American Bar Association
Section of Environment, Energy and Resources

Basic Practical in Nanotechnology
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I. Introduction[1]

Nanoparticles have always existed in the natural world and are a commonly recognized product of naturally occurring combustion (i.e., forest fires and volcanic eruptions). It is not a stretch to understand that internal combustion engines, power plants, fire places, charcoal grills and scented candles all generate nanoparticles as well. However, these particles are merely by-products of combustion and, though man-made, are not "engineered" and are therefore, not really structures.

"Engineered nanostructures" are those products manufactured through construction at the molecular level. Recent developments in methods and equipment can now be used to manipulate single atoms. Single atoms have been manipulated into sheets, tubes and spheres called "buckyballs"[2] all made of simple carbon. Other types of nanoscale engineering include:

- Attaching benzene molecules attached to carbon sheets to conduct electricity;

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[1] The attached reading list prepared by Lynn Bergeson, Bergeson & Campbell, Washington, D.C. has been updated by Ms. Bergeson for this ABA SEER Fall Meeting presentation, and should provide a excellent background for any practitioner interested in the nanotechnology industry, along with the ABA SEER papers drafted for its Nanotechology Project and available: http://www.abanet.org/environ/nanotech/.

[2] See http://www.nanotech-now.com/nanotube-buckyball-sites.html.

- Using the M13 virus to attract and bind cobalt oxide ions on its outside layer to create positive electrodes;[3]
- Killing cancer cells with a nanoparticle of polymer loaded with toxic docetaxel, studded with aptamers (tiny proteins) and polyethylene glycol molecules[4],

The types of equipment used to manipulate atoms include the "scanning tunneling microscope" in 1982, and the atomic force microscope in 1986.[5] This equipment actually allows us to pick up an atom, slide or drag an atom and build nanostructures.

Generally, nanoscale manufacturing occurs in either a "top-down" or "bottom-up" method, and in either a wet or dry environment. Top-down manufacturing involves breaking down a surface through cutting, edging or grinding or impose a pattern through lithography to create computer chips, or optical mirrors. Bottom-up manufacturing involves building materials through chemical synthesis, including both self-assembly (i.e., growing crystals) and positional assembly, to create a variety of products, including cosmetics, fuel additives, displays, or experimental atomic or molecular devices.[6]

Nanoscale materials are manufactured in one, two or three dimensions. One dimensional applications include a dot or point. Two dimensional applications include thin films or engineered surfaces, such as silicon chips and catalyst uses. Three dimensional applications include carbon nanotubes.

These manufacturing methods generally begin by subjecting a medium of solid, liquid or gasto a reaction, which results in a transformation with a particular efficiency, creating a product of a particular purity which must be separated from unreacted byproducts.[7] Essentially, these production stages are very similar to those currently used in manufacturing, in either continuous or batch processes. Thus, points of potential waste generation and possible routes of exposure to waste by-products would likely be similar and, thus, somewhat predictable.

Examples of manufacturing sectors currently utilizing nanotechnology, include:[8]

- Structural applications – ceramics, catalysts, composites, coatings, thin films, powders, metals;
- Skincare products – metal oxides (titanium dioxide, zinc oxide, iron oxide);
- ICT – single wall nanotubes, nano elecronics, optic-electro materials (titanium dioxide, zinc oxide, iron oxide), organic light-emitting diodes;
- Biotechnology – nanoencapsulates, targeted drug delivery, bio-compatible quantum dots, composites, biosensors;
- Instruments, sensors, characterization – MEMs, NEMs, SPM, dip-pen lithography;
- Environmental – nanofiltration, membranes

[3] Researchers trying to make tiny machines have turned to the power of nature, engineering a virus to attract metals and then usint it to build minute wires for microscopic batteries, Reuters, April 6, 2006.
[4] Nanoparticles Annihilate Prostate Cancer, Scientific American, April 11, 2006
[5] The Royal Society & The Royal Academy of Engineering, July 2004, p. 6.
[6] *Id.* at 25 (Table 4.1).
[7] *See generally*, *Id.* at 26 (Table 4.2).
[8] *Id.* at 27; See also EPA Nanotechnology White Paper; Nanomaterials a risk to health at Work? First International Symposium on Occupational Health Implications of Nanomaterials; Nanopaticles and the Environment, Pratim Biswas, Chang-Yu Wu.

A manufacturing process that utilizes nanotechnology, in one form or another, may produce manufactured nanoparticulate of relevant composition that escapes the manufacturing process, as well as byproducts that do not conform to the desired product specifications (and may be discarded as waste or allowed to escape as air pollutant emissions). Current air pollution monitoring methods, ambient air modeling methods, sampling and analytical methods, and control methods, do not perform adequately when applied to nanoparticulate because they were created to identify, measure by mass, capture and control elements or molecules of no particular physical shape or structure (other than size greater than 1000 to 1500 nanometers that behave in predictable ways both chemically and physically). However, when matter gets really small, it behaves differently, and it is this different behavior that those in the fields of nanoscale science and engineering now recognize as an incredible tool in achieving valuable benefits to our society.

The difference in behavior of materials at the nanoscale occurs because atomic properties become more significant as the atom or atoms are freed from the affects of surrounding material. An easy example is gravity – at the nanoscale, gravity doesn't matter, almost.[9] Also, the surface area of an atomic-sized bit of matter is much greater in proportion to the contents of the bit of matter, allowing the atomic-sized bit of matter to become more chemically reactive – important for catalysts in e.g., fuel cells and batteries.[10] The behavior of the matter is also more influenced by "quantum effects," which, simply put, is behavior of matter at the atomic level that's different than the behavior of that very same type of matter on a larger scale. For example, heat is absorbed continuously by normal scale matter, but only in discrete amounts for atomic sized matter,[11] while conductivity has been shown to occur in two dimensional nanoscale applications, such as one layer of graphite, i.e., pencil "lead."[12] The difference in chemical and physical properties and behaviors of this material is one of the biggest challenges facing environmental regulation of this industry.

