

UNIQUE PROPERTIES OF NANOMATERIALS INCREASE LIKELIHOOD OF ENVIRONMENTAL REGULATION

Along with the promise of nanotechnology comes cautionary data regarding the technology itself. Due to concern of potential health risks associated with nanotechnology, the U.S. Environmental Protection Agency (“EPA”) recently conducted a nanotechnology review and found that certain nanomaterials have “unique” properties that suggest the need for additional information regarding risks. Nanotechnology refers to manipulating materials at the molecular level. EPA recently reviewed 15 nanomaterials and found that at least one of the materials, a carbon nanotube, acted in a different manner than standard carbon. Carbon nanotubes are thought to be among nanotechnology’s most promising building blocks because they have a wide range of potential commercial applications. With increased physical strength and excellent conductivity, carbon nanotubes are used in applications for semiconductors and could eventually replace silicon in computer microprocessors.

Despite the tremendous interest and investment in carbon nanotubes, toxicological studies suggest that health and environmental concerns exist. Recently, the U.S. National Aeronautic and Space Administration (“NASA”) reported that when carbon nanotubes were injected into the lungs of rats, significant lung damage occurred. The dosage provided to the rats was roughly equivalent to worker exposure levels over an approximate 17-day period.

The very nature of nanotechnology, which involves the ability to alter the fundamental properties of substances, challenges the existing regulatory structure and creates a tug-of-war between industry and environmentalists regarding the government’s role in its regulation. A wrong or ill-conceived approach to the regulation of nanotechnology could stifle the technology’s tremendous economic benefits.

At issue is whether the existing regulatory framework, especially the Toxic Substances Control Act (“TSCA”), adequately regulates nanotechnology. Congress passed TSCA in 1976 as a gap-filler to the then existing chemical substance regulation. Arising from public concern about the Kepone contamination in the James River, TSCA provides the EPA Administrator with authority to regulate chemicals in commercial use. Current EPA regulatory activities include reviewing new chemicals, creating an inventory of chemical substances (the “Chemical Substance Inventory”), testing of existing chemicals, and establishing reporting and recordkeeping requirements.

TSCA applies to chemical substances and mixtures and defines “chemical substance” as any organic or inorganic substance of a particular molecular identity. Among TSCA’s regulatory tools are certain reporting requirements that apply prior to the manufacture or import of any “new” chemical. A chemical is “new” if it is not on TSCA’s Chemical Substance Inventory, EPA’s official list of existing chemical substances. Under Section 5 of TSCA, the manufacturer of a “new” chemical substance must submit toxicity and other data under a pre-manufacture

notice (“PMN”). The EPA has the power to prohibit or limit the manufacture of particular chemicals based on such data.

Whether a particular nanomaterial is a “new” chemical that requires PMN is unclear. Because currently available chemical nomenclature may be inadequate for some nanoscale materials, uncertainty exists whether to classify nanoscale materials as existing chemical substances or “new” chemical substances which would require a PMN under TSCA. Many commentators do not consider nanomaterials to be “new” chemical substances. Additionally, TSCA’s regulations provide industry with several exemptions to the “new” chemical substance requirements, including: (1) a low volume exemption for manufacturers that create less than 10,000 kilograms per year (nanomaterials, given their microscopic size, generally will qualify for this exemption), (2) a low environmental release and exposure exemption, (3) an exemption for chemicals produced in small quantities solely for experimental or research and development purposes and (4) a test marketing exemption. Nanomaterials manufactured under these exemptions may be eligible for limited notification and would be excluded from the Chemical Substance Inventory.

Avoiding the PMN requirements does not necessarily mean that nanomaterials would be unregulated under TSCA. Section 5 of TSCA additionally provides the EPA with authority to designate a specific use of an existing chemical as a “significant new use” through a significant new use rule (“SNUR”). EPA determines SNURs based on several factors, including the anticipated extent and type of exposure to humans or the environment from the new use. A manufacturer that intends to create a chemical substance for a designated new use must notify EPA at least 90 days prior to doing so. Significant new use notifications are received and reviewed in a similar process to PMNs. The very nature of nanotechnology involves creating new uses which makes it probable that EPA will consider a given nanomaterial to be a “new use” of an existing chemical rather than a “new chemical substance.”

Some environmental groups have sought an outright ban on all nanotechnology until nanomaterials are proven to be absolutely safe. Other groups have sought immediate new environmental legislation to regulate nanotechnology. It seems likely, however, that EPA’s approach will be that nanotechnology regulation is a process, not an event. Accordingly, it is extremely important for companies that are either developing or using nanotechnology in their businesses to retain experienced environmental counsel at an early stage to assist in the administrative process involved in having a particular nanomaterial appropriately classified. Navigating the EPA administrative maze associated with nanotechnology can be difficult, but the consequences of waiting for EPA to select independently the manner in which a particular nanomaterial is to be regulated can impose significant costs on a company.

If you have any questions concerning the foregoing or would like further information, please contact E. Donald Elliott (202-303-1120, delliott@willkie.com), Michael S. Caplan at (202-303-1162, mcaplan@willkie.com) or the attorney with whom you regularly work.

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