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Regulating Risks of Nanotechnologies for Water Treatment

by Reut Snir

Editors' Summary: Commercialization of nanotechnologies for water treatment prior to careful study of their potential risks may put human health and our limited freshwater resources at risk. In this Article, Reut Snir explores the risks surrounding regulating nanotechnologies for water treatment. She analyzes the gaps in the current legislative and regulatory framework managing nano-based applications for water treatment, focusing specifically on EPA's tools for collecting environmental health and safety information. She suggests ways in which EPA can oversee the development of such technologies within its existing authorities, highlighting short-term possibilities to achieve more with less. She acknowledges, however, that in some cases current authorities are simply inadequate for the task.

I. Introduction

Freshwater is one of the most important resources for human existence. Of all water on earth, only 2.5% is fresh. Seventy percent of freshwater is frozen in the polar icecaps, and the remaining 30% is found in soil moisture and underground aquifers. As a result, less than 1% of the world's freshwater (or about 0.007% of water globally) is found in lakes, rivers, reservoirs, or shallow underground sources, readily accessible for direct human uses at an affordable cost.[1] Furthermore, changes in the hydrological cycle and precipitation patterns due to climate change, water contamination, and a continuous increase in demand for water due to population growth and changing standards of living further limit the availability of this scarce resource.[2] Therefore, ensuring accessibility to an adequate quantity and quality of water is emerging as one of the great challenges of the 21st century.

Nanotechnologies for water purification and groundwater remediation have been identified as a high priority area for development. A new generation of nanotechnology companies is focused on this market. A few nano-based water treatments already are marketed and more are underway.[3] Several nanotechnologies, such as iron oxide (Fe_2O_3) nanoparticles, are being used for environmental remediation in the United States and elsewhere; these involve the release of tons of nanoparticles into the water. Meanwhile, the growing number of research studies on the potential human health and environmental risks of nanotechnologies raise concerns that the unique properties of nanomaterials may cause some of them to be toxic.

Since commercialization of nanotechnologies for water treatment prior to careful study of their potential risks may harm our limited freshwater resources and put human health at risk, responsible development in this area is crucial. Yet, current scientific limitations to measure and monitor nanoscale materials, along with inadequate funding for environmental, health, and safety (EHS) studies, leaves regulatory agencies with many uncertainties regarding the risk of nanotechnologies to human health and the environment. These uncertainties paralyze traditional environmental regulation and render it incapable of dealing adequately with the new challenge.

This Article seeks to analyze the gaps in the current legislative and regulatory framework to oversee nanotechnology applications for water treatment. Furthermore, given that the most crucial impediment for adequate regulation is the lack of knowledge and understanding of the actual risks posed by nanotechnologies, the Article specifically focuses on tools used by the U.S. Environmental Protection Agency (EPA) to generate, collect, and verify EHS information. The Article will suggest ways in which EPA can oversee the development of such technologies within its existing authorities, highlighting short term possibilities to achieve more

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1. World Health Organization (WHO), *Health in Water Resources Development Fact Sheet*, http://www.who.int/docstore/water_sanitation_health/vector/water_resources.htm (last visited Feb. 7, 2008).
2. The fourth assessment of the Intergovernmental Panel on Climate Change (IPCC) found that "[t]he population at risk of increasing water stress . . . is projected to be: 0.4 to 1.7 billion, 1.0 to 2.0 billion, and 1.1 to 3.2 billion, in the 2020s, 2050s, and 2080s, respectively." IPCC Report, *Freshwater Resources and Their Management, 2007: Working Group II: Climate Change Impacts, Adaptation, and Vulnerability*, http://www.ipcc-wg2.org/index.html.
3. *See* Melanie Haiken, *Nanotech Takes on Water Pollution*, Business 2.0, *available at* http://money.cnn.com/magazines/business2/business2_archive/2007/07/01/100117050/.

with less. Nevertheless, it acknowledges that in some cases, current authorities are simply inadequate for the task.

II. Introduction to Nanotechnologies and Engineered Nanomaterials

A. Defining Nanotechnologies

Noro Taniguchi, a researcher at the University of Tokyo, Japan, coined the term "nanotechnology" in 1974 to refer to "the ability to engineer materials precisely at the nanometer level."[4] Since then, institutes within the United States and around the world have defined the term in different ways, and there is currently no binding definition for the industry or the regulators to follow in the regulatory context.[5]

The way nanotechnologies and nanomaterials are defined in a policy context may significantly affect the scope of regulation, the way a technology or material is to be regulated, and the effectiveness of the regulatory program.[6] Focusing on specific applications for water treatment, the term nanotechnologies in this Article refers to technologies that incorporate engineered materials and/or features at the nanoscale level.

B. Engineered Nanomaterials: An Overview

1. The Opportunities

Engineered nanomaterials possess nanostructure-dependent properties. At a nanoscale size, materials have a larger surface area relative to mass than the same material produced in a larger form, resulting in a corresponding increase in chemical reactivity.[7] Also, in materials at a nanoscale size, quantum effects start to play a role rather than the classical laws of physics[8]; this means that electrons can pass through thin, electrically isolated materials, which are typically energy forbidden areas.[9] These two characteristics give engineered nanomaterials their novel electrical, catalytic, magnetic, mechanical, thermal, or imaging properties that are useful for applications in the commercial, medical, military, and environmental sectors.[10]

EPA classifies current engineered nanomaterials into four categories: (1) carbon-based materials; (2) metal-based materials; (3) dendrimers; and (4) composites.[11] In the commercial sector alone, at least 450 consumer products incorporating nanotechnology are available in the market, in areas such as health and fitness, home and garden, electronics and computers, automotive, appliances, goods for children, and food and beverage.[12] In addition to consumer products there are many non-consumer products, i.e., intermediate components and industrial equipment items used by manufacturers (current numbers are not available). Lux Research reported over $32 billion worth of nano-incorporated products sold in 2005—more than double the previous year's sales. In 2014, they project that $2.6 trillion in global manufactured goods will incorporate nanotechnologies, or about 15% of total output.[13]

Nanotechnologies are developing rapidly. The first generation of passive nanostructures created around 2001 brought about materials including coatings, polymers, and more reactive catalysts. The second generation, already under way, involves targeted drug delivery systems, adaptive structures, and actuators. The third generation, anticipated around 2010, is predicted to bring novel robotic devices, three-dimensional networks, and guided assemblies. The fourth stage expected around 2015 is predicted to result in molecule-by-molecule design and self-assembly capabilities.[14] In the long term, these developments will also be converged, integrated, and synergized with biotechnology, information technology, and cognitive technology, resulting in dramatically different new products. As technologies move to the next generation of nanoscale-engineered substances, such developments may represent a significant challenge to the traditional manufacturing, use, and recycling or disposal processes, as well as to the development of policies and regulations to protect human health and the environment.[15] For example, it is unclear how traditional chemical regulation approaches can address nanostructure chemicals integrated with biological materials, guided assemblies, and other innovations.

2. The Potential Risks and the Uncertainties

The novel properties of nanomaterials inspire not only promises but also many concerns regarding unintended

4. The United Kingdom Royal Society & The Royal Academy of Engineering, Nanoscience and Nanotechnologies: Opportunities and Uncertainties 5 (2004), *available at* http://www.nanotec.org.uk/report/chapter2.pdf [hereinafter UK RS/RA Eng White Paper].

5. *See* National Nanotechnology Initiative (NNI), *What Is Nanotechnology?*, http://www.nano.gov/html/facts/whatIsNano.html (last visited Feb. 7, 2008); EPA Science Policy Council, Nanotechnology White Paper 1 (2007) (EPA 100/B-07/00), *available at* http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf [hereinafter EPA White Paper]. For more examples of definitions, see American Society for Testing & Materials (ASTM Int'l), Terminology for Nanotechnology, (2006) (E2456-06) (on file with author) and UK RS/RA Eng White Paper, *supra* note 4.

6. J. Clarence Davies, Project on Emerging Nanotechnologies (PEN), The Woodrow Wilson International Center for Scholars (WWICS), Managing the Effects of Nanotechnology 7 (2006), *available at* http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf.

7. *See* UK RS/RA Eng White Paper, *supra* note 4.

8. *Id.*

9. Michael Gleiche et al., Nanoforum.org, Nanotechnology in Consumer Products 17-18 (2006), *available at* http://www.Nanoforum.org/dateien/temp/Nanotechnology%20in%20Consumer%20Products.pdf?10032007145126 (last visited Feb. 7, 2008).

10. *See* EPA White Paper, *supra* note 5, at 10.

11. *See id.* at 7-10.

12. PEN, *A Nanotechnologies Consumers Products Inventory Analysis*, http://nanotechproject.org/44 (last visited Feb. 7, 2008). The inventory contains only nano-based products that are self-identified by the manufacturer, advertised on the Internet, and described in English. Therefore, there clearly could be many more such products available on the market from various countries around the world. *See* Evan Michelson & David Rejeski, Falling Through the Cracks: Public Perception, Risk, and the Oversight of Emerging Nanotechnologies, IEEE International Symposium on Technology and Society Conference Proceedings 8 (2006), *available at* www.nanotechproject.org/file_download/107.