For environmental lawyers, environmental policy and regulation has, to date, been developed relying on familiar chemical and physical properties, for example:

- Solubility, or the degree to which a substance can dissolve in another before reach saturation (e.g., the difference between a positive analysis for BTEX versus free product in an UST cleanup);
- Mass, a measure of the earth's gravitational pull on a material (almost all environmental release restrictions are based on mass);
- Density (mass divided by volume) of specific gravity.

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[9] News for January 2002, Neutrons reveal quantum effects of gravity, 17 January 2002 ("Physicists have observed quantized states of matter under the influence of gravity for the first time; * * *cold neutrons moving in a gravitational field do not move smoothly but jump from one height to another, as predicted by quantum theory; * * *it is extremely difficult to make analogous observations in gravitational fields because the effect of gravity is negligible at the atomic scale.")

[10] The Royal Society & The Royal Academy of Engineering, July 2004, p. 5.

[11] Max Planck, 1900 (energy can be released (or absorbed) by atoms only in "packets" of some minimum size; this minimum energy packet is called a quantum).

[12] Scientific American, November 10, 2005, "Graphite Found to Exhibit Surprising Quantum Effects" ("Albert Einstein, Paul Dirac and other founding physicists may have used pencils to work out the details of relativity and quantum mechanics. Now their modern successors are employing pencil lead in a new way to prove those theories--and potentially point the way toward a whole new form of electronics.")

Additionally, environmental lawyers are familiar with the RCRA hazardous waste characteristics of ignitability (flash point less than 140 ^{o}F), corrosivity (pH≤2 or pH≥12.5), reactivity (reactive with water, generally), and toxicity (extent to which the material leaches specific concentrations of listed constituents).[13]

Environmental policy and regulation of engineered nanostructures, however, will need to identify critical parameters unique to engineered nanostructures. Recently, EPA released a list of information requested seeking specific nanoscale materials physical and chemical properties.[14] This list includes:

- Crystal structure
- Aggolomeration state
- Particle size distribution
- Mean particles size (and standard deviation from mean) (including largest particle size, aspect ratio, and average aerodynamic diameter)
- Average particle mass
- Particle shape
- Surface area
- Average particle surface area
- Surface charge (zeta potential)
- Porosity
- Surface chemical composition
- Suface/volume ratio

In attempting to evaluate the risk posed by the engineered nanostructures, if we look merely at the base element, such as carbon in a carbon sheet, nanotube or buckyball, these forms seem relatively benign. However, when the properties of carbon in such forms reveal increased conductivity depending on the "chirality" or relative twisting of the structure as in DNA's double helix, we are reminded that engineered nanostructures are engineered precisely for these unique properties that arise from the structure itself, rather than the mere element or molecule alone, causing the properties of the structure to be the characteristic properly subject to regulation, rather than the properties of the element or molecule, as is currently regulated.

Evaluating the risk posed by different types of engineered nanostructures becomes even more challenging when the structures utilize elements or chemicals currently regulated due to their systemic toxicity or carcinogenicity, and even more so due the potential synergistic effects of structures combining these high risk elements or chemicals. Finally, without more study, we may not be able to anticipate the fate and transport mechanisms of engineered nanostructures once released to the environment, or their persistence in the environment or potential for bioaccumulation. It's entirely possible that many engineered nanostructures will simply disintegrate, agglomerate or react in the environment and pose no continuing risk. However, it's also possible they may not.

[13] 40 C.F.R. Part 261, Subpart C.

[14] Information Collection in support of EPA's Stewardship Program for Nanoscale Materials; Reporting Form (draft, based on EPA Form 7710-25 (Rev. 5-95)).

In this midst of this factual uncertainty and unknowns regarding risk, this new nanotech industry has taken off in a monumental tsunami. A clear path forward to regulating the nanotech industry pursuant to the existing federal environmental statutes is clouded by the issues discussed herein.

There is an alphabet soup of 25 federal agencies engaged through the National Nanotechnology Initiative or "NNI" including the EPA, Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH), National Toxicology Program (NTP), Food and Drug Administration (FDA), Department of Defense (DOD), National Science Foundation (NSF), Department of Energy (DOE), Department of Health and Human Services (DHHS) and more.

The NNI has clearly targeted the majority of its funds towards development, not protection of human health and the environment. The 2007 NNI budget request (updated) is $1,392 million, and of that: NSF is to receive $373 million; DOD, $417 million; DOE , $293 million; DHHS, $170 million, and on. The EPA is to receive only $8.6 million. Of EPA's nanotechnology budget, $7.9 million is allocated for human health and safety. Of the entire $1,392 million budgeted for all 25 federal agencies, only about $48 million is allocated for human health and safety.[15]

A recent article discussed the following probable timeline for availability of the tools necessary to implement the statutes pursuant to which EPA protects human health and the environment:

- Instruments to assess exposure to engineered nanomaterials in air and water – anticipated in 3 to 10 years;
- Effective and relevant nanotoxicity test methods – 5 to 15 years
- Systems that can predict the potential impact of new engineered nanomaterials – 10 years
- Systems to evaluate the impact of nanomaterials from cradle to grave – 5 to 10 years[16]

But, in the interim, what do nanoscale manufacturers do now to limit their liability? What statutes and regulatory mechanisms clearly apply? This paper is an attempt to capture a snap shot of this changing regulatory landscape.

