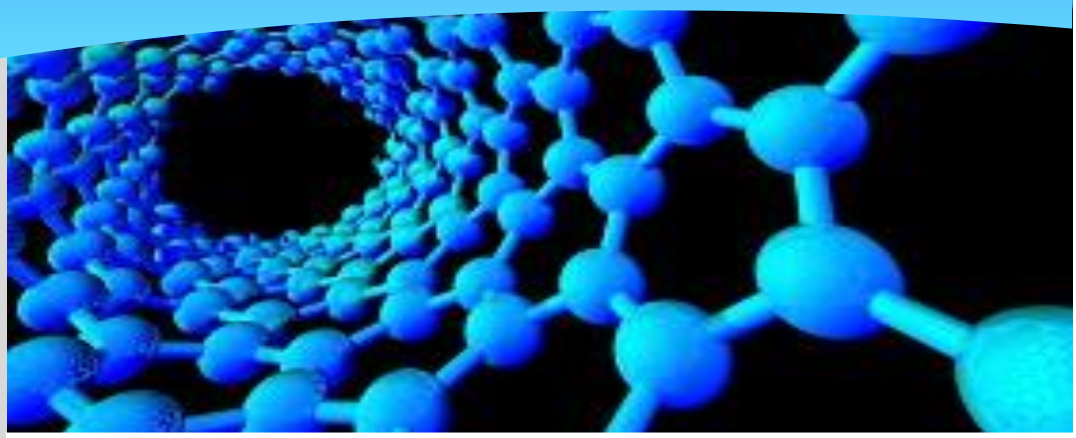
BURNHAM | BROWN

Nanotechnology Client Alert



Contact Information:

Kimberly I. Chew
(510) 835-6729
kchew@burnhambrown.com

Richard J. Finn
(510) 835-6821
rfinn@burnhambrown.com

Burnham Brown
1901 Harrison Street
14th Floor
Oakland, CA 94612
(510) 444-6800
www.burnhambrown.com

By: Kimberly I. Chew **November 2013**

Nanotechnology Regulation Update

I. Recent Court Decision

In a recent decision, the 9th Circuit Court of Appeal vacated a conditional registration issued by the EPA for a nanosilver pesticide to be used in textiles. NRDC v. United States EPA, 2013 U.S. App. LEXIS 22610 (9th Cir. Nov. 7, 2013). While the court's discussion focused on regulations for a product approval, and whether the EPA satisfied these criteria, the case prompted investigation into Nano Technology which in turn, resulted in exploration of the nascent field of Nano Toxicology.

Burnham Brown offers this brief summary of the topic because the advancements of the technology will implicate risk hazards, regulatory concerns and actions, as well as serve to inform claims of product liability and bodily injury.

II. What is Nanotechnology?

- Nanotechnology is the control and restructuring of matter at the nanoscale, in the size range of approximately 1–100 nanometers, in order to create materials, devices, and systems with fundamentally new properties and functions due to their small structure.
- A 2006 National Geographic article describes this phenomenon as:
    - Nanotechnology matters because familiar materials begin to develop odd properties when they're nanosize. Tear a piece of aluminum foil into tiny strips, and it will still behave like aluminum—even after the strips have become so small that you need a microscope to see them. But keep chopping them smaller, at some point –20 to 30 nanometers, in this case ---the pieces can explode. . . . **"It's like you shrink a cat and keep shrinking it, and then at some point, all at once, it turns into a dog."** ---Jennifer Kahn, Nano's Big Future, Nat'l Geographic, June 2006.
    - Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale. A nanometer is one-billionth of a meter, which is near-atomic scale. One sheet of paper is about 100,000 nanometers thick; a single gold atom is about a third of a nanometer in diameter.

- Commercialization:
    - Nanomaterials have the potential for novel applications such as making stain-free textiles or use in cancer treatments, impacting many industries including electronics, healthcare, construction and consumer products.
    - Examples of materials developed with nanotechnology include the following engineered nanomaterials:
        - Carbon buckyballs or fullerenes;
        - Carbon nanotubes;
        - Metal oxide nanoparticles (e.g., titanium dioxide); and
        - Quantum dots, which are nanoscale semiconductor materials (e.g., cadmium selenide).
    - Examples of products that are produced currently using nanotechnologies include: sunscreens and cosmetics; longer-lasting tennis balls and light-weight, stronger tennis racquets; stain-free clothing and mattresses; polymer films used in displays for laptops, cell phones, digital cameras; coatings for easier cleaning glass; bumpers and catalytic converters on cars; and protective and glare-reducing coatings for eyeglasses and cars. As of October 2013, the nanotechnology consumer products inventory contains 1628 products or product lines. Currently available consumer products incorporating nanotechnology include:
        - Appliances (Heating, cooling and air; large kitchen appliances; laundry and clothing care)
        - Automotive (Exterior; maintenance and accessories)
        - Goods for Children (Basics; toys and games)
        - Electronics and Computers (Audio; cameras and film; computer hardware; display; mobile devices and communications; television; video)
        - Food and Beverage (Cooking; food; storage; supplements)
        - Health and Fitness (Clothing; cosmetics; filtration; personal care; sporting goods; sunscreen)
        - Home and Garden (Cleaning; construction materials; home furnishings; luxury; paint)– Project on Emerging Nanotechnologies (2013). Consumer Products Inventory. Retrieved November 12, 2013, from http://www.nanotechproject.org/cpi
    - <u>Known hazards of exposure to nanonmaterials</u>
        - Nanotechnology is a rapidly emerging field; as such, nanotoxicology is emerging as its own field and information as to the hazards of exposure are still being researched. The health and environmental risks associated with nanomaterials is related to their increased potential toxicity and mobility. The health hazard potential depends on the particular nanomaterial and the exposure level. For example, carbon nanotubes and nanofibers may be capable of causing pulmonary inflammation and fibrosis. In toxicology studies (animal testing) certain types of carbon nanotubes caused mesothelioma. Additionally, titanium oxide on a nanoscale has a higher mass-based potency than larger particles such that the nanoscale particles advocates asserting it should be considered a carcinogen.
        - Nanomaterials are more easily taken up by the human body and can cross biological membranes, cells, tissues and organs more efficiently than larger particles. (Holsapple et al., Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs, 88 Toxicological Sciences 12 (2005).) They can be transported within cells and taken up by mitochondria and the nucleus where they interfere with cell signaling and can result in DNA mutation. (Ultrafine particulate pollutants induce oxidative stress and mitochondrial damage, 111 Environ. Health Perspectives 455-60 (2003).