13. *See* Press Release, Lux Research, Nanotechnology in $32 Billion Worth of Products; Global Funding for Nanotech R&D Researches $9.6 Billion (May 8, 2006), *available at* http://www.luxresearchinc.com/press/RELEASE_TNR4.pdf.

14. *See* EPA White Paper, *supra* note 5, at 12-13.

15. *See id.* at 11-12.

risks to human health and the environment. The wide variety of properties among nanomaterials indicates that each nanoparticle can elicit its own unique biological or ecological response.[16] The potential health risk is generally associated with the magnitude and duration of exposure to a particular substance, the persistence of the substance in the body, the inherent toxicity of the material, and the susceptibility or health status of the person.[17] The diverse routes of exposure, including inhalation, dermal uptake, ingestion, and injection, may further complicate the toxicological outcomes of the nanoparticle in question.[18] Thus, once nanoparticles are released into the environment, it is essential to understand their fate in order to determine in which environments they are most likely to occur or accumulate, and hence, which organisms are most likely to be exposed.[19]

Figure 1

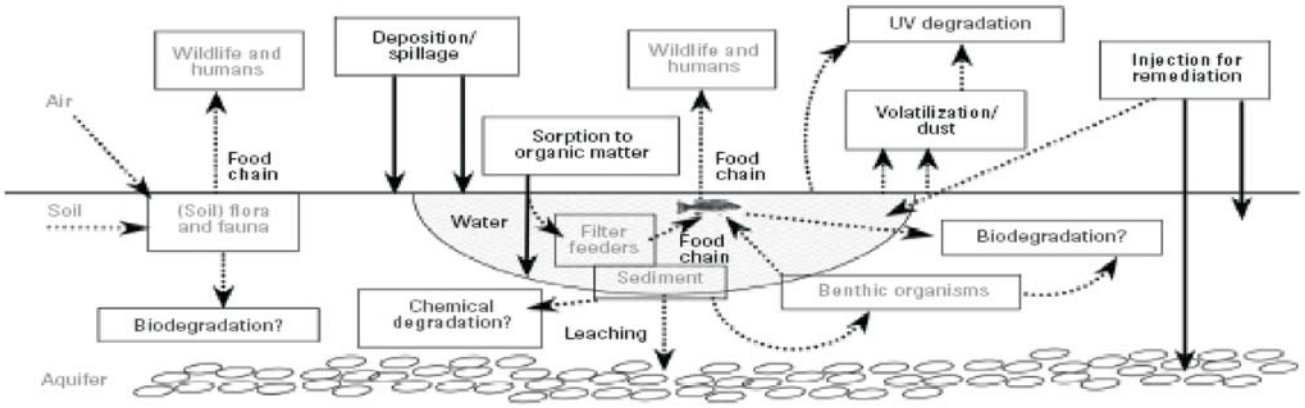


Figure 5. Routes of exposure, uptake, distribution, and degradation of NSPs in the environment. Solid lines indicate routes that have been demonstrated in the laboratory or field or that are currently in use (remediation). Magenta lettering indicates possible degradation routes, and blue lettering indicates possible sinks and sources of NSPs.

Günter Oberdörster et al., *infra* note 44, at 828.

When evaluating the potential risk associated with a nanoparticle release into the environment, both exposure and toxicity hazard need to be considered.[20] While the traditional risk assessment method[21] is appropriate to assess risks from nanoparticles, risk evaluation of nanoscale and structure of materials cannot rely solely on toxicological profiles of equivalent bulk materials. First, traditional risk assessment methods, which express exposure dose in terms of unit weight (mass concentration) rather than in terms of number of particles or total surface area, may severely underestimate the potential contribution of nanoparticles to the overall risk posed by the substance.[22] Second, the size and the shape of the nanoparticle rather than just its chemical composition, as well as its surface modification and its aggregation, dissolution, or degradation properties, must be taken into consideration in hazard determination.[23]

Unfortunately, many aspects of nanoparticles make them challenging to address: first, to date, routine sampling and measuring of particles in the size below detection by the naked eye are very difficult to conduct and the technologies utilized are costly and not widely available.[24] Second, long experience has given scientists a good understanding of what characteristics make a conventional substance harmful, so they can make reasonable judgments even when they lack specific toxicity data, but in the case of nano-

16. *See* Andre Nel et al., *Toxic Potential of Materials at Nanolevel*, 311 Science 622, 624 (2006).

17. Centers for Disease Control & Prevention (CDC)/National Institute for Occupational Safety & Health (NIOSH), Approaches to Safe Nanotechnology: An Information Exchange With NIOSH (draft for public comments) 6 (2006), *available at* http://www.cdc.gov/niosh/topics/nanotech/safenano/pdfs/approaches_to_safe_nanotechnology_28november2006_updated.pdf.

18. Günter Oberdörster et al., *Principles for Characterizing the Potential Human Health Effects From Exposure to Nanomaterials: Elements of a Screening Strategy*, 2 Particle & Fiber Toxicology, Oct. 2005, at 8, 11, *available at* http://www.particleandfibretoxicology.com/content/pdf/1743-8977-2-8.pdf.

19. Günter Oberdörster et al., *Toxicology of Nanoparticles: A Historical Perspective*, 1 Nanotech. 2, 16 (2007) [hereinafter Oberdörster et al. 2007].

20. NNI, Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials 4 (2006), *available at* http://www.nano.gov/NNI_EHS_research_needs.pdf.

21. The National Research Council (NRC) of the National Academies, Risk Assessment in the Federal Government: Managing the Process 18 (National Academies Press 1983).

22. *See* Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated With Engineered and Adventitious Products of Nanotechnologies (SCENIHR) 44, 47 (SCENIHR/002/05), *available at* http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf (modified Mar. 10, 2006) [hereinafter SCENIHR Opinion].

23. *See id.* at 22-23.

24. *Id.* at 18-19, 35-36.

particles, "structure-activity relationships" are only beginning to be developed, and results are often unreliable and contradictory.[25]

Günter Oberdörster and others further point out that with current understanding of the kinetics and effects of nanoparticles, "it appears that it is not possible based on findings with one specific engineered nanoparticle to derive generalized conclusions that all nanoparticles will follow the same pattern of uptake and include the same effects."[26] They further note that "[t]here are too many variables, not only size, but surface characteristics (chemistry, charge, porosity, etc.), persistence of coating and others that influence [nanoparticles] effects and kinetics."[27] Thus, a better understanding of the interplay of factors contributing and affecting uptake and disposition is needed before extrapolating specific nanoparticle results to other nanoparticles.

Adding to the potential real risk of nanotechnologies, the future of their development depends also on public perception of those possible risks. As with other emerging technologies in the past, such as genetically modified food, people fear "unknown risks and consequences" or "unintended uses," and they are worried that the "manipulation will affect natural laws."[28] Therefore, such innovative technologies often face some public resistance during their development. These fears, of course, are not unique to nanotechnologies, but they may affect the pace at which these technologies are developed or accepted.

III. Nanotechnologies for Water Treatment: A Closer Look

A. Applications of Nanotechnologies for Water Treatment

Nanotechnologies may provide part of the solution to the growing problem of adequate freshwater supply through inexpensive decentralized water purification, detection of contaminants, and improved filtration systems.[29] Nanotechnologies can be applied to water treatment in four ways: (1) filtration; (2) pollutant separation; (3) pollution degradation; and (4) detection of contaminants.[30]

1. Filtration

The common treatment for polluted water is conventional treatment[31] that brings water quality to drinking water standards. These methods cannot remove dissolved salts and some soluble inorganic and organic substances.[32] Pressure-driven membrane processes,[33] particularly nanofiltration and reverse osmosis, may close these loopholes in conventional treatment.[34] Nanofiltration membranes are made of carbon nanotube filters that can remove microscale to nanoscale contaminants from water, and have been found to be more resilient and reusable than conventional membrane filters. Other technologies are oxidized aluminum nanofibers on a glass fiber substrate, manipulated naturally occurring zeolites and attapulgite clay, and nanoporous polymers.[35]

2. Separation

The removal of pollutants from water is also possible through magnetic nanoparticles, which are coated with different compounds that have a selective affinity for diverse contaminants. The captured nanomagnet-pollutant can thus be removed from the water with a magnetic pump. Later, this package can be separated, allowing for the reuse of the magnetic nanoparticles and the recycling of the pollutants. This class of technologies is particularly suitable for decomposing organic pollutants and removing salts and heavy metal (such as arsenic) from liquids.[36]

3. Degradation

Another method of water treatment, and of most interest to this Article, is the promotion of a chemical reaction of materials in contaminated water that results in pollutant degradation. Catalytic particles—either dispersed in solution or deposited onto membrane structures—can chemically degrade pollutants rather than just removing them from the water.[37] Nanocatalysts such as titanium dioxide (TiO_2), nanoscale zero-valent iron (nZVI), Fe_2O_3, and nanoscale fullerene (C_{60}) can be used to degrade organic pollutants and remove salts and heavy metals from liquids. Photocatalysis may achieve additional degradation as water passing through a nanomaterial is also subject to ultraviolet light, leading to the destruction of contaminants.[38]

25. *Id.*

26. Oberdörster et al. 2007, *supra* note 19, at 13.

27. *Id.*

28. Jane Macoubrie, PEN, Informed Public Perceptions of Nanotechnology and Trust in Government 10-11, (2005), *available at* http://www.wilsoncenter.org/events/docs/macoubrie report.pdf.

