



Environmental Law and Nanotechnology

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Overview

- Concerns
- Current Environmental Regulations that May Affect Nanotechnology
- Challenges

Environmental Regulatory Agencies

- Federal Environmental Protection Agency – charged with promulgating regulations in accordance with federal environmental laws to protect human health and the environment
- State environmental agencies – state laws must be at least as stringent as federal laws and rules, but states can be more stringent than federal requirements. Some states, such as California and New York, have often been in front of the federal EPA on various environmental issues

Concerns

- The perceived need for specific environmental regulation applicable to nanoparticles or nanochemicals arises from concern regarding their potential effect on the following:
 1. the environment, including animals, plants, water, air, soil, and overall ecosystem effect
 2. human health

Environmental Concerns

- On the one hand, Nanotechnology has shown great promise in changing the manner in which environmental remediation is conducted. Examples include –
 1. Use of nanofilters;
 2. Use of nanotechnology to “attack” environmental contaminants
- On the other hand, some believe that nanotechnology and the consequences of the production of nanoproducts has gotten “ahead” of an understanding of the possible consequences

Environmental Concerns

- Ultimately, the concerns center on the unknown toxicity of some nanostructures
- Concern that do not want to repeat a DDT or asbestos type scenario
- In broad terms, the concerns regarding the potential effect of nanostructures on the environment are related to
 - The transport of such structures through the environment
 - The bio-assimilation of such structures in ecosystems

Transport Concerns

- Currently, the transport of nanostructures through the environment is not well understood
 - ▮ Potential pathways for the transport of nanostructures include an air pathway, aqueous pathway, and a general particle “hitch-a-ride” pathway
 - ▮ Despite numerous years of research, the dynamics of pollutant transport through the air over long distances is still not completely understood

Transport Concerns

- Concern that some nanoparticles, through sorption, could attach to larger particles in the environment and travel long distances
- Concern that such nanoparticles could introduce risks to the environment or human health depending on the fate of such particles

Bioavailability Concerns

- Concern that some organisms could bio-assimilate nanostructures with such bio-assimilation being amplified up the food chain (e.g., similar to a mercury situation in which mercury that enters an aqueous environment will be bio-magnified up the food chain resulting in relatively low levels released to the environment creating human health concern regarding eating fish from the affected ecosystem)
- Concern that most nanoparticles are not biodegradable, so the particles could bio-accumulate (e.g., like DDT or other man-made pesticides whose persistence in the environment presents expensive cleanup challenges)
- Also unknown effect of nanostructures on biota in ecosystems

Human Health Concerns

- Related to bio-availability concerns regarding nanostructures potential affect on human health
- Other speakers have or will discuss this topic on a more detailed level, but from an environmental law perspective, EPA has increasingly become concerned about the effect that small particles have on human health
 - EPA recently promulgated national ambient air quality standards for “fine” particulate matter (defined as having a diameter of 2.5 or less microns)

Human Health Concerns

- Some are also concerned that nanostructures could serve as carriers of toxins that normally would be excluded from cells
- Possibility that proteins absorbed onto nanoparticles could lead to some autoimmune disorders

Current Environmental Laws

- Given the concerns outlined above, the question arises whether existing environmental laws are in place to address the concerns
- Currently, when discussing the potential environmental impact of nanotechnology, EPA has focused in its authority under the Toxic Substance Control Act (“TSCA”)
- Other environmental laws that may affect nanotechnology include the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, the National Environmental Policy Act

TSCA Overview

- Congress enacted TSCA in 1976 in an attempt to address concerns regarding new chemical compounds before such chemicals are introduced into commerce or the environment
- In support of legislation, EPA cited several examples of chemicals that, in retrospect, should not have been introduced (PCBs, vinyl chloride, chlorofluorocarbons)

TSCA Overview

- TSCA required EPA to:
 1. establish an inventory of chemical substances existing in U.S. commerce (the list may be found on the Internet at: msds.ehs.cornell.edu/tscasrch.asp);
 2. Review “new” chemicals before such chemicals are introduced into commerce;
 3. Test existing chemicals for their effect on human health and the environment;
 4. Establish reporting and recordkeeping requirements for chemicals;
 5. Establish import and export requirements for chemicals

TSCA Overview

- TSCA defines a “chemical substance” as

any organic or inorganic substance of particular molecular identity, including any combination of such substance occurring in whole or part as a result of a chemical reaction or occurring in nature and any element or uncombined radical
- TSCA defines a “new chemical substance” as “any chemical substance which is not included in the chemicals substance list....”