II. Environmental Statutes

a. TSCA[17] and FIFRA[18]

Unlike most of the substantive environmental statutes, both the Toxics Substances Control Act (TSCA), 15 U.S.C. §§ 2601 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 et seq., regulate products, rather than wastes or releases to the environment.

TSCA provides EPA with authority to regulate "chemical substances," defined as:

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[15] See the NNI Budget, available at: http://www.nano.gov/html/about/funding.html. See also the NNI Supplement to the President's FY 2008 budget, available at: http://www.nano.gov/NNI_08Budget.pdf.

[16] Project on Emerging Nanotechnologies, Nature Vol. 444/16 November 2006.

[17] See ABA SEER, Regulation of Nanoscale Materials under the Toxic Substances Control Act (June 2006), available at: http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf.

[18] See ABA SEER The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides (May 2006), available at: http://www.abanet.org/environ/nanotech/pdf/FIFRA.pdf.

> any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and any element or uncombined radical. [19]

With TSCA, EPA has a robust process for regulating potentially toxic chemical products introduced into commerce. For this reason, it is likely the statute of most immediate interest to environmental lawyers focusing on nanotechnology at this point in time.

TSCA regulates chemicals by maintaining a registry of chemicals and requiring registration of new products as well as significant new uses of chemicals that are already on the list. TSCA § 5 allows EPA to assess the risk from individual chemical substances and regulate the limitations on the substances manufacture, processing, distribution and use, and EPA can prohibit the substances manufacture altogether. TSCA § 5(a)(1) addresses new substances, Section 5(a)(2) addresses significant new uses of existing substances for those already recognized by TSCA on its Chemical Substances Inventory

With TSCA § 5(a)(1), new chemical substances are generally prohibited from manufacture unless the manufacturer has submitted a premanufacture notice (PMN) to EPA pursuant to TSCA § 5(a)(1) ninety days before manufacturing the substance. Within that 90 period, EPA will may include the substance on its Inventory either with or without limitations, which could include certain use restrictions, EPa could ask for more data, or EPA could prohibit manufacture completely. With TSCA 5(a)(2), existing chemical substances applied to significant new uses are regulated in the same manner as new chemical substances, once EPA has promulgated a significant new use regulation (SNUR).

These regulatory mechanisms seem relatively clear for conventionally sized materials and also for new nanoscale products that are clearly chemically distinct from previously listed products. Thus, the question becomes how to address a chemical substance that consists of the same elements as its conventional scale equivalent, either in simple atomic or a more complicated molecular form, but in a new nanoscale form with where its discrete structure bestows upon it new chemical and physical properties. Until EPA promulgates regulatory mechanisms for distinguishing these two types of the same material that are unique to engineered nanostructures apart from use of properties that are common to both conventionally sized and nanoscale products, such as actual size (because all materials again consist of atoms or molecules which exist as the least common denominator in both the nanoscale and conventional scale material), TSCA's existing mechanisms are not always adequate.

For these reasons, there must be some basis for distinguishing a material based upon its discrete engineered nanoscale structure, apart from the likely associated molecular structure identifying a portion of it as a particular chemical. This policy route will require EPA to promulgate a definition based upon structure which would necessarily distinguish the new nanoscale structure from the previously approved structures.

FIFRA provides EPA with authority to regulate "pesticides," defined as:

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[19] TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A) (excluding pesticides regulated pursuant to FIFRA, foods and drugs regulated by the Food and Drug Administration, and tobacco).

> (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, * * *[20]

Pursuant to FIFRA, EPA regulates the risk posed by pesticides, and their use, and determines conditions restricting such use, if any, necessary to limit potential risks. This authority would extend to pesticides manufactured using nanomaterials as well.

With FIFRA, EPA imposes requirements for pre-registration of research and development (R&D) through experimental use permits (EUP), requirements for pre-registration testing, requirements for registration including regulation of the use and handling of a pesticide, requirements for registrants to submit post-registration adverse effects information as well as possible requirements for post-registration testing, and finally, reregistration requirements. Additionally, EPA can enforce FIFRA provisions to prevent use of unregistered pesticides or those found to cause unreasonable risk to human health or the environment.

Like TSCA, FIFRA's regulatory scheme also raises an issue regarding how to regulate existing listed pesticides that may be modified using substances that do not differ chemically from those previously listed and registered, but instead differ due to structure. Another separate and interesting challenge to prospective FIFRA application to nanoscale pesticides is the issue of pesticide application, as opposed to chemical composition, should pesticide manufacturers develop a new method of application that relies on delivery of the pesticide, e.g., in a smaller droplet(arguably nanoscale), or in a time release form. However, FIFRA has provisions specifically dictating review and approval of use conditions, and thus, on its face, appears to be less problematic than the issue of chemical composition.

For these reasons, the challenges EPA faces in applying both TSCA and FIFRA to products consisting of, or containing, engineered nanostructures, include:

- Determining whether to distinguish engineered nanostructure from other previously listed products or pesticides;
- If creating a newly listed product or pesticide:
    - lack of toxicological data sufficient to assess risks from exposure via air water contaminant sources, including inhalation and ingestion pathways;
    - Lack of fate and transport data sufficient to determine need for regulation;
    - Lack of complete risk analysis;
- Determining whether previously listed product should be reregistered merely due to nanoscale form;
- Determining whether previously listed product, if used in nanoscale form, should be regulated as "significant new use" under TSCA or additionally regulated under FIFRA;
- Resolving past determinations regarding exemptions and variances to ensure consistency in TSCA or FIFRA implementation;
- Considering whether to develop a new regulatory scheme for nanoscale product and pesticides.