29. Foresight Nanotech Institute, *Foresight Challenges: Supplying Clean Water Globally*, http://foresight.org/challenges/water.html (last visited Feb. 25, 2008).

30. For an overview of nano-based technologies for water treatment, see Meridian Institute, Global Dialogue on Nanotechnology and the Poor: Opportunities and Risks, Overview and Comparison of Conventional Water Treatment Technologies and Nano-Based Technologies (2006), *available at* http://www.merid.org/nano/watertechpaper/watertechpaper.pdf.

31. The conventional water treatment process includes pretreatment to remove suspended solids, coagulation, and flocculation to precipitate dissolved impurities through sedimentation, disinfection, and aeration to treat the bacteria, and filtration to remove any suspended particles. *See* Thembela Hillie et al., Nanotechnology, Water, and Development 19 (2006), *available at* http://www.merid.org/nano/waterpaper/NanoWaterPaperFinal.pdf.

32. *See id.*

33. The pressure-driven membrane is a barrier that separates solutes of a fluid mixture by allowing some solutes to pass through but reject the permeation of others. The driving force can be pressure difference, concentration gradient, temperature difference, or electrical potential difference. A membrane process does not require chemicals and massive energy, and is easily operated and maintained. There are four pressure-driven membrane processes: microfiltration and ultrafiltration that are commonly used in pretreatment, and nanofiltration and reverse osmosis which are most widely used in water treatment. *Id.* at 20.

34. *See id.*

35. *See id.* at 21-22.

36. *See id.* at 25.

37. *See id.* at 24; *see also* Rice University Center for Biological & Environmental Nanotechnology (CBEN), *Nanocatalysis for Remediation of Environmental Pollutants*, http://cohesion.rice.edu/centersandinst/cben/research.cfm?doc_id=5099 (last visited Feb. 7, 2008).

38. Hillie et al., *supra* note 31, at 24; *see also* D. Sun et al., *Removal of Natural Organic Matter From Water Using a Nano-Structured Photocatalyst Coupled With Filtration Membrane*, 49 Water Sci. & Tech. 103 (2004).

4. Detection

An essential part of choosing the appropriate treatment method of contaminated water is identifying the polluting components. Nanosensors can detect single cells or even atoms, making them far more sensitive than counterparts with larger components.[39] Technologies for nanosensors include single- and multi-walled carbon nanotubes (SWCNT/MWCNT) that can detect chemicals in water in real time.[40]

Some of these technologies are commercially available and are used in municipal water treatments or in groundwater remediation sites around the United States.[41] More advanced technologies such as self-assembling membranes, membranes with antimicrobial coating, mixed metal oxide nanostructured materials for biological toxins destruction and whole-cell microbial biosensors are under development and have the potential to be applied commercially within the next five years.[42] To properly utilize the commercial potential of these technologies, it is important to understand at an early stage of their development what unintended negative consequences may occur.

B. The Potential Risks to Human Health and the Environment

To date, only a limited number of nanotoxicology studies address the effects of nanomaterials in a variety of organisms and environments. An even smaller number of studies focus specifically on ecotoxicity or cytotoxicity of nanomaterials upon contact with water. Likewise, few studies have examined dermal or oral routes of exposure, which are the most relevant for applications of nanotechnologies for water treatment. Thus, there is still insufficient information to adequately describe the potential risks associated with the specific nanomaterials used in water treatment technologies.

In terms of exposure risk, generally speaking, in oral exposure, the smaller the particles, the faster they are likely to penetrate the mucus and reach the colon through the gastronomical system.[43] Most studies have shown that nanoparticles pass through the gastrointestinal tract and are eliminated rapidly via feces; a small percentage is eliminated via urine, indicating some uptake into the blood.[44] In dermal exposure, penetration is likely to be minimal under normal conditions but increases in areas of broken skin. Once in the dermis, uptake is likely in the lymph, blood circulation, and sensory nerves in the dermis, suggesting significant dermal hazard.[45] The prediction of the rate and extent of absorption through the skin of applied nanomaterial is challenging due to difficulties in determining their location in skin or within the systemic circulation.[46]

In terms of particle toxicity risk, generally, soluble materials are likely to produce short-term toxicological responses which can be readily detected by cell-based testing procedures, while insoluble nanoparticles are persistent within the biological system and may provoke a range of long-term effects.[47] Examples of the potential toxicity of nanoparticles commonly used in water treatments follow.

1. C_{60}

C_{60} is the most thoroughly studied engineered nanomaterial. Several studies have indicated toxicity from C_{60} aggregates to aquatic organisms and cultured human cells.[48] Yet, some studies suggest that previous research using organic solvents such as tetrahydrofuran (THF) to mobilize the C_{60} in the solution cannot conclude that toxicity was not due to the THF component rather than the C_{60}.[49] To date, studies conducted with C_{60} extended mixing in water (aqu/n C_{60}) suspension reached different results. Some concluded that no significant toxicity was observed on aquatic organisms.[50] Others observed statistically significant concentration-dependent deoxyribonucleic acid (DNA) damage in different types of human cells such as lymphocytes. The latter studies also observed sub-lethal effects such as lipid peroxidation and resultant membrane damage.[51] Furthermore, aqu/nC_{60} has been found to form nanoscale agglomerates that at low concentrations ($\leq$0.4 milligrams per liter), inhibit the growth of *E. coli* and *Ba-*

39. *See id.* at 26.

40. *See id.*

41. *See* U.S. EPA, Technology Update #1: Nanotechnology, Nease Chemical Site (2006), *available at* http://www.epa.gov/region5/sites/nease/pdfs/nanotechupdatefs1200509.pdf. For information about the U.S. Navy's experience using nZVI in groundwater remediation, see Arun Gravaskar et al., Cost and Performance Report: Nanoscale Zero-Valent Iron Technologies for Source Remediation (2005), *available at* http://www.cluin.org/download/remed/cr-05-007-env.pdf. For further discussion of the state-of-the-art of nanotechnologies for water treatment, see Foresight Nanotech Institute, Focus on Challenge #2: Providing Abundant Clean Water Globally 56 (2006), *available at* http://www.foresight.org/publications/FNUpdate56.pdf.

42. *See* Presentation Abstracts, U.S.-Israel Workshop on Nanotechnology for Water Purification (Mar. 2006), *available at* http://www.nanoisrael.org.

43. *See* SCENIHR Opinion, *supra* note 22, at 40-41.

44. *See* Günter Oberdörster et al., *Nanotoxicology: An Emerging Discipline Evolving From Studies of Ultrafine Particles*, 113 Envtl. Health Persp. 823, 833-34 (2005), *available at* http://www.ehponline.org/members/2005/7339/7339.pdf.

45. *Id.*; *see also* Nancy A. Monteiro-Riviere et al., *Challenges for Assessing Carbon Nanomaterials Toxicity to the Skin*, 44 Carbon 1070, 1073 (2006), *available at* http://cctrp.ncsu.edu/pdf/308.pdf.

46. *See* Monteiro-Riviere et al., *supra* note 45, at 1071.

47. Tobias J. Brunner et al., *In Vitro Cytotoxicity of Oxide Nanoparticles: Comparison to Asbestos, Silica, and the Effect of Particle Solubility*, 40 Envtl. Sci. Tech. 4374, 4380 (2006).

48. *See, e.g.*, Eva Oberdörster, *Manufactured Nanomaterials (Fullerenes, C_{60}) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass*, 112 Envtl. Health Persp. 1058 (2004), *available at* http://www.ehponline.org/members/2004/7021/7021.pdf; Christine M. Sayes et al., *The Differential Cytotoxicity of Water-Soluble Fullerenes*, 4 Nano Letters 1881 (2004); J.D. Fortner et al., *C_{60} in Water: Nanocrystal Formation and Microbial Response*, 39 Envtl. Sci. Tech. 4307 (2005); Christine M Sayes et al., *Nano-C_{60} Cytotoxicity Is Due to Lipid Peroxidation*, 26 Biomaterials 7587 (2005), *available at* http://nanonet.rice.edu/publications/2005/Sayes_Nano-C60_cytotoxicity.pdf [hereinafter Sayes et al. 2005]; and Alok Dhawan et al., *Stable Colloidal Dispersions of C_{60} Fullerenes in Water: Evidence for Genotoxicity*, 40 Envtl. Sci. Tech. 7394 (2006), *available at* http://pubs.acs.org/cgi-bin/sample.cgi/esthag/2006/40/i23/pdf/es0609708.pdf.