TSCA Overview

- Section 5 of TSCA requires a manufacturer of a new chemical substance to submit a premanufacturer notice (“PMN”) to EPA at least 90 days before the date of the intended start of production or import of the new chemical
- EPA receives about 1,500 PMNs annually
- TSCA may apply to the manufacture of nanoparticles to the extent that the substances are “new chemicals”

TSCA Premanufacturer Notice

- Exemption to PMN Requirement –
 1. Not required for Research and Development chemicals
 2. Polymers
- PMN must contain information on –
 1. Chemical identity/structure
 2. Description of chemical uses
 3. Production or Import Volume
 4. Description of byproducts
 5. Description of human exposure
 6. Available information on human health/environmental effects
 7. Description of disposal practices

TSCA Review

- During EPA's review period, the agency will review the chemical structure and develop the possible exposure and release profile for the chemical (including the chemical's physical and chemical properties)
- EPA will also evaluate the chemical's potential health and environmental effects and, based on its review, establish the chemical's health and environmental hazard potential
- EPA will also group the chemical within one of the established categories (currently there are 45) or establish a new category

TSCA - Exposure and Release Profile

- EPA establishes an Exposure and Release Profile for the chemical based on the toxicity data and the potential release scenarios
- EPA uses the information in the PMN in its review to determine whether to ask for additional information regarding the chemical, accepting the chemical and adding it to the inventory, or banning the chemical
- EPA can add a chemical to the inventory and allow the chemical's manufacture but impose conditions on such manufacture (e.g., require the development of toxicity or exposure information)

Other Environmental Laws CAA

- Clean Air Act – as stated previously, EPA has promulgated standards for fine particulate matters, which, in theory, would apply to nanoparticles (although the measurement of such particles in ambient air may be difficult)
- States can use the fine particulate matter standard as a basis to require air permits
- The Clean Air Act also regulates the emission of “hazardous air pollutants” which, in the future, may include nanoparticles or substances

Other Environmental Laws CWA

- Clean Water Act – any discharge of a “pollutant” into a water of the United States (which is extremely broadly defined) requires a permit
- Thus, companies producing nano-products have to obtain a permit for the discharge of nanoparticles into the sink (if the sink drains to a city sewer treatment system or a stream, creek, river etc.)

Other Environmental Laws

NEPA

- National Environmental Policy Act requires the federal actions that have the potential to impact significantly the environment to undertake an analysis of the action's potential impact
- A “federal action” under NEPA has been interpreted to include any action that involves federal funds (e.g., the construction of a highway)
- Depending on the action, NEPA may require an environmental assessment or an environmental impact statement be prepared and made available to the public

Other Environmental Laws State Laws

- As described previously, states are free to enact environmental laws that are more stringent than the federal government
- Therefore, states, such as California, may act to regulate nanostructures before EPA
- In addition to EPA, other federal agencies, such as FDA (safety of devices and rugs containing nanotechnology) and OSHA (workplace safety) may also influence environmental regulation

State Environmental Laws

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Challenges

- The biggest challenge at this point is the relatively small amount of information/studies specific to the potential environmental and health effects of nanostructures (including products containing nanotechnology)
- Studies regarding the life cycle of such products are needed
- Studies regarding specific mechanisms of fate and transport of nanostructures are needed
- Ultimately, some sort of risk profile for nanostructures must be established in order to make a threshold decision regarding the need for specific regulations

Challenges

- Most believe that nanotechnology is so unique compared to other manufacturing techniques that, if environmental regulation is necessary, the regulations must be specific to nanostructures
- Of course, the development of such regulations will take years and require countless peer-reviewed studies
- EPA and nano-manufacturers share the goal of avoiding an asbestos-type situation, where the eventual regulation did not prevent crippling toxic tort suits

Challenges

- In the interim, EPA appears to have focused on using TSCA's new chemical provisions (relying on manufacturers) to evaluate the potential health and environmental effects
- EPA may also rely on other federal agencies like the Food and Drug Administration, which regulates the use of nanotechnology in drugs, devices and other products that come into contact with the human body
- The Occupational Safety and Health Administration, which regulates worker safety, could also step in and develop workplace standards