[20] FIFRA § 2(u), 7 U.S.C. § 136(u).

b. Clean Air Act[21] and Clean Water Act[22]

The Clean Air Act (CAA), 42 U.S.C. §§ 7401 et seq., and the Federal Water Pollution Control Act or Clean Water Act (CWA), 33 U.S.C. §§ 1251 et seq., are very similar statutes, utilize similar statutory mechanisms and apply to similar regulatory scenarios. Additionally, both the CAA and CWA utilize similar methods for analyzing concentrations of regulated constituents in the regulated matrix, i.e., air and water respectively. For these reasons, both statutes share the same challenges when extended to nanotechnology, and for this reason are discussed together here.

The CAA provides EPA with authority to regulate releases of "air pollutants" into the ambient air. The CAA defines "air pollutant" as:

> any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive (including source material, special nuclear material, and byproduct material) substance or matter which is emitted into or otherwise enters the ambient air. Such term includes any precursors to the formation of any air pollutant, to the extent the Administrator has identified such precursor or precursors for the particular purpose for which the term "air pollutant" is used. [23]

The CAA provides a regulatory structure which requires EPA to identify types of pollutants, characterizing the risk of exposure to these pollutants once released to the atmosphere, control the release of these pollutants to the degree necessary to protect human health and the environment (based upon the potential risk once released), and monitor the ability of regulated entities to capture these pollutants to prevent or mitigate their release.

The CAA requires EPA to regulate a list of air pollutants emitted by "numerous and diverse" sources, the presence of which in the ambient air "may reasonably be anticipated to endanger public health or welfare." The CAA contemplates differently ambient pollutants which are "generally present in the ambient air in all areas of the nation" and "are generally detectable through monitoring systems and devices" as compared to those pollutants emitted from only a few discrete sources and which would therefore have an impact only in close proximity to the emitting source.

EPA regulates pollutants generally present in ambient air as "criteria pollutants," listed pursuant to CAA § 108, including particulate matter (less than ten microns and less than 2.5 microns in diameter), nitrogen dioxide, sulfer dioxide, ozone (as volatile organic compounds or VOC), carbon monoxide and lead. EPA regulates air pollutants deemed to endanger health and welfare but impacting a smaller area close to a discrete source, pursuant to CAA § 112, which contains a list of 189 individual hazardous air pollutants (HAPs).

Emissions of engineered nanostructures could be regulated as either a criteria pollutant (e.g., particulate matter or VOC), or as a HAP, if the released material consisted of a chemical listed on the CAA § 112 list. However, the criteria pollutant permitting threshold is generally 100 tons per year. The HAP permitting threshold is either 10 tons for a single HAP, or 25 tons for combined

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[21] See ABA SEER CAA Nanotechnology Briefing Paper (June 2006), available at: http://www.abanet.org/environ/nanotech/pdf/CAA.pdf.

[22] See ABA SEER Nanotechnology Briefing Paper Clean Water Act (June 2006), available at: http://www.abanet.org/environ/nanotech/pdf/CWA.pdf.

[23] CAA § 302 (g), 42 U.S.C. § 7602 (g).

HAPs. When manufacturing facilities of engineered nanostructures are struggling to achieve annual production rates of 100,000 pounds, or 50 tons, it is difficult to see how emissions could reach the 20 to 50% of production capacity necessary to trigger permitting requirements even under the lower HAP permitting threshold.

In any case, it will be difficult to design air pollution control strategies specifically for emissions of engineered nanostructures, which, though they may consist of constituents that are currently regulated under the CAA, may behave very differently from those currently regulated due to their small size, negligible mass and higher reactivity resulting from larger surface areas. As a result, application of conventional methods to identify, monitor and measure, and control engineered nanostructure emissions separate from other regulated constituents is, for the most part, inappropriate.

EPA may address these existing technology gaps through the CAA's provisions providing EPA with authority develop appropriate tools to identify, monitor and measure emissions of engineered nanostructures and establish proper emission limitations and compliance tools.

The CWA provides EPA with authority to regulate the discharge of "pollutants" to "navigable waters." The CWA defines "pollutants" as:

> dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water. This term does not mean (A) ``sewage from vessels or a discharge incidental to the normal operation of a vessel of the Armed Forces" within the meaning of section 1322 of this title; or (B) water, gas, or other material which is injected into a well to facilitate production of oil or gas, or water derived in association with oil or gas production and disposed of in a well, if the well used either to facilitate production or for disposal purposes is approved by authority of the State in which the well is located, and if such State determines that such injection or disposal will not result in the degradation of ground or surface water resources. [24]

Thus, the CWA defines "pollutant" sufficiently broadly to also encompass discharges of engineered nanostructures into navigable waters as a discharge of a pollutant. However, as with the CAA, if EPA chooses to regulate discharges engineered nanostructures separately and distinctly from currently regulated pollutants, EPA will have to demonstrate that the discharged engineered nanostructures poses sufficient risk to merit such regulation and that regulation is necessary to avoid a potential adverse effect to human health or the environment. And then, as with the CAA, technology will have to be developed allowing its detection in water, adequate water treatment methods, and methods to allow monitoring and modeling.