49. *See, e.g.*, Eva Oberdörster, *Ecotoxicology of Carbon-Based Engineered Nanomaterials: Effects of Fullerene (C_{60}) on Aquatic Organisms*, 44 Carbon 1112 (2006); and Theodore B. Henry et al., *Attributing Effects of Aqueous C_{60} Nano-Aggregates to Tetrahydrofuran Decomposition Products in Larval Zebrafish by Assessment of Gene Expression*, 115 Envtl. Health Persp. 9757 (2007), *available at* http://www.ehponline.org/members/2007/9757/9757.pdf (last visited Feb. 7, 2008).

50. *See id.*

51. Sayes et al. 2005, *supra* note 48, at 7591; and Dhawan et al., *supra* note 48, at 7398.

cillus subtilis.[52] Some studies suggest that modification of the C_{60} surface may yield nanoparticles with biologically useful antioxidant activity.[53]

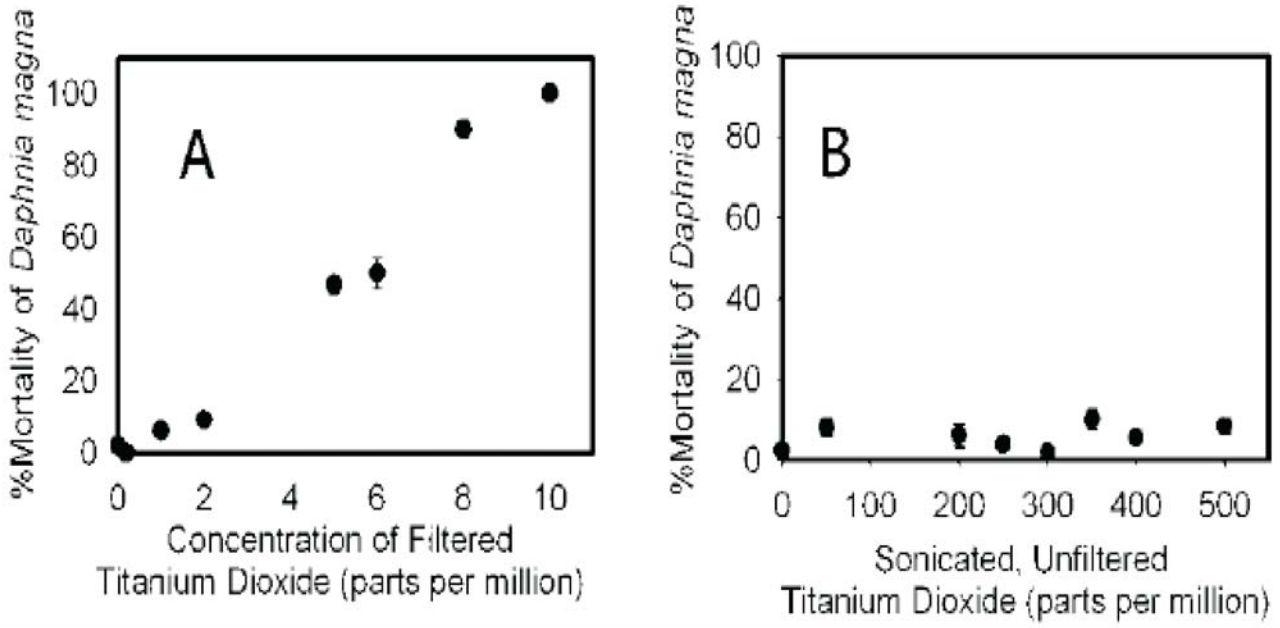
2. Fe_2O_3

In another study, examining the cytotoxicity of oxide nanoparticles dispersed in aquatic solution on cultured human mesothelioma cells, researchers found that uncoated Fe_2O_3 is toxic at concentrations 40 times lower than the chemical toxicity of iron ions.[54] This demonstrates the presence of an additional nanoparticle-specific cytotoxic effect. It is also assumed that the rapid uptake of the nanoparticles may transport the uncoated Fe_2O_3 into different compartments of the cell not normally accessed by aqueous iron ions.[55] The cytotoxic response of nano Fe_2O_3 in this research was shown to be greater than that of asbestos, a well-established carcinogen.[56]

3. TiO_2

Similar results received after *Daphnia magna*, an aquatic model species, exposed to filtered nanoparticle solutions of TiO_2 at concentrations ranging from 0 to 10 parts per million, showed an increase in mortality with an increases in concentration.[57] On the other hand, exposure to a 25- and 30-fold greater concentration of unfiltered, sonicated TiO_2 powder that contained both microparticles and nanoparticles did not cause significant increases in mortality.[58] Because previous studies on macroparticles of TiO_2 showed no health risks to various organisms, TiO_2 is considered to be a suitable particle for use as an antibacterial substance. However, as Sarah Lovern and others concluded: "[C]lassification of TiO_2 as nontoxic may need to be re-evaluated at the nanoparticle level . . . ."[59]

Figure 2



Source: Lovern & Klaper, *supra* note 57, at 1134.

52. Fortner et al., *supra* note 48, at 4312-13.

53. *See* Nel et al., *supra* note 16, at 624.

54. Brunner et al., *supra* note 47, at 4379.

55. *See id.*

56. *See id.* at 4377-78.

57. Sarah B. Lovern & Rebecca Klaper, *Daphnia Magna Mortality When Exposed to Titanium Dioxide and Fullerene (C_{60}) Nanoparticles*, 25 Envtl. Toxicology & Chemistry 1132, 1134 (2006), *available at* http://www.allenpress.com/pdf/entc_25_423_1132_1137.pdf.

58. *See id.* at 1135.

59. *Id.* at 1136.

4. nZVI

Another example is nZVI, which usually is used in groundwater remediation. Initial studies on nZVI's potential for remediation indicate that the reaction of iron nanoparticles with water form charged particles of Fe_2O_3 that can penetrate brain cells and cause oxidative stress.[60] nZVI also reacts with the dissolved oxygen which results in a substantial decrease of oxygen in the water,[61] leading to deleterious effects.[62] Furthermore, studies found that nZVI can travel over a distance of 20 meters in groundwater and can remain reactive for four to eight weeks.[63] Therefore, understanding the transport and fate of nZVI in the subsurface is essential to optimize treatment and minimize unwanted exposures and risks.[64] The United Kingdom Royal Society recommended that the use of free manufactured nanoparticles in environmental applications such as remediation be prohibited until it can be demonstrated that the potential benefits outweigh the potential risks.[65]

IV. The Applicability and Adequacy of Existing Laws to Oversee the Development and Use of Nanotechnologies for Water Treatment

Giving the potential risks of nanotechnologies to human health and the environment along with the many uncertainties, it is clear that at the current stage, oversight of nanotechnologies should focus on risk data generation, collection, and verification. Such data can better inform further regulatory decisions to protect human health and the environment.

To date, the 21st Century Nanotechnology Research and Development Act of 2003[66] is the only U.S. federal legislation specifically addressing nanotechnology. Yet, this act aims to promote the development of nanotechnologies, and is not intended to regulate their human health and environmental effects. Likewise, state nanotechnology programs are part of each state's economic development strategy, and potential human health and environmental risks are not addressed by them.[67]

One exception, at the local government level, is the recent amendment to Title 15 of the Berkeley Municipal Code, Hazardous Materials and Waste Management, requiring health and safety disclosure of manufactured nanoparticles.[68] The amendment requires that "[a]ll 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."[69] In addition, "[a]ll manufactured nanoparticles . . . shall be reported in the disclosure plan."[70] Berkeley is the first governmental entity in the United States to regulate nanotechnology, and it is uncertain whether this step is a harbinger of more extensive actions, or a mere isolated attempt to regulate nanotechnologies.[71]

Nevertheless, other laws, not specifically addressing nanotechnologies, may be applicable to nanotechnologies oversight as well. Generally speaking, there are two categories of laws to address human health and environmental issues: one that focuses on products regulation, e.g., chemicals, consumer products, food, drugs, cosmetics, and medical devices, and deals with the engineering, manufacturing, and marketing of such products. The other focuses on media regulation, e.g., air, water, soil, and working place, and deals mainly with the disposal/release/spill of waste byproducts resulting from industrial processes.[72] Yet, in nanotechnologies application to environmental remediation or water purification, when nanoparticles are intentionally put in direct contact with water this distinction becomes blurred. In these cases, the media-based regulation that aims to protect groundwater, surface water, and drinking water also ought to play a role in overseeing the performance of water treatment technologies.

As discussed in the previous section, there are four types of nanotechnologies for water treatment: (1) filtration; (2) pollutant separation; (3) pollution degradation; and (4) detection of contaminants. Some of the technologies are more product-like materials, while others are used as free particles. Some are used at the point of entry (POE), and others at the point of use (POU) or somewhere in between. Some are designed for self-use, while others are made for commercial use. Each of these distinctions may affect the way these technologies are characterized for regulatory purposes. While many laws—federal, state, and local—may play a role in overseeing the development of nanotechnologies, this Article focuses only on federal laws governing EPA's authority.

