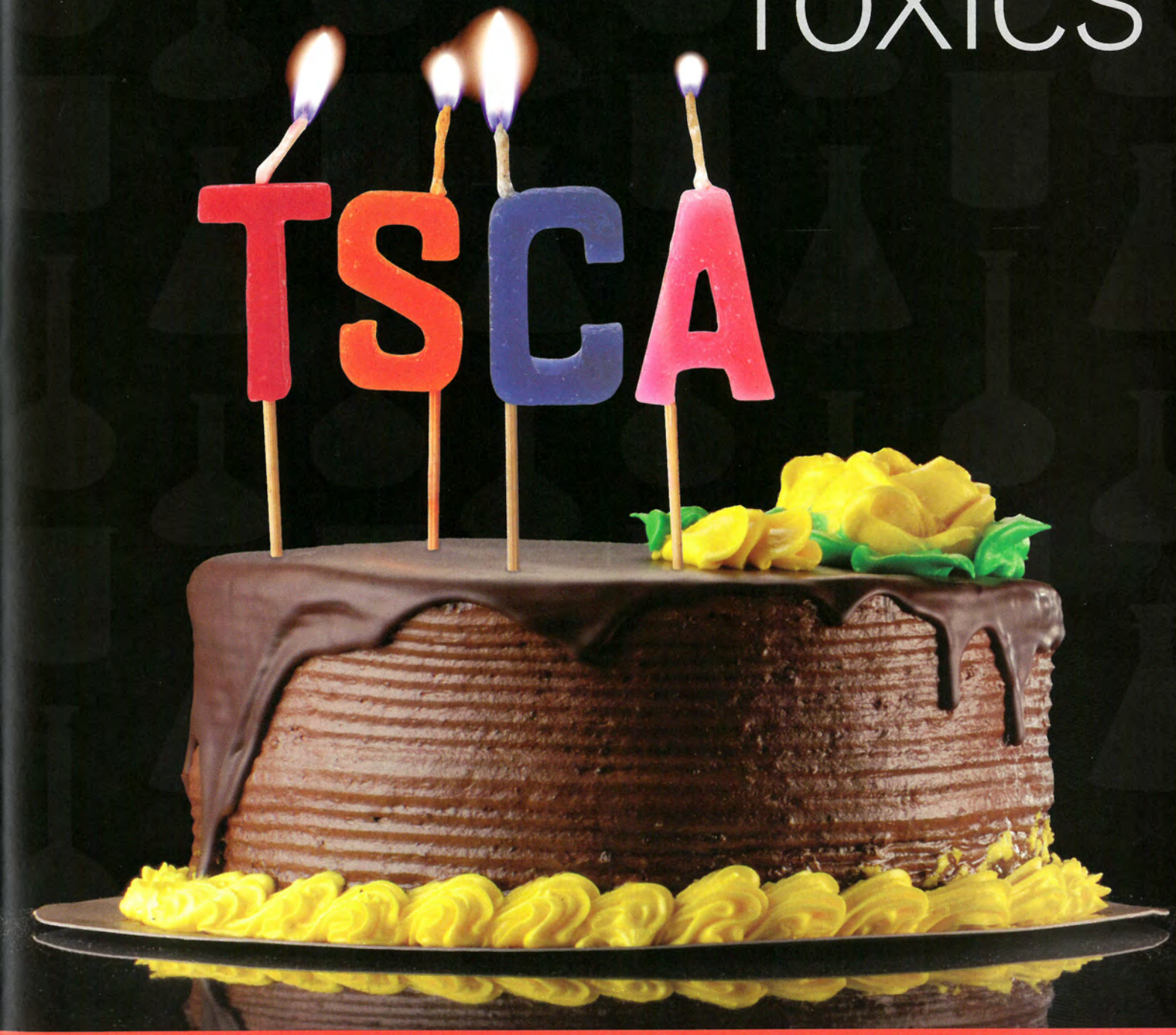
Natural Resources & Environment

ABA Section of Environment, Energy, and Resources

Volume 29, Number 4, Spring 2015

TOXICS



- INTERVIEW OF JIM JONES, AA OF EPA'S OCSPP
- TSCA REFORM PROPOSALS, PREEMPTION, EPA'S TSCA WORK PLAN
- DISCLOSURES AND FIRST AMENDMENT SCRUTINY
- RENEWABLE CHEMICALS AND NANOMATERIALS REGULATION

Regulation of nanomaterials: What are they? How are they regulated? And who decides?