Thus, the challenges in applying both the CAA and the CWA to emissions or releases of engineered nanostructures or from nanoscale manufacturing facilities appear to include the following:

- Determining whether to distinguish engineered nanostructure from other nonengineered nanoparticles currently regulated as air pollutants, hazardous air pollutants or CWA pollutants, such as particulate or volatile organic compounds or as other water pollutants

[24] CWA § 502(6), 33 U.S.C. § 1361.

such as total dissolved solids, total suspended solids, chemical oxygen demand and others;

- If creating a newly listed pollutant:
  - lack of toxicological data sufficient to assess risks from exposure via air water contaminant sources, including inhalation and ingestion pathways;
  - Lack of fate and transport data sufficient to determine need for regulation;
  - Lack of complete risk analysis;
- Resolving current mass emission thresholds that far exceed anticipated emissions from nanoscale manufacturing facilities;
- Lack of air pollution control equipment and water treatment methods, including new technology for sampling, analysis, monitoring and modeling applicable to nanostructures.

c. RCRA[25] and CERCLA[26]

The Resource Conservation and Recovery Act (RCRA), 42 U.S.C. §§ 6901, et seq., and the Comprehensive Response, Compensation and Liability Act (CERCLA), 42 U.S.C. §§ 9601, et seq., share the same goal of protecting the environment from releases of hazardous waste, and hazardous substances (which includes RCRA hazardous waste by definition).

RCRA and CERCLA address a similar scope of regulated constituents but differ primarily in when the material is regulated and how. RCRA regulation of hazardous waste begins at "the cradle," or upon point of generation of the waste and ending upon disposal, or when its in "the grave," and thus contemplates the life cycle of the waste from generation to ultimate disposal. CERCLA begins "beyond the grave," or after the material has escaped a proper funeral and has been released to the environment.

Under RCRA, EPA has the authority to regulate the generation, transportation, management, and disposal of secondary materials that become solid wastes that EPA has identified as listed hazardous waste or that exhibits a hazardous characteristic, pursuant to 42 U.S.C. § 6921, pursuant to which EPA is required to consider the substance's "toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics. Such criteria shall be revised from time to time as may be appropriate." EPA has identified and listed what it considers to be hazardous waste with 40 C.F.R. Part 261 (listed categories F, K, U and P; characteristic categories, ignitable, corrosive, reactive, toxic).

With this broad authority to consider possible hazards in determining what constitutes "hazardous waste," there is no doubt that EPA can expand the scope of its RCRA regulations to specifically include nanoscale manufacturing waste. However, at this time, there are no specific regulations contemplating such waste streams as distinct from other manufacturing waste, or evidence that these waste streams would necessarily exhibit any hazardous characteristic. Additionally, to date, no delegated state hazardous waste management programs have implemented more stringent regulations governing nanoscale manufacturing waste.

Though nanoscale manufacturing waste that fits within EPA's current definition of RCRA hazardous waste would certainly be subject to these regulations, it seems questionable whether the amount of waste generated by any one facility would exceed the RCRA waste generation

[25] See RCRA Regulation of Wastes from the Production, Use, and Disposal of Nanomaterials, ABA SEER (June 2006).

[26] See CERCLA Nanotechnology Issues, ABA SEER (June 2006).

threshold of 220 pounds of hazardous waste, or 2.2 pounds of acutely hazardous waste, per month. 40 C.F.R. § 261.5.

CERCLA gives EPA authority to address risks to human health and the environment posed by uncontrolled releases of hazardous substances. CERCLA defines "hazardous substances" as:

> (A) any substance designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act [33 U.S.C. 1321(b)(2)(A)], (B) any element, compound, mixture, solution, or substance designated pursuant to section 9602 of this title, (C) any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act [42 U.S.C. 6921] (but not including any waste the regulation of which under the Solid Waste Disposal Act [42 U.S.C. 6901 et seq.] has been suspended by Act of Congress), (D)any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act [33 U.S.C. 1317(a)], (E) any hazardous air pollutant listed under section 112 of the Clean Air Act [42 U.S.C. 7412], and (F) any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act [15 U.S.C. 2606]. * * *[27]

CERCLA requires reporting of hazardous substance releases above "reportable quantities," 40 C.F.R. § 312, and provides the basis for initiating a CERCLA response or remedial action pursuant to the National Contingency Plan, codified at 40 C.F.R. Part 300.

In order to implement CERCLA in a manner meaningful to the nanoscale manufacturing industry, releases of nanoscale manufacturing waste to the environment must be recognized as releases of a hazardous substance, capable of being measured, and in most cases, released in an amount that exceeds promulgated reportable quantities.

Issues that will arise in RCRA and CERCLA implementation will almost certainly be:

- Determining whether to distinguish engineered nanostructure from other nonengineered nanoparticles currently regulated as hazardous wastes or hazardous substances;
- If creating a newly listed waste or hazardous substance:
  - lack of toxicological data sufficient to assess risks from exposure via air water contaminant sources, including inhalation and ingestion pathways;
  - Lack of fate and transport data sufficient to determine need for regulation;
  - Lack of complete risk analysis;
- Resolving current mass generation and mass release thresholds that may far exceed anticipated the amount of waste or releases that could be generated by any single nanoscale manufacturing facility;
- Lack of material handling methods, control and treatment methods, including new technology for sampling, analysis, monitoring and modeling applicable to engineered nanostructures;
- Inapplicability of SW-846 to identification of nanoparticle structure and identity (sample preparation and analysis destroys nanoparticle);
- Considering whether to develop a new regulatory thresholds for nanoscale manufacturing waste materials and releases.

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[27] CERCLA § 101(14), 42 U.S.C. § 9601(14).

IV. OSHA

The Occupational Safety and Health Administration (OSHA), 29 U.S.C. §§ 651, et seq., regulates employee safety with specific standards, including general standards implemented with 29 C.F.R. Part 1910.

OSHA also imposes a general duty upon employers to create a safe work place, pursuant to the General Duty Clause (GDC), OSHA § 5(a)(1), which states: "Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."

Under the General Duty Clause, an employer has an obligation to protect its workers from serious and recognized workplace hazards, arguably, even where there is no actual standard. Employers would be well-advised to evaluate and implement feasible abatement actions to eliminate known or likely hazards. If an employer fails to take proper action, the employer is vulnerable to a possible OSHA citation under the General Duty Clause.