A. Product-Based Approach

In the United States, oversight of nanotechnologies is likely to focus on products containing nanoscale materials, rather than on the releases of nanoparticles into the environment during manufacture processes.[73] There are three general patterns of regulatory systems for products: (1) prod-

60. Greg Lowry, *Nanoiron in the Surface: How Far Will It Go and How Does It Change?*, 31-32 (EPA Workshop on Nanotechnology for Site Remediation, Oct. 20-21, 2005), *available at* http://es.epa.gov/ncer/publications/workshop/pdf/10_20_05_nanosummary.pdf.

61. Wei-xian Zhang, *Nanoscale Iron Particles for Environmental Remediation: An Overview*, 5 J. Nanoparticle Res. 323, 327 (2003), *available at* http://www.lehigh.edu/nano/WeiZhang2.pdf.

62. Oberdörster et al. 2007, *supra* note 19, at 19.

63. Zhang, *supra* note 61, at 332.

64. Lowry, *supra* note 60, at 31.

65. *See* UK RS/RA Eng White Paper, *supra* note 4, at 47.

66. Pub. L. No. 108-53, 117 Stat. 1923 (2003).

67. J. Clarence Davies, PEN, EPA and Nanotechnology: Oversight for the 21st Century 41 (2007), *available at* http://www.nanotechproject.org/file_download/197 [hereinafter Davies 2007].

68. Berkeley Municipal Code (BMC), §§15.12.040 I., 15.12.050 C.7. (2007), *as amended by* Ordinance 6,960-N.S. (Jan. 11, 2007), *available at* http://www.ci.berkeley.ca.us/citycouncil/ordinances/2006/6960.pdf.

69. *Id.*

70. *Id.*

71. On Jan. 8, 2007, the City Council of Cambridge, Massachusetts, adopted a resolution calling the City Manager to examine the nanotechnology ordinance for Berkeley, California, and recommend an appropriate ordinance for Cambridge. The resolution is available at http://www.cambridgema.gov/cityclerk/PolicyOrder.cfm?item_id=16916.

72. Davies 2007, *supra* note 67, at 19.

73. Mark Greenwood, PEN, Thinking Big About Things Small: Creating an Effective Oversight System for Nanotechnology 10 (2007), *available at* http://www.nanotechproject.org/file_download/166.

uct-specific approval; (2) product-specific screening; and (3) regulation by governmental initiative.[74] These patterns are implemented in U.S. chemicals and pesticides laws, and their adequacy to oversee the risks of nanotechnologies is discussed in this section. With current understanding of the potential risks of nanotechnologies, neither product-specific screening nor regulation by governmental initiative is a sufficient approach to protect human health and the environment, because both require initial determination of "unreasonable risk" supported by the evidence. Evidence, we currently do not have. On the other hand, product-specific approval, which shifts the burden of proof to the regulated entity, may be an appropriate approach if uncertainties of the potential risks are properly addressed prior to product approval. In particular, the following discusses how each regulatory approach addresses risk data generation, collection, and verification.

1. Chemicals: The Toxic Substances Control Act

The Toxic Substances Control Act (TSCA) was enacted to ensure that innovation and commerce in chemical substances, mixtures, and articles containing such substances or mixtures do not present an unreasonable risk of injury to health or the environment.[75] Therefore, TSCA is the predominant statute to regulate nanoscale materials, including those used for water treatment. It is argued that while some of the programs under TSCA can be somewhat helpful in feeling the current risk data gap, others are not adequate. The following discussion also offers some suggestions for how TSCA's programs can be implemented more effectively to perform this task.

a. The Premanufacture Review Program

When enacting TSCA, the U.S. Congress recognized that "the most desirable time to determine the health and the environmental effects of a substance, and to take action to protect against any potential adverse effects, occurs before commercial production begins."[76] Accordingly, TSCA §5 established the premanufacture review program, which is an example of a regulatory approach for product-specific screening.[77] Although generally a powerful regulatory tool, some critical aspects of the program make it inadequate to regulate nanomaterials.

First, the key to EPA's ability to regulate nanomaterials under the premanufacture review program is the requirement for premanufacture notification (PMN) or significant new use notice (SNUN) submission.[78] The notice should include all available data on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposures.[79] Based on the disclosed information, EPA can determine if the new chemical or the new use "presents or will present an unreasonable risk of injury to health or the environment," or if the data are insufficient to allow a sound evaluation of the health and environmental effects. Upon such determinations, EPA can prohibit or limit the product's commercialization.[80] To be an effective tool, though, EPA must first determines by rulemaking that nano-based products are new chemicals, or significant new uses of existing chemicals, so to trigger the notification requirement. The question is whether EPA is likely to make such determinations.

 New Chemical Substances. TSCA and EPA regulations define a "new chemical substance" as "any chemical substance[81] which is not included on the Inventory."[82] Recently, EPA released a proposed policy clarifying its approach to TSCA's Chemical Substance Inventory (Inventory) status of nanomaterials[83] according to which: "[i]n determining whether a nanoscale substance is a new or existing chemical, the Agency intends to continue to apply its current Inventory approaches based on molecular identity, rather than focus on physical attributes such as particle size."[84]

The proposed policy further clarifies that

> EPA views molecular identity as being based on such structural and compositional features as the types and number of atoms in the molecule, the types and number of chemical bonds, the connectivity of the atoms in the molecule, and the spatial arrangement of the atoms within the molecule. EPA considers chemical substances that differ in any of these structural and compositional features to have different molecular identities.[85]

It can be argued that in focusing entirely on the molecular identity of the substance, EPA ignores the fact that nanotechnology mainly involves creating substances with fundamentally different and novel properties, as well as the vast majority of scientific evidence showing that size makes a difference.[86] In addition, while EPA claims never before to have considered units of matter beyond molecules, such as physical aggregates and thus particle size, as reportable under TSCA, its own example of different molecular identity based on different crystal lattice forms of TiO_2 shows otherwise.[87]

74. *See id.* at 11-12.

75. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412. Under TSCA §8(b)(1), all chemical substances manufactured or processed in the United States must be listed in the TSCA chemical substances inventory. TSCA therefore distinguishes between listed chemical substances (existing chemicals) and those that are not yet in the inventory (new chemicals).

76. H.R. Rep. No. 94-1679, at 65 (1976) (Conf. Rep.).

77. *See* Greenwood, *supra* note 73, at 11.

78. *See* TSCA §5(a)-(b), 15 U.S.C.A. §2604(a)-(b) (2007).

79. *See* 40 C.F.R. §720.45 (2007).

80. *See* TSCA §5(e)-(f), 15 U.S.C.A. §2604(e)-(f).

81. TSCA defines "chemical substance" as "any organic or inorganic substance of a particular molecular identity . . . ." TSCA §3(2), 15 U.S.C.A. §2602(2).

82. TSCA §3(9), 15 U.S.C.A. §2602(9); 40 C.F.R. §720.3(v).

83. Nanoscale Materials Stewardship Program and Inventory Status of Nanoscale Substances Under the Toxic Substances Control Act; Notice of Availability, 72 Fed. Reg. 38083 (July 12, 2007).

84. U.S. EPA, EPA Proposed Policy on TSCA Inventory Status of Nanoscale Substances—General Approach 5 (2007), *available at* http://epa.gov/oppt/nano/nmsp-inventorypaper.pdf [hereinafter EPA Proposed Policy on TSCA Inventory].

85. *Id.* at 3.

86. *Nanoscale Materials Stewardship Program: EPA Public Meeting* 3 (Aug. 2, 2007) (testimony of J. Clarence Davies), *available at* http://www.nanotechproject.org/file_download/212 (last visited Feb. 7, 2008) [hereinafter EPA Public Meeting (testimony of J. Clarence Davies)].

87. EPA Proposed Policy on TSCA Inventory, *supra* note 84, at 3-4; *Nanoscale Materials Stewardship Program: EPA Public Meeting*, 4 (July 12, 2007) (testimony of Richard A. Denison, Environmental Defense), *available at* http://www.environmentaldefense.org/documents/6749_EnvironmentalDefenseStmt2007NanoHearing.

While some nanotechnologies such as C_{60} and carbon nanotubes are clearly novel, most current nanotechnologies are found to have the same molecular identity as that of listed chemical substances.[88] As a result, even though more than 450 consumer products incorporating nanotechnology are on the market, and even more non-consumer applications and raw materials are available, only a handful of nano-substances have been reported through the PMN, two of which were related to water treatment.[89] Thus, regardless of the differences in their risk profiles, manufacturers of so-called existing nanoscale chemicals are currently not obliged to submit a PMN. Therefore, unless EPA classifies them as significant new uses, they can be manufactured and distributed in the United States without additional risk assessment.

 Existing Chemical Substances. In the current public debate on the adequacy of TSCA to regulate nanotechnologies, some argue that EPA can and should promulgate a significant new use rulemaking (SNUR) for categories of existing nanomaterials,[90] which will ultimately list individual nanotechnologies within the categories.[91] Yet, promulgating a SNUR has its own limitations. For example, as proponents themselves point out, in promulgating a SNUR, EPA has to show that a particular use is "new." EPA's traditional position is that "to establish a significant new use, EPA must determine that the use is not ongoing."[92] If a substance is being used in a particular manner at the time that a SNUR is proposed, that specific use is not new, and cannot be subject to a SNUR.[93] This means that applications of nanotechnologies already in commerce, such as anatase TiO_2 for environmental remediation,[94] are beyond the scope of the premanufacture screening process, and their obtained risk data are not reportable.

