

**ENVIRONMENTAL GROUPS PETITION THE FDA
TO REGULATE NANOTECHNOLOGY**

The first legal action to address the potential human health and environmental risks of nanotechnologies was brought by eight consumer, health and environmental groups against the Food and Drug Administration (“FDA”) on May 16, 2006. This legal action was a petition formally requesting the FDA to amend its regulations for products containing engineered nanoparticles. Should the FDA not develop a substantive response within 180 days, the environmental groups assert that they will file suit in federal court.

Although there is no official definition of nanoparticles (which is part of the issue), the term often refers to chemical structures in the size range of 1 to 100 nanometers. To place this in context, one nanometer is equal to one-billionth of a meter, about 10 times the diameter of a hydrogen atom. Currently, ASTM International, a standards development organization, has established a committee on nanotechnology to help develop standard words and definitions of terms specific to nanotechnology.

The ability to manipulate matter at the nanoscale has become a commercial reality. There are already many nanotechnology materials and applications in the marketplace today each with unique and novel properties. Silica nanoparticles are incorporated into paints to aid in application. Plastic fuel lines with nanostrands of carbon keep fuel lines from accumulating an electrical charge. Nanotechnology applications are now being used for everything from sunscreens to cosmetics.

Many nanotechnology applications promise significant environmental advancements including new tools to detect, monitor and remediate pollution; cleaner and improved energy production; and the availability of environmentally benign manufacturing processes. For example, last year the Environmental Protection Agency (“EPA”) announced a proposed cleanup plan for the Nease Chemical superfund site in Columbiana County, Ohio which uses “nanoscale zero-valent iron” particles to remediate deep groundwater contaminated with pesticides. The EPA believes the advantage of nanotechnology at the Nease Chemical superfund site is that the method is expected to be more effective than traditional techniques used for cleaning groundwater. The nanoscale iron particles would be able to reach into small cracks in the bedrock under the site.

The FDA is charged with ensuring that drugs are “safe and effective.” Under this authority, the FDA regulates numerous nanomaterial products, including sunscreens and cosmetics (which are classified as “drugs”) that contain engineered nanoparticles. The petition asserts that the FDA has taken no regulatory steps to formally recognize the inherent differences of nanomaterials from their bulk material counterparts. With new nanotechnology products quickly coming to market, a significant concern is whether commercial applications of nanoscale materials may present a potential risk to human health and the environment. For example, from a pulmonary health standpoint, small is not always a good thing. The environmental groups petitioned the FDA to take a variety of steps to address nanotechnologies such as:

- declare that sunscreens made with nanomaterials be classified as an imminent hazard to public health and recall such sunscreens until the FDA develops appropriate regulations;
- conduct environmental impact statements, as required by the National Environmental Policy Act, to determine appropriate policies to address how nanomaterials affect the environment;
- require toxicity tests for nanomaterials; and
- mandate that products that contain nanoparticles be labeled appropriately.

Although the FDA was petitioned, the EPA may be next. The EPA currently regulates nanotechnology under the Toxic Substances Control Act (“TSCA”), an oft-used regulatory gap-filler. The EPA considers some of the nanoscale materials as new chemical substances subject to TSCA’s Section 5 notification requirements and, therefore, subject to review for potential human health and environmental risks before they are manufactured and enter commerce. The EPA considers other nanoscale materials as existing chemical substances that may enter commerce without notification to the EPA. A chemical substance is “new” if it is not on the TSCA Chemical Substance Inventory. Accordingly, a nanoscale material not on the TSCA Chemical Substance Inventory should be reported to the EPA in a premanufacture notification under TSCA Section 5 before commercial activities are allowed.

A difficulty with the current regulatory framework is that available chemical nomenclature may not be adequate for some nanoscale materials and ambiguity exists regarding how and when to distinguish nanoscale materials as new or existing chemical substances. The EPA recognizes that issues exist with the current state of development of structural characterization. With scientists able to manipulate matter at the nanoscale, chemicals that are currently on the TSCA Chemical Substance Inventory can possibly exhibit novel properties. The concern from some groups at this point is whether such substances will be regulated at all.

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

Willkie Farr & Gallagher LLP is headquartered at 787 Seventh Avenue, New York, NY 10019-6099 and has an office located at 1875 K Street, NW, Washington, D.C., 20006-1238. Our New York telephone number is (212) 728-8000 and our facsimile number is (212) 728-8111. Our Washington, D.C. telephone number is (202) 303-1000 and our facsimile number is (202) 303-2000. Our website is located at www.willkie.com.

July 11, 2006

Copyright © 2006 by Willkie Farr & Gallagher LLP.

All Rights Reserved. This memorandum may not be reproduced or disseminated in any form without the express permission of Willkie Farr & Gallagher LLP. This memorandum is provided for news and information purposes only and does not constitute legal advice or an invitation to an attorney-client relationship. While every effort has been made to ensure the accuracy of the information contained herein, Willkie Farr & Gallagher LLP does not guarantee such accuracy and cannot be held liable for any errors in or any reliance upon this information.