- Environmental risks associated with nanomaterials are not well characterized. There has been scientific studies that suggest that silver nanoparticles may adversely affect the environment by increasing nitrous oxide fluxes, changing the microbial community composition, biomass and extracellular enzyme activity.

- The EPA is involved in efforts to understand the potential risks to humans, wildlife and ecosystems that nanomaterial exposure entails. However, there are difficulties with assessing environmental risk because the manner in which some studies have been conducted does not allow for valid comparisons with newer studies or because there has been a greater focus on certain nanomaterials and not others. EPA has undertaken a multipronged approach to understanding and regulating the risks of nanomaterials, including conducting research and implementing a voluntary data collection program. EPA faces challenges in effectively regulating nanomaterials that may be released in air, water, and waste because it lacks the technology to monitor and characterize these materials or the statutes include volume based regulatory thresholds that may be too high for effectively regulating the production and disposal of nanomaterials.

- Like the United States, Australia, Canada, the United Kingdom, and the European Union have begun collecting data to understand the potential risks associated with nanomaterials and are reviewing their legislative authorities to determine the need for modifications. Other countries have established Occupational Exposure Levels for various nanomaterials. For example, the British Standards Institute recommends working exposure limits for nanomaterials based on various classifications such as solubility, shape, and potential health concerns as related to larger particles of the same substance. Germany's Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung, an institute for worker safety, has published similar guidelines.

- In the absence of governmental or consensus guidance on exposure limits, some manufacturers have developed suggested Occupational Exposure Levels for their products. For example, Bayer has established an Occupational Exposure Levels of 0.05 mg/m3 for Baytubes® (multiwalled carbon nanotubes). For Nanocyl carbon nanotubes, the no-effect concentration in air was estimated to be 2.5 $\mu g/m^3$ for an 8-hr/day exposure.

III. On the Horizon and other recent developments:

OSHA published a Fact Sheet concerning working safely with nanomaterials in April 2013. This publication recommends that employers check with manufacturers of chemicals and materials used in their facility to determine if unbound nanomaterials are present. It highlights that there are few occupational exposure limits relating to nanomaterials, which include:

- Respirable carbon nanotubes and carbon nanofibers not exceed 1.0 micrograms per cubic meter as an 8-hour-time-weighted average

- Worker exposure to nanoscale particles of titanium oxide not exceed 0.3 milligrams per cubic meter.

Employers are encouraged to minimize worker exposures as exposure limit do not exist for other nanomaterials. Further, employers should assess exposures by identifying and describing processes and job tasks that could expose workers, determine the physical state of the nanomaterial (dust, powder, droplet, etc.), determine routes of exposure, identify appropriate sampling methods, and determine what additional controls may be needed for exposure assessment.

Another Conditional Registration: On August 27, 2013, EPA announced its proposed conditional decision to register another pesticide containing nanosilver—an antibacterial product, intended to be incorporated into plastic products and textiles to reduce mold, mildew, stains and odors made by Nanosilva LLC. The Agency found little risk from exposure to Nanosilva in acute animal toxicity studies.

NIOSH, the federal agency that conducts research and makes recommendations to prevent work-related injuries, illnesses and deaths, issued new recommendations on November 8, 2013 for controlling worker exposures to nanoengineered materials during the manufacture and industrial use of such materials. In this document, NIOSH recommends that employers conduct a preliminary hazard assessment (PHA) encompasses a qualitative life cycle analysis of an entire operation, including evaluation of the magnitude of the emissions (or potential emissions) and the effects of exposure to these emissions. After the PHA is complete, a nanomaterial risk management plan will need to be designed to avoid or minimize hazards discovered during the assessment. NIOSH recommends considering engineering controls to protect workers by removing hazardous conditions or placing a barrier between the worker and the hazard.