Another challenge for EPA in promulgating a SNUR for nanotechnologies is meeting the evidentiary burden with current knowledge and understanding of nanoscale materials.[95] Before determining that a use of a chemical is a significant new use, EPA has to consider "all relevant factors . . . ."[96] Such consideration involves issues with scientific uncertainty, such as the extent of the increased magnitude and duration of human exposure to the nanoparticles. Thus, any "significant new" determination can be challenged in court under the arbitrary and capricious standard of the Administrative Procedure Act.[97]

Another reason for the inadequacy of the premanufacture program is that EPA bears the burden of proof to show that the product may present an unreasonable risk. In its risk assessment, EPA relies on information that the manufacturers enclose to the notification.[98] Since EPA generally does not have sufficient data when reviewing a new chemical, it uses a method known as the "quantitative structure activity relationship analysis" to screen and evaluate the chemical's toxicity. This method is based on a comparison of new chemicals with chemicals with similar molecular structures for which test data on health and environmental effects are available.[99] At least in the short term, EPA is going to rely on

pdf (last visited Feb. 7, 2008) [hereinafter EPA Public Meeting (testimony of Richard A. Denison)].

88. *See* EPA Proposed Policy on TSCA Inventory, *supra* note 84, at 3.

89. While a search for nanomaterials in the *Federal Register* can be misleading, as substances are not always specified in their nanoscale form, it still gives some indication as to the extent of reporting. As of July 2007, a nano indication was found with regard to only five premanufacture notifications (PMNs). Altair Nanomaterials Inc. submitted PMNs for three chemicals: (1) lanthanum carbonate oxide to be used for water treatment. 70 Fed. Reg. 39769, 39772 (July 11, 2005); lanthanum for the removal of ionic phosphate from recreational water. 70 Fed. Reg. 73238, 73241 (Dec. 9, 2005) (Nanocheck™, the product incorporating this substance, is already in commercial use; *see* Altair website at http://www.altairnano.com/markets_perfmaterials.html#water (last visited Feb. 7, 2008)); and lithium titanium oxide used as an anode for lithium-ion battery. 71 Fed. Reg. 2933, 2935 (Jan. 18, 2006) (NanoSafe™ Battery, the product incorporating this substance, is already in commerce; *see* Altair website at http://www.altairnano.com/documents/NanoSafe Backgrounder060920.pdf (last visited Feb. 7, 2008)). Additionally, two unidentified companies submitted PMNs for siloxane coated alumina nanoparticles for use as additive. 70 Fed. Reg. 46513, 46518 (Aug. 10, 2005). Both companies began manufacturing of the product in 2006. 71 Fed. Reg. 33449, 33454 (June 9, 2006); and 71 Fed. Reg. 46475, 46480 (Aug. 14, 2006).

90. TSCA §26(c) provides that any action under the Act that EPA is authorized to take with respect to chemical substance, it is also authorized to take with respect to a category of chemical substance. The section further defines "category of chemical substance" to mean "a group of chemicals substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter . . . ." 15 U.S.C.A. §2625(c).

91. Mark Duvall, *Regulating Nanomaterials Under Section 5 of the Toxic Substance Control Act*, 209 Daily Env't Rep. (BNA) B-1 (2006). Christopher L. Bell et al., American Bar Association-Section of Environment, Energy, and Resources (ABA-SEER), Regulation of Nanoscale Materials Under the Toxic Substance Control Act 15 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf [hereinafter ABA-SEER Article]; and EPA Public Meeting (testimony of J. Clarence Davies), *supra* note 86, at 4-5.

92. 55 Fed. Reg. 17376 (Apr. 24, 1990).

93. ABA-SEER Article, *supra* note 91, at 17.

94. *See, e.g.*, Altair Nanomaterials Inc., *Market Applications*, http://www.altairnano.com/markets_applications.html (last visited Feb. 7, 2008).

95. Environmental Defense, A Response to ABA's "Regulating Nanomaterials Under TSCA Section 5": Why "Existing Chemical SNURs" Won't Suffice to Protect Human Health and the Environment 3 (2007), *available at* http://www.Environmentaldefense.org/documents/5421_EnDefNanoBriefing.pdf; *see also* EPA Public Meeting (testimony of Richard A. Denison), *supra* note 87, at 5-6.

96. These factors include:

> (A) the projected volume of manufacturing and processing of a chemical substance, (B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance, (C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and (D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

TSCA §5(a)(2), 15 U.S.C.A. §2604(a)(2).

97. 5 U.S.C. §706(2)(A), *available in* ELR Stat. Admin. Proc.

98. TSCA §5(b), 15 U.S.C.A. §2604(b). According to a U.S. Government Accountability Office (GAO) report: "EPA estimates that most premanufacture notices do not include test data of any type, and only 15 percent include health or safety test data." *Actions Are Needed to Improve the Effectiveness of EPA's Chemical Review Program: Hearing Before the Senate Comm. on Environment and Public Works*, 109th Cong. 8 (2006) (testimony of John B. Stephenson, Director, Natural Resources and Environment, U.S. GAO), *available at* http://www.epw.senate.gov/109th/Stephenson_Testimony.pdf. [hereinafter U.S. GAO Statement].

99. *See* U.S. GAO Statement, *supra* note 98.

the database developed under this approach to assess risks of nanoscale chemicals; however, such analogy is not capable of addressing toxicity that may be associated with the novel properties and behaviors of nanoscale materials.[100]

This becomes even more complicated because each nanoscale chemical is subject to several manufactured, purified, or coated methods, all of which can result in different properties.[101] Also, future generations of nanotechnologies integrating nanostructure chemicals with biological materials, guided assemblies, and other innovations will impose great challenges to any analogy approach.[102] Consequently, an analogy approach raises concerns for underestimation of risk, and in turn, insufficient regulation to protect the public or the environment.

Finally the premanufacture program is inadequate because of the various exemptions that TSCA provides from it. For example, under the program, research and development (R&D) is exempted, and developers of new chemical substances have no obligation to notify EPA of any aspects of their R&D activities.[103] Thus, all experiments along the development process, which may result in release of nanoparticles into the environment, are taking place without EPA awareness. Similarly, EPA promulgated the low volume exemption (LVE) rule which allows manufacturers of all new chemical substances manufactured in quantities of 10,000 kilograms (kg) or less per year to request exemption from PMN submission.[104] Since nanomaterials are inherently produced in low volumes, this exemption raises grave concerns regarding the effectiveness of the premanufacture program in regulating nanotechnologies. While EPA can deny an LVE request if it determines that the chemical may cause serious acute, chronic, or significant environmental effects,[105] given current knowledge and understanding of the risks of nanomaterials, it is unlikely to make such a determination. Therefore EPA would have to amend the LVE in order to regulate more effectively nanomaterials.[106]

Consequently, although the premanufacture program seems powerful in theory, it is not quite so in practice because it regulates almost an empty set of nano-based products. Giving that for the most part, current developments of nanotechnologies for water treatment fall within the definition of existing chemicals, the next two sections discuss how EPA can regulate them, and what tools it has to collect data on their potential risks.

100. *See* Greenwood, *supra* note 73, at 16-17.

101. *See, e.g.*, Karen F. Schmidt, PEN, Nanofrontiers: Visions for the Future of Nanotechnology 17-18 (2007).

102. Greenwood, *supra* note 73, at 16-17.

103. TSCA §5(h)(3), 15 U.S.C.A. §2604(h)(3); 40 C.F.R. §720.36(c)(2); *see also* U.S. EPA, *New Chemical Program, Research and Development (R&D) Exemption*, http://www.epa.gov/opptintr/newchems/pubs/randdexemp.htm (last visited Feb. 7, 2008).

104. 40 C.F.R. §723.50; *see also* U.S. EPA, *New Chemicals Program, Low Volume Exemption*, http://www.epa.gov/opptintr/newchems/pubs/backlvem.htm. For comparison, under the European Community regulation on chemicals, notification requirements for new substances start at a production level of 10 kg. *See* Q&A on the New Chemicals Policy, REACH (2006), *available at* http://europa.Eu/rapid/pressReleasesAction.do?reference=MEMO/06/488&format=HTML&aged=0&language=EN&guiLanguage=en.

105. 40 C.F.R. §723.50(d).

