

## Nanotechnology: Reducing Liability Exposure When Risks Are Unknown

By Jesse Ash, Antony Klapper and James Wood\*

Products that contain engineered nanomaterials are unique in that they are composed of elements one billionth to ten millionth of a meter — or about 100,000 to 1000 times smaller than the diameter of a human hair. As a result of their incredibly small size, engineered nanomaterials can behave in ways that are dramatically different than larger-sized variants of the same substance and thus have tremendous commercial appeal. Perhaps more than 800 consumer products contain engineered nanomaterials, including foods, food packaging, cosmetics, devices, drugs, household products, clothing and sporting gear.

While many of these products are in use by the public today, companies that manufacture products containing nanomaterials should be mindful that uncertainty exists as to the possible toxicological, human health and environmental effects of nanomaterials. Companies therefore *must* institute risk management and good product stewardship measurements today to limit potential liability exposure in the future.

While there has not been a single lawsuit filed where someone claimed injury because they were exposed to engineered nanomaterials, questions abound regarding the manufacturing of nanomaterials and its effects on workforces, researchers and consumers. For example, some scientists wonder whether engineered nanomaterials will become the next asbestos. No one can say for sure. However, one thing is clear: the plaintiffs' bar is already looking for the next asbestos, the next toxic tort. In their search, these lawyers read the conclusions drawn by scientists in peer-reviewed papers; they review the statements made by regulatory bodies; and they evaluate the steps taken by public interest groups who historically have paved the way for private litigation through oftentimes creative and expansive interpretations of science and law.

For example, the plaintiffs' bar likely took note of a recent study showing that certain types of carbon nanotubes, graphite-based structures commonly used in nanotechnology applications, both resemble and behave like asbestos fibers. Because they are as light as plastic and stronger than steel, carbon nanotubes will likely see use in a variety of new applications, including medical nanodevices. Based on toxicity studies, scientists found that inhaling long, thin multi-walled carbon nanotubes had the *potential* to cause lung disorders similar to those caused by exposure to asbestos. While this conclusion is alarming, the authors of this study were quick to point out that additional research will be required to fully answer whether carbon nanotubes truly are pathogenetic in humans. Regardless, the “carbon nanotube” story is an important one for companies to stay on top of and monitor. And so too are developments in the story about the toxicological properties of nanosized silver, a substance used in some medical devices to prevent infections.

The plaintiffs' bar is also monitoring activities at FDA. In May 2006, a coalition of environmental NGOs filed a petition asking the FDA to, among other things, force manufacturers of sunscreens that use nanoparticles to cease production and to recall their products. The petition discusses at length the possibly increased toxic properties of nanomaterials, citing to various scholarly articles and reports. FDA has not formally responded to this particular petition, but has held several public meetings on nanotechnology risks during the past three years.

Whether the studies on carbon nanotubes or the public petitions simply mark the beginning of private lawsuits is unknown. Certainly if the science on nanomaterials more conclusively raises human health concerns, the risk of litigation increases dramatically. Because there are many unanswered questions regarding risk, it is essential that companies follow the principles of good product stewardship activities and good risk management strategies in the design and manufacturing of products made with engineered nanomaterials. Core questions that affect whether a company has followed such principles include:

- Has the company designed the product with safety in mind?
- Has the company educated its workers and consumers about known exposure risks?
- Has the company tracked what scientists, regulators and other members of industry are saying and doing about the product's risk and ways to reduce that risk?
- Has the company itself evaluated, or collaborated with others to evaluate, risks that are still unknown?
- Are the company's *public* pronouncements about the risks associated with its products consistent with its own internal evaluations and assessments of its products?
- Has the company taken affirmative steps to implement recommended controls to reduce exposures?
- Has the company taken steps to monitor the health of its workforce and its consumers that are exposed to its product?

If a company follows these basic tenets of product stewardship and implements risk management strategies, it will also reduce its liability exposure.

*\*Jesse Ash, Antony Klapper and James Wood are part of a team of more than two dozen attorneys specializing in nanotechnology at the law firm of Reed Smith.*