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INSIDE LEGAL SERVICES

Prepare now for future nanotech legal issues

Nanotechnology has the potential to create materials that may behave in completely new ways. While these unique properties hold the promise of creating new and useful products, they also have raised concerns with regulators and the public that the environmental risks associated with the products may not be fully understood.

GUEST COLUMN

Mark Kaplin

James Votaw

Regulatory agencies in the United States and abroad are working to better understand these potential risks, and whether new standards or practices will be necessary to protect human health and the environment. At the same time, both industry and environmental organizations — recognizing that nanotechnologies present some short-term uncertainties but have the potential for enormous long-term benefits — have expended considerable effort to make sure that they are developed with appropriate caution. While a consensus has emerged that nanotechnology will be developed responsibly, the principal question that remains is how?

Most developed countries, like the United States, have robust and well-developed environmental regulatory systems. After considerable debate, it appears the United States will rely for the foreseeable future on voluntary measures and existing environmental regulatory programs — such as the Toxic Substances Control Act, Clean Air Act, and Clean Water Act — to control any risks from the applications of nanotechnology. It is not clear, however, whether other countries or the European Union will follow suit, or will instead decide to develop entirely new regulatory schemes.

These emerging regulatory and policy developments have, not surprisingly, led to some degree of business uncertainty — especially when companies working with or investing in nanotechnology evaluate how current rules may apply to their products, and whether future government regulation will prohibit or restrict the manufacture or use of those products. To address this uncertainty, companies operating in the nanotechnology sector should take definitive actions to minimize the potential regulatory risk and best position themselves for the market opportunities that will develop.

As an initial matter, companies operating in the nanotechnology sector should develop a coordinated risk management strategy, the ultimate goal of which is to balance the company's business goals with the control of its legal risks. The aim is to reduce uncertainty and provide early opportunities for the company to mitigate an adverse outcome if a risk does materialize.

The first step of this process involves identifying the current and likely future legal duties applicable to the business from an environmental, health and safety perspective, and undertaking those actions that are required to comply with applicable and emerging regulations. While many companies are attuned to evaluating and providing adequate precautions to address worker safety, companies operating with nanomaterials should evaluate whether the foreseeable use of their products may present an unreasonable risk to the environment or human health or safety. As part of this evaluation, each company should determine whether — based on the nature and properties of the specific nanoscale material in question — it is appropriate to provide additional worker safeguards, or notices or warnings to customers and end-users concerning the need to use special handling or disposal practices until the potential risks associated with the use of nanomaterials is better understood.

Nanotechnology companies also should evaluate their business model to determine whether it can be adjusted to minimize the degree of uncertainty and associate risk. Companies developing products based on nanotechnology patents, or investors seeking to place bets in the nanotechnology sector, need to keep abreast of both domestic and international regulation efforts and evaluate the potential impact that emerging regulatory decisions may have on their contractual relationships with other entities in the supply and distribution chain. In this regard, companies can consider outsourcing the manufacturing of high-risk materials to qualified third parties. In addition, prudent companies should require that their vendors provide certifications with respect to regulatory compliance and material exposure issues. At the same time, however, the company should evaluate the extent of any similar certification that it provides to its customers. Finally, each company should carefully review its purchase and sale agreements to ensure that it remains in compliance with any representations and warranties that may be triggered by emerging regulatory developments in this area.

Mark Kalpin and **JAMES VOTAW** are members of the environmental department and nanotechnology practice group of WilmerHale, and are resident in the firm's Boston and Washington, D.C. offices, respectively. They can be reached at mark.kalpin@wilmerhale.com and james.votaw@wilmerhale.com.