106. Davies, *supra* note 6, at 11.

b. Regulation of Listed Hazardous Chemicals

Once a chemical substance is listed in the Inventory, TSCA §6 authorizes EPA to regulate the manufacturing, processing, commercial distribution, use and/or disposal of such a chemical substance if the substance "presents or will present an unreasonable risk of injury to health or the environment."[107] This authority over existing chemicals in commerce is an example for regulation by government initiative.[108] The burden of proof is on EPA to show that the chemical substance may present a risk, and that such risk is unreasonable. If EPA can meet this standard, it may determine by rulemaking whether to allow, condition, or ban the distribution of the chemical substance in commerce, and whether to require its labeling.[109] Any regulation under this section must be cost-effective so as "not to impede unduly or create unnecessary economic barriers to technological innovation."[110]

With current knowledge and understanding of the potential risks presented by nanotechnologies, EPA is not likely to be able to meet the evidentiary burden of this standard.[111] Thus, nanomaterials which escaped the premanufacture screening may be "safely" distributed in commerce without burdensome oversight for many years to come.

c. Risk Data-Gathering Tools

 Mandatory Tools. Generally, TSCA §4(a) authorizes EPA to require by rulemaking additional testing if it can show significant risk or substantial exposure, insufficiency of existing data, and the necessity of testing to develop the data.[112] Under this authority, however, not only does EPA carry the evidentiary burden to show those triggers are met, it must also follow the cumbersome rulemaking process, subjected to public comment and judiciary review. Therefore EPA may find it difficult to use this authority in the near future.

Once the product is in the market, TSCA §8 also authorizes EPA to collect a variety of information from industry to support appropriate regulation.[113] Under this authority, EPA promulgated several rules. First, it promulgated a rule requiring manufactures to report production-, use-, and exposure-related information on listed chemical substances.[114] Nanoscale substances are not currently listed, but under certain conditions EPA can add them to the list.[115] Still, EPA will have to amend the exemptions to the rule; otherwise, including nanoscale substances in the list will be meaningless. For example, manufacturers are exempted if they are quali-

107. 15 U.S.C.A. §2605.

108. *See* Greenwood, *supra* note 73, at 11-12.

109. *Id.*

110. TSCA §2(b)(3), 15 U.S.C.A. §2601(b)(3). These authorities have long been criticized as inadequate to regulate uncertain risks from chemicals in commerce.

111. EPA found it difficult to meet the unreasonable risk standard even with conventional chemicals because the standard imposes huge information demands and invites judicial intervention. *See* Albert C. Lin, *Size Matters: Regulating Nanotechnology* 90 (University of California at Davis Legal Studies Research Paper No. 19-20, 2006).

112. 15 U.S.C.A. §2603(a).

113. *Id*. §2607 (2007).

114. TSCA §8(a), 15 U.S.C.A. §2607(a); 40 C.F.R. §712.

115. *Id.* §712.1(b).

fied as small: if the total production of the listed substance at the plant site is below 45,400 kg or if total sales are below $30 million.[116] These measures may not be adequate to address risks to human health and the environment from exposure to nanomaterials.

Second, a rule was promulgated requiring manufacturers and processors of chemicals to create and maintain records of "allegations" that the chemical "caused a significant adverse reaction to health or the environment."[117] EPA can request those records from certain industry sectors of most concern, e.g., those which develop technologies to be used as free particles, or those for self-use that may be handled unsafely.

Third, another rule was promulgated requiring reporting of any "health and safety study, of specific listed chemical substances,"[118] and EPA can further request submission of underlying data or preliminary reports of ongoing studies.[119] Currently, nanoscale substances (as a category or as individuals) are not listed in the rule, and EPA would have to amend the list in order to require such studies regarding nanoscale substances.[120] In addition, EPA would probably have to amend some of the requirements under the rule to better address the unique properties of nanotechnologies. For example, under the rule, health and safety studies of physical and chemical properties must be reported only if performed for the purpose of determining the environmental or biological fate of a substance, and only if they investigated one or more of the listed properties.[121] This list of properties does not include nano-unique properties such as chemical shape, aggregation, and surface area, which are critical for nanoparticle risk assessment; and thus, studies investigating those properties are not reportable.

In addition, TSCA §8(e) establishes an early warning system to identify harmful effects in their early stages before clinical disease is manifested, and to help minimize future exposure of affected persons.[122] Under this section, companies are required to inform EPA immediately of any obtained information that reasonably supports the conclusion that a chemical substance or mixture that they manufacture, process, or distribute in commerce presents a substantial risk[123] of injury to health or the environment.[124]

Yet, substantial risk determination is only likely in cases where EPA determines that a particular nanoparticle is a contaminant, and the nanoparticle concentration in the data exceeds the regulatory benchmark for that nanoparticle. For example, this means that because neither the Clean Water Act (CWA)[125] nor the Safe Drinking Water Act (SDWA)[126] list TiO_2—in its micro or nano ($nTiO_2$) form—as a pollutant, and therefore no maximum concentration level (MCL) in water has ever been established for it, information regarding its harmful effects is not reportable. Thus, if the aforementioned study on the impacts of $nTiO_2$ on *Daphnia magna*[127] had been conducted by a manufacturer of $nTiO_2$, it would not have had to be reported even if the study showed a significant mortality rate at a low concentration.

Thus, while the mandatory tools standing for EPA to generate and collect risk data are somewhat limited at their current state, relatively minor amendments can make them much more effective. It is suggested that EPA make the necessary amendments and start using these tools more proactively. In addition, the American Bar Association (ABA) suggested that EPA consider a voluntary approach—similar to the high production volume (HPV) testing program[128]—for nanomaterials.[129] Such a step could be perused simultaneously as a backup for remain loopholes, but it should not come instead of using the data-gathering rules to the maximum extent possible.

 Voluntary Tools. EPA recently released for public comments the concept for its nanoscale materials stewardship program (NMSP) under TSCA.[130] The NMSP contains two phases: (1) a basic phase that would request participants to report all known or reasonably ascertainable information regarding specific nanoscale materials[131]; and (2) an in-depth phase that would require development of data needed to better characterize hazard, risk, and exposure issues relating to the material. Participants can agree to take the following actions: characterize the physical/chemical properties of the material; test their product for health and environmental hazards; monitor or estimate exposures and releases; determine fate and transport characteristics; evaluate the effectiveness of protective equipment or engineering controls; develop a model worker education program; and complete other evaluations.[132]

Based on data collected under the program, EPA will identify what data are missing in order to conduct an informed risk assessment of a specific nanoscale material.[133] If the hazard, exposure, and risk data submitted indicate that potential risks may exist for a specific nanoscale material, EPA and the participant will work together to determine the

116. *See id.* §712.25.

117. TSCA §8(c), 15 U.S.C.A. §2607(c); 40 C.F.R. §717.

118. TSCA §8(d), 15 U.S.C.A. §2607(d); 40 C.F.R. §716.

119. *See id.* §716.40.

120. *See id.* §716.120.

121. *See id.* §716.50.

122. 15 U.S.C.A. §2607(e). *See* Office of Pollution Prevention & Toxics (OPPT), U.S. EPA, Overview: Office of Pollution Prevention and Toxic Programs 4 (2007), *available at* http://www.epa.gov/oppt/pubs/oppt101c2.pdf.

123. *See* TSCA §8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129, 33138 (June 3, 2003).

124. OPPT, U.S. EPA, TSCA Section 8(e) Reporting Guide (1991), *available at* http://www.epa.gov/oppt/tsca8e/pubs/rguide.htm#whatissubstantialriskinformation.

125. 33 U.S.C. §§1251-1387, ELR Stat. FWPCA §§101-607.

126. 42 U.S.C. §§300f to 300j-26, ELR Stat. SDWA §§1401-1465.

127. Lovern & Klaper, *supra* note 57.

128. The High Production Volume Challenge Program covers chemicals manufactured in or imported into the United States in amounts equal to or greater than one million pounds per year. Under this voluntary program, industry chemical manufacturers and importers are committed to developing data summaries of existing hazard data and to conducting tests to fill any data gaps to provide the public with basic information about the chemicals produced in the largest quantities. *See* U.S.EPA, *HPV Challenge Program*, http://www.epa.gov/chemrtk/ (last visited Feb. 7, 2008).

129. ABA-SEER Article, *supra* note 91, at 18.

130. U.S. EPA, Concept Paper for the Nanoscale Materials Stewardship Program Under TSCA (2007), *available at* http://www.epa.gov/oppt/nano/nmsp-conceptpaper.pdf. [hereinafter U.S. EPA NMSP Concept Paper].

131. The types of data that EPA has identified as reportable are detailed in Annex B, and include information on material characterization, hazard, use, potential exposures, and risk management practices. *See id.* at 13-15.

132. *See id.* at 5.

133. *See id.* at 6.

appropriate action necessary to avoid or mitigate the risks.[134] After the initial two-year phase, EPA will publish a report evaluating the program and determine the future of both phases.[135]

There are two major faults in this concept: (1) the basic phase specifies no deadlines for companies to sign up, deliver information, or apply basic management practices[136]; and (2) EPA's proposal does not include any regulatory backstop, such as a SNUR and/or reporting rules applicable to nanoscale materials.[137] In the absence of these two elements, companies have little incentive to participate in the program. Inadequate participation would result in very limited and selective data submission, which could draw a misleading picture regarding the range of nanoscale materials in or soon to be in commerce.[138]

Another limitation of the program concerns its scope. While TSCA applies to articles containing chemical substances or mixtures, the NMSP is not intended to include products that have an already-applied nanoscale film or coating.[139] Rather, it focuses on risks posed by free particles without considering the risk from the final product. Likewise, the program does not intend to cover materials that originally are not at a nanoscale size but will self-assemble into such upon application and treatment,[140] regardless of the fact that human and environmental exposure is likely to happen only after the transformation has taken place.