By Roger Hanshaw

Few developments in science and technology have presented more opportunity to revolutionize so many aspects of daily life – medicine, food, electronics, agriculture, cosmetics, and others – as the creation and use of nano-scale materials. Even though nanotechnology research and nanomaterial production have been on the scene for years, the extent to which nanomaterials can be leveraged to create advances in daily life is yet to be fully understood. However, questions about the possible health implications, environmental and occupational effects, and even the manner in which nanomaterials interact with other known chemical compounds already arise with great frequency. It is not surprising that lawyers and policy makers struggle to create a suitable regulatory structure for nanomaterials when even those professionals who work in the field of nanotechnology and nanomaterials struggle to define what the term 'nanomaterial' means.

As practitioners who work at the complex interface of science, law, and public policy are often aware, law and public policy typically lag behind science and technology. It can take time for legislators, regulators, and other policy makers to understand how advances in science and technology can potentially affect society, and it can take even longer for that understanding to develop into a legal and regulatory framework for the oversight of these advances.

While the prefix "nano" is technically proper when describing things measured in increments of one one-billionth of a meter (10^{-9} meters), the popular definition of a nanomaterial is anything with a single dimension between 1 and 100 nanometers (nm). By way of

comparison, a typical strand of human hair is approximately 100 µm (or 100,000 nm). A typical mammalian cell has a diameter of approximately 20 µm (or about 20,000 nm), and a typical *E. coli* bacterium is around 2 µm (or about 2,000 nm) long. At the opposite end of nanomaterial size is a typical protein, with dimensions of between 1-20 nm, and an individual hemoglobin molecule, with a diameter of approximately six nanometers. Nanomaterials occupy a space dimension in the middle - larger than small molecules, pharmaceuticals and most proteins, yet much smaller than even the smallest living cells.

Recent advances in the ability of scientists to manipulate and control matter at the nano scale have created new opportunities in diagnostic and therapeutic medicine, food preservation, and even consumer electronics. For example, nanoscale quantum dots are revolutionizing the field of molecular imaging in diagnostic medicine, and titanium oxide nanoparticles exhibit an important antibacterial effect now utilized in certain preservative applications. These advances create tremendous potential benefits for a wide spectrum of industries, but they have so far presented a challenge for regulatory bodies charged with developing and implementing chemical safety protocols around the world.

The most challenging aspect of nanomaterial regulation is properly characterizing the proposed species to be regulated and how it interacts with other chemical species in the environment. A key question is often whether the nanomaterial is actually a "new" chemical species. For example, cadmium selenide (CdSe) quantum dots encapsulated in a zinc sulfide (ZnS) shell are useful in molecular imaging applications. These and similar quantum dots are typically between two and ten nanometers in diameter. The photochemical properties of these CdSe-ZnS quantum dots offer biomedical researchers and those working in related fields greater opportunities to visualize aspects of biology in new and interesting ways that have been

otherwise unavailable using traditional organic fluorophores. However, regulating CeSe-ZnS quantum dots is challenging.

All the components of a CdSe-ZnS quantum dot are well known and very well characterized, yet the combination of these constituent components into a quantum dot produces a species with different physical and chemical properties than any of the constituents. Regulatory agencies around the world are faced with the challenge of adapting existing chemical, and even biological, regulatory frameworks to cover nanomaterial species like CdSe-ZnS quantum dots.

In the United States, nanomaterial regulation remains largely an ad hoc regulatory process. Various federal regulatory agencies are interested in learning more about the perceived need to develop modified rules specific to nanoscale materials, yet no major federal initiatives have advanced to deal squarely with the issue. The United States Environmental Protection Agency (US EPA), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the Office of Science and Technology Policy, the National Institute of Standards and Technology, and the Department of Labor are all among the more than twenty (20) federal agencies and departments that have been involved in attempts to develop a coordinated approach to regulating nanomaterials in the United States. Still, no such coordinated approach exists.

In the absence of a regulatory regime specifically tailored to address nanomaterials, federal agencies in the United States are left to police nanomaterials under a menagerie of acts and statutes generally applicable to chemical (and sometimes biological) products. Arguably, the primary regulatory tool for nanomaterials in the United States is the

Toxic Substances Control Act ("TSCA"). Under Section 5(a) of TSCA, a new chemical substance must be registered with the US EPA before it can be manufactured in the United States. This requirement has traditionally allowed US EPA to perform a gatekeeping function and monitor the development of new chemical species as they enter the marketplace.

