed and the resultant data burden to be imposed upon a given manufacturer varies considerably within these product classifications. A longstanding history of safe use is another critical variable. If all such nanotech products are to be effectively removed from this established structure and some new paradigm of their own, regulatory barriers to entry into the marketplace will be markedly, and perhaps permanently, increased. The Center’s petition also seeks to impose new labeling requirements upon the nanotech products regulated by the FDA, a development which would have unknown but presumably significant impact upon all future marketing of the technology.

On May 22, the public interest group Environmental Defense submitted a letter to the EPA explaining that nanoscale chemicals should be considered new chemicals under the Toxic Substances Control Act. The group’s position stands in contrast to the American Chemical Council’s Nanotechnology Panel, which circulated a document on

March 2006 suggesting that a nanomaterial is not a new chemical if it has a chemical structure that is already listed on the TSCA inventory. This distinction is important, because if a chemical is labeled ‘new,’ it is not considered part of the TSCA’s existing chemical inventory, and the producer/importer of the nanoscale chemical would have to submit a notice to the EPA for agency review before putting the chemical on the market. Environmental Defense argued that the EPA currently considers other factors beyond chemical structure in order to define a chemical substance and nanoscale chemicals, because of their novelty, require the EPA go beyond molecular identity in considering their classification.

ALTERNATIVE REGULATORY APPROACHES: HOW MUCH IS ENOUGH?

So far, three schools of thought have emerged to address the question of how nanotechnology should be regulated. One school of thought is that existing regulations, with some slight modifications are adequate to handle the task. Speaking at a Nanobusiness Alliance Forum, Senator George Allen (R-Va) suggested that existing regulations

may be modified to address some of the concerns, but an entirely new regulatory regime would hamper U.S. competitiveness with no appreciable benefit to risk management.

A second school of thought endorses a more aggressive modification and review of various regulatory programs, but without new authorizing

legislation. The International Center for Technology Assessment and Environmental Defense advocates this approach (at least for now). It calls for new classifications for all nanomaterials and also supports research that focuses on the risk of nanomaterials independent of the products of which they are a part. This approach also advocates restricting products from entering commerce until after the risks have been researched, assessed, and regulated. Whether existing statutory authorizations permit agencies to amend their regulations to address these concerns is open to question.

A third school of thought, endorsed by the Woodrow Wilson’s Project on Emerging Nanotechnologies, argues that existing statutes are inadequate to handle the risks posed by nanotechnology and that new laws are required to effectively manage the risks. Most existing environmental laws are ‘media based’ (focusing on air, water or the land, each with different types of standards). Adverse impacts from nanomaterials, however, can cross these lines. Instead of a media specific approach which would have standards entirely dependent on how the nanomaterials creates specific risks, those favoring new legislation

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argue that what is needed is a new statute that regulates nanomaterials regardless of the context in which they are used. This approach, it is argued, would help ensure that there is a comprehensive protocol to evaluate these new materials, since they can impact multiple environments. Others argue that these regulatory regimes are already being used to regulate ecosystems (called, in EPA parlance, 'multi-media' approaches).

Enacting new legislation is enormously difficult, and the result is often imprecise. As a result, there seems to be some consensus among those seeking more stringent and comprehensive regulation of nanotechnology, that most changes should be sought at the regulatory level. Because of the enormous difficulty associated with enacting new legislation, both the minimalist camps and the consumer and environmental groups have decided to focus their energies on addressing this problem at the regulatory level. Whether the underlying statutes authorize the regulatory action that may be proposed, is unknown.

WHAT DOES THE PUBLIC THINK?

In a survey conducted by the Wilson Center, 1,250 respondents were asked if voluntary standards for industry would be sufficient to manage the potential risks of nanotechnology: 55 percent stated that mandatory government controls were necessary.¹⁸

The Wilson Center study also noted that in light of other recent products that developed problems after they went to market, there is some skepticism in what is perceived as a 'race' to get products into commerce without weighing the risks.¹⁹ Further, according to some, even

stakeholders in nanotechnology development companies seem to favor a stronger regulatory regime. In a recent report by Innovest, a significant portion of the 60 nanotechnology companies indicated a preference for having a set of standards in place.²⁰

SUMMARY

Whether and how nanotechnology is regulated will be determined by a variety of factors. The careful and well thought out development of logical, appropriate and comprehensive but focused regulatory regimes is the best way to balance the need for regulation with the desire to encourage the safe and effective development and commercialization of this technology. But regulation through reaction – either reaction to an incident, or reaction to a petition for rulemaking or legal ruling—will more likely than not drive the regulatory action and create the higher potential for a less efficient set of regulations.

Consumer and environmental groups are already petitioning federal agencies to quicken the pace of regulatory oversight; some call for a complete evaluation before nanomaterials can even be introduced into the marketplace. Even those who favor a minimalist approach to regulating nanotechnology for fear of stifling the entrepreneurship behind it recognize that the revolutionary nature of nanoscale materials requires some changes to the current regulatory regime. As such, as more and more data become available, it seems likely that nanotechnology will endure higher and higher levels of regulatory scrutiny in the near term.²¹

ENDNOTES

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