

Nanotechnology's Big Legal Issues

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In the view of some, nanotechnology is expected to become the transformational technology of the 21st century. This technology focuses on controlling matter at the scale of one billionth of a meter (approximately 100,000th the width of a human hair) in order to create new materials with novel properties and functions. The National Science Foundation predicts that nanotechnology “eventually could impact the production of virtually every human-made object” and “lead to the invention of products yet to be imagined.” Yes, the technology of the very small could become very big.

Not surprisingly, the promise of nanotechnology also carries with it unique risks and technical issues. Studies have already shown that certain nanoparticles may pass through cell membranes and distribute to sensitive sites throughout the body, including bone marrow, spleen, heart and brain. Other nanomaterials have been found to potentially interfere with the body's antioxidant defenses. The assessment of nanotechnology hazards, which is only in its preliminary stages, is complicated by the difficulty of detecting nanoparticles at low concentrations and the difficulty of applying studies of macro materials to their nano counterparts.

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Nanotechnology is likely to have a significant impact on both our environment and the laws that regulate it in the next decade. Since it is far more efficient than the macro-technologies of today, nanotechnology can drastically reduce consumption of natural resources, as well as the generation of waste. There is already a market for remediation technologies using nanoparticles that can inexpensively clean the environment by breaking down contaminants into less harmful materials. Nanotechnology also has the potential to make an impact on the detection of pollutants, such as toxic substances in drinking water.

Unfortunately, nanomaterials may also present risks to the environment. For example, waterborne nano-engineered Carbon 60 was found to lead to “oxidative stress” in the brains of largemouth bass. Some scientists are concerned that runaway nanoparticles could self-replicate into destructive masses, either accidentally or through acts of terrorism. Based on the perception that the current, very limited regulatory frameworks in the United States and in other parts of the world do not adequately address the use of nanomaterials, a task force of the [Section of Environment, Energy and Resources](#) of the American Bar Association prepared briefing papers for the Environmental Protection Agency to assist the Agency with the creation and implementation of new laws to regulate the development and use of nanotechnology. Existing environmental laws, such as the [Toxic Substances Control Act](#), already provide EPA with broad powers over manufacturers of products using nanomaterials, including the ability to review new materials and new uses of materials before they enter the stream of

commerce, as well as the power to require manufacturers to develop new data to assess potential risks.

Nanotechnology will also have great implications on occupational safety and health and other workplace issues. Studies of ultrafine aerosol particles in the workplace have shown that inhalation of nano-sized fibers and particles can lead to increased rates of cancer, lung disease and respiratory problems. Given the emerging indications that the toxicity of nanomaterials depends on their shape, solubility, surface chemistry and surface area, scientists have already concluded that typical toxicity screening studies cannot be effectively used to evaluate nanomaterials and that, therefore, little is really known about how such materials could effect exposed workers. Not surprisingly, OSHA does not have any specific standard which addresses permissible exposure limits for nanomaterials and, given the potential for a wide variety of nanomaterials being introduced into the workplace, developing standards on a substance-by-substance basis may be impossible. In the fall of 2005, the National Institute for Occupational Safety and Health released its plans for pursuing strategic nanotechnology research. If research identifies a clear, quantifiable hazard involved with the production or use of nanomaterials, OSHA can be expected to utilize the general duty clause or even its authority to issue emergency temporary standards to regulate these materials, at least on a limited basis.

It has been estimated that by 2004, there were already \$13 billion worth of products incorporating nanotechnology in the global marketplace; it is estimated that the number will rise to \$1 trillion by 2015. The [Project on Emerging Nanotechnologies](#) reports that there are already approximately 1,200 nano-tech start-ups worldwide, with more than

60% of these located in the United States. This activity suggests the possibility that nano-products will be pushed to market before their risks, particularly long-term risks, are fully understood. Since nanoparticles can enter the body through a variety of routes, including the possibility of penetrating the skin, and since – as noted earlier – nanoparticles may travel within the body in unconventional ways, the risk assessment which is typically done before a product is introduced in commerce may be very difficult for nanomaterials.

The evolving situation indicates that there is a critical need for research findings to be shared widely so that product risk assessment can be done as quickly and as thoroughly as possible. The Project on Emerging Nanotechnologies is compiling an inventory of worldwide risk-related research in order to facilitate this process. Although we know little about the risks associated with nanoproductions, we know enough to be aware that the premature introduction of such materials into the marketplace and the environment could produce significant product liability litigation and result in unknown potential environment impact and corresponding legislative changes.