OSHA utilizes a well proven regulatory scheme relying on Material Safety Data Sheets providing known toxicology, including properties from which are determined the Permissible Exposure Levels, and recommended and proven Best Management Practices, with recommended and proven Personal Protective Equipment (PPE) for each known hazard.

However, OSHA's existing protections have been developed for known toxic and hazardous substances that do not include the potentially different hazards posed by engineered nanostructures. Thus, OSHA implementation faces the same challenges as the other statutes, implementation of which relies on lists that never contemplated the nanoscale form of a previously recognized and well known chemical substance. Therefore, lacking a complete data base of nanoscale properties exhibited by the variety of engineered nanostructures that would normally be factored into the classic risk assessment calculus including: hazard identification, dose-response assessment, exposure assessment and ultimate risk characterization, insufficient data exists to apply the normal OSHA process.

For these reasons, current OSHA standards appear problematic in application, and unless the individual employer has information providing sufficient notice regarding risks of exposure, then the employer is arguably not on notice regarding best management practices, proper personal protective equipment, hazard communication or training. Moreover, OSHA's criteria for issuing a General Duty Clause Citation, including presence of a hazard that is recognized, that causes or is likely to cause serious harm or death, and that must be correctable, appear difficult to apply where the hazard, causation and best management practices are unclear.

To assist, NIOSH has focused on worker safety in the nanotech context. In August of 2006, NIOSH posted a guidance document entitled "Approaches to Safe Nanotechnology: An Information Exchange with NIOSH, August, 2006.[28] With this guidance, NIOSH suggested that nanomanufacturers control nanoparticles as aerosols, including the use of:

- Process enclosure;

[28] Available http://www.cdc.gov/niosh/topics/nanotech/safenano/. See also, Progress Toward Safe Nanotechnology in the Workplace (June 2007), available at: http://www.cdc.gov/niosh/docs/2007-123/pdfs/2007-123.pdf.

- Exhaust ventilation;
- HEPA filters;
- Wet materials management/cleaning methods;
- NIOSH certified respirators: “particulates as small as 2.5 nm in diameter are efficiently captured, in keeping with single fiber filtration theory.”

Along with Basic Risk Communication and Training, these practices and any others recommended by NIOSH could probably suffice as “best management practices,” until practices are adopted that are specific to the various nanoscale manufacturing industries and contemplate the nanoscale materials to which their employees are exposed.

V. Local Ordinances

a. Berkeley

On December 12, 2006, pursuant to recommendations from its Community Environmental Advisory Commission, the Berkeley, California City Counsel adopted an ordinance that requires businesses to report nanoparticles being used, provide available toxicological information and outline measures for safe handling of the materials. Issue arose during the design phase of the molecular foundries at the University of California and Lawrence Berkeley Lab, where both institutions admitted lack of special knowledge or tools on how to manage nanoparticles.

The CEAC Recommendation stated:

> Nanoparticles behave differently than macro-particle compounds and should be handled and mitigated differently. Handlers may not know much about the materials they are handling, as new information is published, the handlers should keep updating their knowledge, since government is not doing a good job regulated these materials.

The CEAC adopted revisions to the Berkeley Municipal Code Sections 15.12.040 and 15.12.050, addressing disclosure requirements for hazardous materials and waste management. Section 15.12.040 providing which facilities trigger disclosure requirements, now includes:

> All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate such materials. (Ord. 6960-NS § 1 (part), 2006: Ord. 6824-NS § 3, 2004)

While section 15.12.050 providing quantities triggering disclosure requirements now lists no quantity all, requiring categorical disclosure regardless of quantity:

> All manufactured nanoparticles, defined as a particle with one axis less than 100 nanometers in length, shall be reported in the disclosure plan. (Ord. 6960-NS § 2 (part), 2006: Ord. 6824-NS § 3, 2004)

b. Cambridge

In January, 2007 newspapers reported that Cambridge, Massachusetts, City Council was considering enacting similar measures. Boston Globe (Jan. 26, 2007). Cambridge has an interesting history that may be used to address nanotechnology.

In the 1960s and 1970s, Harvard and MIT, both located in Cambridge, became recognized as leaders in the area of biotechnology research involving recombinant DNA.[29] Due to public concern regarding risk to human health of such work, in 1976, the Cambridge City Council created the Cambridge Experimentation Review Board (CERB). CERB developed guidelines for managing risk to public safety and worker health, which were later codified into ordinance, which is enforced by the Cambridge Biosafety Committee.

This early controversy allowed the development of a savvy public body with extraordinary sophistication that allows promotion of new scientific developments, rather than allowing new developments to attacked out of fear. This model, termed the “Cambridge Model” is helpful in considering public response to developments in nanotechnology and may be used in local regulations applicable to the nanoscale manufacturing industry.

VI. Voluntary Efforts

EPA may be successful in implementing the existing environmental statutes in a manner that safely controls the impact of the nanomanufacturing industry to human health and the environment. However, there are many challenges, including primarily the gap in data for nanomaterials regarding toxicology and environmental fate and transport. However, once these gaps are filled such that EPA has clear authority to regulate certain nanomaterials, sufficient methods for identifying, detecting, controlling and monitoring releases of these materials must also be available. All sources indicate that it will be some time before these regulatory tools are available.