However, nanomaterials which are formed from the combination of previously-registered chemical species may fall outside the scope of a "new chemical substance" as the language of TSCA Section 5 provides. Typically, a chemical substance is considered "new" for purposes of TSCA Section 5 if the substance is not listed on the TSCA chemical inventory. However, in the case of a CdSe-ZnS quantum dot discussed above, if all the chemical species involved in its manufacture are listed on the TSCA inventory, does a quantum dot made from these components constitute a new chemical species? The answer can determine which regulatory approach applies. On the one hand, the CdSe-ZnS quantum dot is arguably nothing more than a new use for an existing chemical species already listed on the TSCA inventory, making Section 5 inapplicable and negating the requirement for a pre-manufacture notice to US EPA. On the other hand, the fully-assembled quantum dot is a wholly new chemical species with properties completely different from those of its components. Under this view, TSCA Section 5 does apply, and the requirement for premanufacture notice is applicable. The approach generally taken by US EPA has been the former, where new materials produced by combining existing chemical species listed on the TSCA inventory are not considered to be new chemical species for purposes of TSCA.

Even if a new nanomaterial product is determined not to be a new chemical species, under TSCA Section 5(a)(2), US EPA may still issue a significant new use rule ("SNUR") applicable to the new product. A SNUR requires the manufacturer to provide certain

additional information to US EPA before the product enters the market. Even this requirement can be a meaningful barrier to getting a new nanomaterial into the marketplace. In cases where a new nanomaterial consists only of a combination of chemical species already on the TSCA inventory, US EPA is forced to shoehorn these materials into the existing regulatory box of TSCA, despite the inherently different chemical and physical properties of the new product. TSCA Section 5(a)(2) requires US EPA to consider certain factors before issuing a SNUR, including (1) the projected volume of manufacturing of the substance, (2) the extent to which a use changes the type or form of exposure of humans or the environment to a chemical substance, (3) the extent to which a use increases the magnitude and duration of exposure of humans or the environment to a chemical substance, and (4) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance. Clearly, these factors force US EPA to perform a complicated balancing exercise when determining how to handle a new nanomaterial, with uncertain guidance from the United States Congress.

Nanomaterials have been among the catalysts for recent, proposed TSCA reform in the United States Congress. For example, recent proposals to amend TSCA have defined the term "special substance characteristic." The Safe Chemicals Act, proposed by former Senator Frank Lautenberg of New Jersey, defined "special substance characteristic" as follows:

> (A) IN GENERAL – The term 'special substance characteristic' means a physical, chemical, or biological characteristic, other than molecular identity, that the Administrator determines, by order or rule, may significantly affect the risks posed by substances exhibiting that characteristic.
>
> (B) CONSIDERATIONS. – In determining the existence of special substance characteristics, the Administrator may consider –

(i) size or size distribution,

(ii) shape and surface structure,

(iii) reactivity; and

(iv) any other properties that may significantly affect the risks posed.

Though proposals to amend TSCA have yet to be adopted, the proposal to move away from a regulatory approach based on molecular identity and toward an approach based on the properties of a particular material is important. The latter approach recognizes the key features of many nanomaterials – the physical and chemical characteristics of the fully-formed nanomaterial which differ from those of its chemical components. Regulation based on physical and chemical properties rather than molecular identity would give US EPA clear authority to regulate nanomaterials, no matter what their composition. Thus, the CdSe-ZnS quantum dots discussed above would be subject to regulation based on their properties rather than their composition. Property-based regulation of chemical species would represent a fundamental shift in how federal agencies regulate new chemical compounds.

Unless or until Congress acts to amend TSCA, TSCA remains the primary tool for the regulation of new chemical species, including nanomaterials. However, certain species that clearly fall within the definitional sphere of nanomaterials are beyond the reach of US EPA regulation under TSCA because they are covered by one or more exemptions. For example, the definition of "chemical substances" under TSCA specifically excludes (1) mixtures, (2) pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), (3) tobacco and certain tobacco products, (4) substances regulated under the Atomic Energy Act, (5) ammunition and firearms, and (6) those materials regulated under the Federal Food, Drug, and Cosmetic Act. Certain materials covered by TSCA exemptions, especially pesticides and

certain agrochemicals, have been popular targets for development of new nanomaterials. These new species and the exemptions provided in TSCA have forced US EPA to reach for other tools to regulate these materials.

