Size Matters: Regulating Nanotechnology

by Albert C. Lin

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Nanomaterials and products containing nanomaterials are quickly being integrated into a wide range of commercial and noncommercial applications. As nanomaterials grow more commonplace, we are coming in contact with these substances on an increasingly regular basis, in products ranging from stain-resistant khaki pants to sunscreens. Despite the expanding use of nanomaterials, relatively little is known about the possible harm they could pose. Current forms of government regulation are proving inadequate in addressing this potential harm. Therefore, it is imperative that new mechanisms be developed to learn more about these new substances, while protecting against the unknown risks they present to society.

Nanotechnology is the term used to describe the burgeoning field of manipulating matter at a nanometer scale. Engineered nanomaterials are derived from conventional chemical substances, but have unique characteristics and surface coatings that often lead them to behave very differently. The small size and high surface-area-to-mass ratio of nanosized particles enhance the mechanical, electrical, optical, catalytic, and/or biological activity of a substance. This unusual behavior, however, along with known hazards presented by naturally occurring particles of somewhat similar size, has caused concern over the effects that nanomaterials could have on human health and the environment. Free nanoparticles that may be released into the environment, whether intentionally or incidentally as a product is used, are of particular concern. These substances are believed to be the most likely to be able to enter the body, react with cells, and cause tissue damage. There is very little data on harmful effects from real world exposure to engineered nanoparticles, but this uncertainty should not be used as an excuse for regulatory inaction.

The existing statutes that might be used to regulate nanomaterials are inadequate. The Toxic Substances Control Act (TSCA) is the main authority that could be used to regulate nanomaterials, supplemented by media-based environmental statutes, consumer safety statutes, the Occupational Safety and Health Act (OSHA), and statutes specific to drugs and certain other products. TSCA's purpose is to address the concern that humans and the environment are exposed to numerous chemical substances that pose unknown or unreasonable risks. However, there is great difficulty in the implementation of this statute, especially as to nanomaterials. TSCA's general approach is that no information on the risk of a chemical means that there is no risk. This places too heavy a burden on the EPA to demonstrate that a risk is or may be unreasonable in order to require testing of a substance or in order to regulate its manufacture or use. In addition, chemical manufacturers sometimes take the position that engineered nanomaterials should not be deemed a new class for purposes of TSCA, and thus subject to more regulation, because they are derived from conventional substances. Other potentially applicable statutes such as OSHA only provide for protection and testing under limited circumstances. The government needs to become proactive and establish a new regulatory approach for nanomaterials.

The government should engage and educate the public about the relevant risks and benefits of nanomaterials. This means switching the regulatory paradigm of nanomaterials from the harm principle, to a more appropriate precautionary principle. Instead of regulating only when harm is demonstrated, as under TSCA, we should develop a statute that does not require conclusive evidence of risk as a prerequisite for the adoption of measures to address potential risks. The regulatory plan put in place needs to protect human health and the environment while facilitating planning and commercialization efforts.

All products that contain nanomaterials should be subject to a notification and labeling requirement. Promoting the development of uniform nomenclature and metrology for nanomaterials would help ensure effective notification and labeling. Notification would help regulators to keep track of nanotechnology developments and to identify regulatory needs, and labeling would assist the public in making more informed choices. Because free nanomaterials pose potentially greater risks, they should be required to undergo a screening process to help minimize the exposure of workers and consumers to nanomaterials with the greatest like-

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lihood of toxicity. Such materials should also be subject to post-market monitoring, which will help to identify latent or previously undetected health risks. Finally, we should require manufacturers to internalize potential liability costs by imposing a bonding requirement for products containing free nanomaterials. This requirement will assure that there are funds to pay for potential damages, while giving nanotechnology companies an incentive to make sure their products are safe. By implementing a new statute based on a different regulatory paradigm, we should be better able to protect the public while encouraging the development of valuable new products and technology.