The void in regulation is being targeted by voluntary efforts, such as EPA’s Stewardship Program under TSCA. On June, 2005, EPA formed an Interim Ad Hoc Work Group on Nanoscale Materials as part of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), a federal advisory group tasked with advising OPPT on TSCA and pollution prevention issues.[30] In November, 2005, NPPTAC issued Overview Document on Nanoscale Materials, providing voluntary “Nanoscale Materials Stewardship Program (NMSP)” for nanoscale materials now in, or soon to enter, commerce. Versions of participation include “Basic” and “In-depth”

Through the NMSP, manufacturers supply necessary information regarding material characterization, hazard, use and exposure potential and risk management practices. Currently available through EPA’s SP are the Concept Paper, the TSCA Inventory Request, the Information Collection Request which asks for specific properties of nanomaterials, and possible risk management practices developed from a stakeholders meeting in October, 2006.[31]

With this forum, hopefully EPA will achieve an acceptable method to prospectively address debates regarding product registration requirements where engineered nanostructure consists of material previously registered, but registered in larger particle form.

[29] See The Cambridge Model, by Sam Lipson, GeneWatch, Volme 15, Number 5 (Sept. – Oct. 2003).
[30] Available at: http://epa.gov/oppt/nano/nmspfr.html.
[31] Final Meeting Summary Report for Risk Management Practices for Nanoscale Materials, U.S. EPA, OPPTS (March 13, 2007).

Also, there is the Nano Risk Framework (NRF) posted on the world wide web June 21, 2007 by Dupont and Environmental Defense (ED).[32] With this material, Dupont and ED provides a method to characterize and address risk from nanomaterials, as well as case studies illustrating application of the concepts in the NRF.

Specifically, the NRF contemplates an iterative (feedback) assessment process beginning with a description of the material and its application, profile of the lifecycle of the material including its properties, hazard and potential exposures, both of which inform an assessment of the risk posed by the material. The risk assessment allows development of risk management methods which are then adopted and implemented. And of course, all of this continues to inform the review continues to inform the process when applied to newly developed materials.

VII. Conclusion

At this point, the environmental statutes do not exempt the nanoscale manufacturing industry, thus, emissions, releases, wastes and products that all meet the defined regulatory terms of the existing environmental statutes are regulated as any other material.

However, with TSCA and FIFRA, it is not clear exactly what additional restrictions are required, if any, for nanoscale versions of existing and previously listed products. The duty of nanoscale manufacturers is also not clear under TSCA or FIFRA. And though wastes and other releases in the form or air emissions or discharges to water from nanoscale manufacturing facilties are also not exempt from RCRA, CERCLA, CAA or CWA, it is not clear whether, and if so, which, nanoscale manufacturing constituent by-products meet the definitions under the statutes, or if they fit within the definitions, whether they would be released in quantities which would trigger regulatory requirements. Even if regulated, there are no currently identified specifically targeted technologies that have been developed purely to capture, identify, monitor or model these emissions or releases as discrete engineered nanostructures separate and distinct from their chemical components, or any reliable toxicity or risk assessment data upon which to rely in determining alternative lower or more specific regulatory thresholds.

The most definitive statement we have at this point addressing risk to human health and providing structure moving forward appears to be the NIOSH guidance developed for the work place, including guidance suggesting management of nanoscale manufacturing by-products as aerosols, which may constitute a "best management practice" at this point.

Nanotechnology is as revolutionary as the discovery of electricity, the internal combustion engine and plastic. There will come a time soon when our lives will be changed to the same extent through applications of nanotechnology. Hopefully, we will have learned from prior lessons and proceed conservatively and efficiently to maximize benefits and minimize risks.

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[32] Nano Risk Framework, Environmental Defense and Dupont Nano Partnership, (June 21, 2007), available at http://nanoriskframework.com.

Nanotechnology and Environmental Regulation Reading List[33]
August 2007

Lynn L. Bergeson and Joseph E. Plamondon, TSCA and Engineered Nanoscale Substances, 4 *Nanotechnology L. & Bus.* 617 (March 2007), available at http://www.lawbc.com/other_pdfs/00010729.PDF.

Lynn L. Bergeson, EPA Considers How Best to Regulate Nanoscale Materials, *Envtl. Quality Mgmt.* (Autumn 2005), available at http://www.lawbc.com/other_pdfs/EQM%20Autumn%202005.pdf.

Lynn L. Bergeson, TSCA and Nanoscale Materials Update, *ABA Pesticides, Chemical Reg., and Right-to-Know Committee Newsl.* (Aug. 2005) at 9-11, available at http://www.lawbc.com/other_pdfs/ABA%200805%20Bergeson.pdf.

Lynn L. Bergeson, Avoid Mistakes of Past: Develop Nano Responsibly, *The Envtl. Forum* (July/Aug. 2005) at 41, available at http://www.lawbc.com/other_pdfs/nanotech%20forum.pdf. This article is one of several published as No Small Task: Regulating Nanotechnology To Ensure Safety, Maximize Benefits, at 38-45.

Lynn L. Bergeson, Nanotechnology Readies for a Wastewater Role, *Chemical Processing* (June 2005), available at http://www.lawbc.com/other_pdfs/Chemical%20Processing%20June%202005.pdf.

Lynn L. Bergeson, Nanotechnology: EPA Considers How to Proceed, *Pollution Engineering* (June 2005), available at http://www.lawbc.com/other_pdfs/Pollution%20Engineering%20June%202005.pdf.

Lynn L. Bergeson, Nanotechnology and TSCA, *ABA Pesticides, Chemical Reg., and Right-to-Know Committee Newsl.* (Apr. 2005) at 11-12, available at http://www.lawbc.com/other_pdfs/ABA%20Newsletter%200405.pdf.

Lynn L. Bergeson, Nanomaterials and Protecting Health Risk, *Envtl. Expert Newsl.* (Feb. 2005) at 34-35, available at http://www.lawbc.com/other_pdfs/3774.pdf.