As suggested above, pesticides and certain other agrochemicals specifically exempted from regulation under TSCA are covered by a federal statute all their own – FIFRA. US EPA's authority to regulate chemical species under FIFRA is arguably broader than its authority under TSCA. Not only may US EPA require the manufacturer of a pesticide to provide premanufacture notice before commercial quantities of the material are produced, US EPA may also regulate research and development activities associated with bringing the product to market. The scope of US EPA's authority under FIFRA allows the agency to regulate any nanomaterial so long as the product is a pesticide.

The FIFRA approach to chemical species regulation is a likely direction for future efforts by Congress to restructure chemical regulation to address perceived inadequacies in the regulation of new substances like nanomaterials. Regulation based on chemical and physical properties of particular species rather than molecular identity is the basis of proposed overhauls to TSCA, though none have gained significant traction in Congress. Under a properties-based regulatory approach, CdSe-ZnS quantum dots, carbon nanotubes, and titanium oxide nanoparticles could all be regulated by US EPA under TSCA without regard to whether the chemical species of each component entity are listed on the TSCA inventory. This is so because these materials exhibit properties distinct from those of their components.

Much thought and discussion has been had on whether existing federal statutes and regulations are sufficient to empower agencies to properly regulate nanomaterials. US EPA

has worked hard to shape its approach to nanomaterial regulation within the contours of TSCA and FIFRA. Other agencies have been forced to examine the adequacy of their regulatory programs in the face of new developments in nanomaterials. For example, the Occupational Safety and Health Administration (OSHA) has issued guidelines for workers and employers whose business brings them in contact with nanomaterials. However, OSHA's regulatory authority is derived not from a statute or regulation aimed at nanomaterials, but from the general Occupational Safety and Health Act. Section 5(a)(1) of the Act requires that employers "furnish to each of [their] employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to [the] employees." This "General Duty" provision, gives OSHA wide discretion to regulate workplace safety-related issues across the entire spectrum of industries and businesses. Similarly-general statutes empower the National Institute of Standards and Technology, the Department of Agriculture, the Department of Labor, and various other federal regulatory agencies.

Under a majority of circumstances, the legal issue facing a nanomaterial in the marketplace is not whether it is a nanomaterial *per se*, or whether it is a new chemical species or simply a combination of known chemical species. Rather, whether the key issue is the product's chemical or physical properties pose a risk to human health or the environment. Current federal law generally affords regulators the power they need to safeguard the public and the environmental from unsafe chemical products. Proposals to specifically address nanomaterials may come with unintended consequences. Given the rapid pace with which science and technology advance compared to the slower legal and regulatory apparatus charged with their oversight, it would be wholly unsurprising if entirely new classes of chemical species not covered by proposed new regulatory requirements were available for the marketplace before

proposed new regulations were even fully implemented. By focusing less on what materials constitute a nanomaterial and more on whether a particular product represents a potential threat to health, safety, or the environment, regulators can better achieve their mandates and provide certainty to industries based on science and technology.

The European approach to nanomaterial regulation focuses much more on risk analysis and risk-based regulation than on the structural or compositional properties of particular products. In 2006, the European Parliament adopted the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which set up a comprehensive regulatory structure applicable to chemicals and "substances" throughout the European Union. Rather than determining whether a nanomaterial is or is not a new chemical species, as US EPA would do under TSCA, the European Chemicals Agency has flexibility under REACH to regulate a new nanomaterial simply because it, and all nanomaterials, fall within the definitions of either "substance" or "article" under REACH.

The scope of many regulations is often a function of definitions, and REACH provides a broad scope for European chemical regulators to address nanomaterials by ascribing very expansive definitions to "substance" and "article." Under REACH, a "substance" is "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition." An "article" is defined to be "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition." Though REACH does not specifically mention nanomaterials, all nanomaterials are within the definition of a substance under REACH,

therefore giving the European Chemicals Agency regulatory authority over nanomaterials as a class.