Lynn L. Bergeson, The Regulatory Implications of Nanotechnology, *Envtl. Quality Mgmt.* (Autumn 2004), available at http://www.lawbc.com/other_pdfs/EQM%20Autumn%202004%20-%20Bergeson.pdf.

Lynn L. Bergeson, Nanotechnology Trend Draws Attention of Federal Regulators, *Manufacturing Today* (Mar./Apr. 2004), available at http://www.lawbc.com/other_pdfs/Manufacturing%20Today%20Mar-Apr%202004.pdf.

Lynn L. Bergeson and Bethami Auerbach, The Environmental Regulatory Implications of Nanotechnology, *BNA Daily Env. Rep.* (Apr. 14, 2004) at B1-B7, available at http://www.lawbc.com/other_pdfs/The%20Environmental%20Regulatory%20Implications%20of%20Nanotechnology.pdf.

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[33] Thanks to Lynn Bergeson, Bergeson & Campbell, P.C., for providing this helpful comprehensive list of relevant reading materials.

Lynn L. Bergeson and Bethami Auerbach, Reading the Small Print, *The Envtl. Forum* (Mar./Apr. 2004) at 30-32, 34, 36-38, available at http://www.lawbc.com/other_pdfs/Nanotechnology%20Env.%20Forum%20M-A%202004.pdf. This article is one of several published at 30-49.

Lynn L. Bergeson, Nanotechnology and TSCA, *Chemical Processing* (Nov. 2003), available at http://www.lawbc.com/other_pdfs/Chemical%20Processing%20November%202003.pdf.

Linda K. Breggin and John Pendergrass, Where Does the Nano Go? End-of-Life Regulation of Nanotechnologies (July 2007), available at http://www.nanotechproject.org/reports.

J. Clarence Davies, EPA and Nanotechnology: Oversight for the 21st Century (May 2007), available at http://www.nanotechproject.org/reports.

Mark Greenwood, Nanotechnology - Thinking Big About Things Small: Creating an Effective Oversight System for Nanotechnology (Mar. 2007), available at http://www.nanotechproject.org/reports.

American Bar Association Section of Environment, Energy, and Resources, Nanotechnology Briefing Papers (May-June 2006), available at http://www.abanet.org/environ/nanotech/.

Vivienne Parry, The Nano State Is Here, *The Times* (Feb. 25, 2006), available at http://www.timesonline.co.uk/tol/news/uk/health/article734268.ece.

J. Clarence Davies, Managing the Effects of Nanotechnology (Jan. 2006), available at http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf.

International Risk Governance Council, Survey on Nanotechnology Governance: Volume A - The Role of Government (Dec. 2005), available at http://www.irgc.org/irgc/IMG/pdf/Survey_on_Nanotechnology_Governance_-_Part_A_The_Role_of_Government.pdf.

Environmental Law Institute, Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up To the Job? *A Dialogue* (Oct. 2005), available at http://www.elistore.org/reports_detail.asp?ID=11116.

Drew L. Harris, A Review of Nanotechnology: Environmental Implications and Solutions, 2 *Nanotechnology L. & Bus.* 305 (2005).

Kristen M. Kulinowski & Vicki L. Colvin, Environmental Implications of Engineered Nanomaterials, 1 *Nanotechnology L. & Bus.* 52 (2004).

Paul C. Lin-Easton, It's Time for Environmentalists to Think Small -- Real Small: A Call for the Involvement of Environmental Lawyers in Developing Precautionary Policies for Molecular Nanotechnology, 14 *Geo. Int'l Envtl. L. Rev.* 107 (2001), available at http://www2.arch.uiuc.edu/elvin/nanotech_files/lineaston.pdf.

Tina Masciangioli & Wei-Xian Zhang, Environmental Technologies at the Nanoscale, *Envtl. Sci. & Tech.* (Mar. 1, 2003) at 103A-108A, available at http://www.nano.gov/html/res/GC_ENV_PaperZhang_03-0304.pdf.

Glenn Harlan Reynolds, Nanotechnology and Regulatory Policy: Three Futures, 17 *Harv. J.L. & Tech.* 179 (2003), available at http://jolt.law.harvard.edu/articles/pdf/v17/17HarvJLTech179.pdf.

Scott H. Segal, Environmental Regulation of Nanotechnology: Avoiding Big Mistakes For Small Machines, 1 *Nanotechnology L. & Bus.* 290 (2004).

Peter J. Tomasco, Manufactured Nanomaterials: Avoiding TSCA and OSHA Violations for Potentially Hazardous Substances, 33 *B.C. Envtl. Aff. L. Rev.* 205 (2006), available at http://www.bc.edu/schools/law/lawreviews/meta-elements/journals/bcealr/33_1/ealr_33_1_web.pdf.

CYV Wang, G Roam, Good Governance or Grey Governance? Taiwan EPA's Approaches in Responsible Nanotechnology (2004), available at http://www.epa.gov.tw/attachment_file/GOOD%20GOVERNANCE%20OR%20GREY%20GOOVERNANCE2.pdf.

Jason Wejnert, Regulatory Mechanisms for Molecular Nanotechnology, 44 *Jurimetrics J.* 323 (2004), available at http://www.law.asu.edu/files/Programs/Sci-Tech/Commentaries/Wejnert-%20Regulatory%20Mechanisms%20for%20Molecular%20Nanotechnology-%20Final.pdf.

Joel Rothstein Wolfson, Social and Ethical Issues in Nanotechnology: Lessons from Biotechnology and Other High Technologies, 22 *Biotechnology L. Rep.* 376 (2003), available at http://www.blankrome.com/publications/Articles/WolfsonNanotechnology.pdf.