Aside from the expansive scope of materials that may be regulated as a substance under REACH, the aspirational principles of REACH also make it clear that REACH extends to nanomaterials. In Article 1(3) of REACH, we find that "[t]his Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment." This aspirational statement suggests that REACH is meant to serve as more than a simple gatekeeper for chemical products. It is meant to empower the European Chemicals Agency to protect human health and the environment.

REACH occupies a position in the EU similar to that occupied by TSCA in the United States. Like those who have called for TSCA reforms in order to address recent developments in science and technology, some sectors within the EU have questioned whether or not it is time to reform REACH to address these same developments. There is ongoing debate over the sufficiency of REACH to adequately regulate nanomaterials throughout the European Union, and some advocates for more stringent regulation have called for adoption of a specific regulation tailored directly to nanomaterials.

In 2011, the European Commission adopted a recommended definition by which "nanomaterial" means "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm. In specific cases and where warranted by concerns for the environment, health,

safety, or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%." The recommendation also specifically includes fullerenes, graphene flakes and single-wall carbon nanotubes (each of which are hydrocarbon consisting only of carbon and hydrogen atoms) with one or more external dimensions below 1 nm in the definition of nanomaterial. Though REACH has not yet been amended to specifically address nanomaterials, the adoption of this recommended definition is perhaps a step in the direction of greater regulation of these products.

Recent calls to amend REACH to specifically tackle nanomaterials have included calls for regulation based on similarity of chemical and physical properties, yearly production volumes, and suspected implications for human health and the environment. However, none have been widely accepted as conclusive directions for new regulation. The arguments for amending REACH to specifically cover nanomaterials are much the same as those for amending TSCA, though REACH already goes well beyond TSCA in terms of the kind and amount of data that must be provided if a chemical species is to be introduced into the marketplace.

The future of REACH and its impact on commercialization and marketing of nanomaterials in Europe is yet to be written, but specific regulations applicable to nanomaterials have already begun to make their way into certain industrial sectors. For example, in 2009 the European Parliament enacted Regulation No. 1223/2009, which requires that cosmetics which containing nanomaterials be labeled to disclose the nanomaterial with a bracketed "nano" following the chemical species present in the product as a nanomaterial. For the chemical industry, such piecemeal regulation of the use of nanomaterials is a potential problem, and for consumers, the appearance of "[nano]" on a consumer product, without greater explanation, is likely to lead to a more uncertain, rather than a more informed, public.

Enforcement of nanomaterial regulation differs between the United States and Europe. For example, in the United States, TSCA, the primary federal law regulating the development, marketing, and use of nanomaterials, is administered by the US EPA, a federal agency. In European Union countries, the member nations administer REACH. This state-level enforcement approach has led to calls from various EU member nations for modification of REACH as it applies to nanomaterials.

As public demand for additional information on the health and environmental implications of nanomaterials grows, so will the pressure to develop expanded legal tools which can be used by government regulators to provide enhanced safeguards to public health, safety, and the environment. The question of whether a "new" product is a nanomaterial is likely to soon be displaced by inquiries directed more toward the potential for the product to pose a risk to human health, safety, or the environment. As regulation across the globe moves in this likely direction, manufacturers wishing to capitalize on the very real benefits offered by nanomaterials should prepare to focus more time and resources on proving the safety of products rather than determining whether a new product does or does not contain a nanomaterial.

The future of chemical regulation around the world is likely to look more akin to FIFRA and REACH than to the current TSCA. Developments in science and technology have always outpaced the legal and regulatory environment in which they exist, and developments based on chemicals and chemical compounds are the building blocks for many of the most exciting and transformative technologies our world will experience. At the most basic level, nanomaterials are simply new combinations of known chemicals and molecules assembled for a (perhaps) new purpose. The properties of these new and exciting materials should be viewed with an eye toward opportunity rather than fear. Just like every other chemical and compound

ever prepared, nanomaterials exhibit chemical and physical properties that can lead to benefit or harm, depending on their use and the precautions taken to protect the user. Industry leaders and practitioners who work at the interface of science, law, and public policy are moving, albeit slowly, away from an environment in which a product receives special regulatory attention simply because it bears the label of a 'nanomaterial,' and toward an approach where chemical species are regulated based on their properties and their potential to offer benefits and pose risks. Regulatory bodies around the world will be looking to each other in the coming years to develop a sound approach to nanomaterial regulation. It is imperative that professionals who practice at the interface of science and the law work with these policy makers to keep these very tiny products from becoming a very large problem.