Thus, while any initiative to draw more light on the uncertainties involve with nanotechnologies is praiseworthy, careful attention should be given to the conceptual architecture to ensure that the initiative is indeed capable of doing the job it aims for. It seems that the NMSP comes too little too late. It could have been a good concept a few years ago when fewer products were on the market, but with the current pace of development, it is just not good enough.

As discussed above, TSCA's programs are inadequate to oversee the development of nanotechnologies as currently implemented. The effectiveness of both the product-specific screening approach and the regulatory by government initiative approach is very limited when uncertainties regarding the potential risks are predominant. On the other hand, as discussed in the following section, the product-specific approval approach is much more appropriate to deal with the current scientific uncertainties. Yet, TSCA can still play a role in collecting and verifying obtained risk data to increase certainty and enhance future regulation.

2. Pesticides: The Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was enacted to protect public health and the environment from dangerous pesticides.[141] It is an example of a regulatory approach for product-specific approval. The core of this approach lies in FIFRA §3, which forbids the distribution or sale of any unregistered pesticide.[142] Because FIFRA covers only products that are pesticidal, the first and most important question is whether nanotechnologies can be classified as pesticide products.

a. Nano-Based Pesticide Products

Generally speaking, water purifiers are classified as "general disinfectant antimicrobial pesticides."[143] Nanotechnologies for water treatment will be classified as pesticides, required to register under FIFRA §3 if they consist of substances or a mixture of substances that act against any microorganism.[144] If the technology, however, does not contain such substances or mixtures of substances, e.g., nanofiltration, which only provides a physical barrier against microorganism access, and does not contain toxicants to destroy them, or if it aims to act against other pollutants such as persistent organic pollutants or inorganic pollutants, e.g., heavy metals and fertilizers, it will not be covered by FIFRA.

Despite the emerging concept that substances with antimicrobial properties have these properties enhanced when presented in a nanoparticle form,[145] and despite the large number of nano-containing products in the market, to date, EPA has dealt with only a handful of products under FIFRA. The first case was Samsung's Silver Wash® washing machine, which releases nanosilver particles to kill bacteria in fabric without the need for hot water and bleach.[146] Initially, EPA classified the Silver Wash® as a "device," thus exempted from registration requirements.[147] However, this decision has been reversed to require registration as a "pesticide product"[148]; based on Samsung's claim that the silver in the washing machine aims to kill bacteria.[149] A *Fed-*

134. *See id.*

135. *See id.*

136. *See* EPA Public Meeting (testimony of Richard A. Denison), *supra* note 87, at 2-3 (asserting that the basic phase should last no longer than three months—one month for signing up and two months for data submission).

137. *See id.*; *see also* EPA Public Meeting (testimony of J. Clarence Davies), *supra* note 86, at 4-5.

138. *See id.*

139. U.S. EPA NMSP Concept Paper, *supra* note 130, at 10.

140. *See id.* at 9.

141. 7 U.S.C.A. §136a(a) (2007).

142. *See id.*

143. *See* U.S. EPA, *Fact Sheet: Antimicrobial Pesticide Products*, http://www.epa.gov/pesticides/factsheets/antimic.htm (last visited Feb. 7, 2008).

144. The Act and regulations define pesticide as any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest, including any microorganism which is deleterious to man or the environment. *See* FIFRA §2(t)-(u), 7 U.S.C.A. §136(t)-(u); and 40 C.F.R. §152.5. The Act further defines antimicrobial pesticide as pesticide that is intended to disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms. FIFRA §2(mm), 7 U.S.C.A. §136(mm).

145. Oberdörster et al. 2007, *supra* note 19, at 19-20.

146. *See* Samsung website at http://ww2.samsung.co.za/silvernano/silvernano/washingmachine.html (last visited Feb. 7, 2008).

147. FIFRA define a device as any article that uses physical or mechanical means to prevent, destroy, repel, or mitigate pests. 7 U.S.C.A. §136(h). As summarized by Lynn Bergeson: "In general, if an article uses physical or mechanical means to act against a pest, it is a device. If it incorporates a substance or mixture of substances to act against the pest, it is a pesticide." Basic Practice Series: FIFRA 8 (Lynn L. Bergeson eds., ABA 2000). Devices are not required to be registered under FIFRA §3, but they are subject to several other provisions under the Act. For more information on the differences between pesticides and pest control devices, see U.S. EPA, *Fact Sheets, Pest Control Devices*, http://www.epa.gov/pesticides/factsheets/devices.htm (last visited June 17, 2007).

148. 40 C.F.R. §152.3.

149. Jeff Kinney, *EPA to Regulate Nanoscale Silver Used in Washing Machines to Kill Bacteria*, 224 Daily Env't Rep. (BNA) A-3 (2006).

eral Register notice clarifies the rationale for the reversal and has put all producers and distributors of similar equipment on notice.[150]

After the decision was made, the question arose as to whether EPA would still require registration if Samsung withdrew the "pesticidal claim" from the product because deodorizers, bleaches, and cleaning agents are not considered as pesticides unless a "pesticidal claim" is made on their labeling or in connection with their sale and distribution.[151] Responding to the issue, EPA stated that "Samsung and other manufacturers of washing machines that use silver ions will not be able to avoid pesticide regulations simply by eliminating pesticide claims from their marketing materials."[152]

Thus, if the manufacturer of a nano-based water treatment avoids labeling the product as antimicrobial, or explicitly markets it as "treatment for organic pollutants and not for use as [a] disinfectant," but the product is in fact well known for treating microorganisms, it will be required to register.[153] TiO_2, for example, is well known for its antibacterial properties[154]; thus, water treatment methods containing this substance, such as Kokusai Eisei Co., Ltd., Panafino,[155] if imported into the United States, should trigger FIFRA registration even if the manufacturer markets them as deodorizing devices. Likewise, Altair Nanomaterials Inc., which tests anatase TiO_2 in water purification systems,[156] may be required to register.

A similar loophole to the device exemption is the "treated article" exemption.[157] Under this exemption, a manufacturer does not have to register an article treated with a registered pesticide, as long as such a product is used for its registered purpose and the pesticide claim is limited to protection of the article itself.[158] Recently, in the case of another nanosilver product, EPA expressed its opinion that silver-infused nanotechnology clothing would fall under the treated article exemption if silver nanoparticles were used solely to protect the clothing from stains or damage; however, the clothing would not be exempted if the silver nanoparticles were used to kill germs and marketed as such.[159] Water treatment articles aim to kill germs and thus are not likely to qualify for the exemption.

Given that some of the nanotechnologies used for water treatment will be classified as pesticide products, the following sections discuss EPA's authority to oversee their development and use. Generally speaking, EPA can prohibit, condition, or allow the manufacture and use of nanopesticides. Along with the regulatory authority, EPA has strong enforcement options to ensure compliance with the act.[160] The following discussion focuses on EPA's tools to enhance risk data generation, collection, and verification under FIFRA.

b. The Pesticides Pre-Registration Program

At the pre-registration stage, FIFRA §5(a) establishes the experimental use permit (EUP), which authorizes EPA to regulate R&D activities conducted to develop information needed for registration purposes.[161] EPA regulations set forth the data submission requirements needed to approve EUPs.[162] FIFRA also authorizes EPA to require a producer of nanopesticides to perform certain studies to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment.[163]

The latter authority, however, applies only to "pesticide[s] containing any chemical or combination of chemicals which has not been included in any previously registered pesticide."[164] The question is whether nano-substances of conventional registered pesticides are deemed new pesticides under the program. The ABA's Section of Environment, Energy, and Resources article suggests that "[w]here a conventional registered pesticide contains the same 'chemical or combination of chemicals' used in a nanopesticide, this provision apparently would not apply."[165] However, because FIFRA, unlike TSCA, does not define "chemical," EPA is not required to look to the substance's molecular identity to determine whether the chemical already exists. Thus EPA may clarify that the substitution of a nanoscale ingredient for its macro counterpart constitutes a new chemical for registration purposes. EPA should also modify the data submission requirements in light of the unique properties of nanopesticides. Alternatively, EPA may promulgate a specific EUP provision for nanopesticides, as it did for genetically modified microbial pesticides.[166] Under such a provision, EPA can require additional testing tailored to the unique properties of nanoparticles.

Nevertheless, since the EUPs program applies only to R&D conducted in relation to the registration process, the question still remains whether EPA can meaningfully oversee such R&D. Because some of the products incorporating

150. Pesticide Registration; Clarification for Ion-Generating Equipment, 72 Fed. Reg. 54039 (Sept. 21, 2006).

151. 40 C.F.R. §152.10(a).

152. Kinney, *supra* note 149.

153. 40 C.F.R. §152.15.

154. For general discussion of the antibacterial property of TiO_2, see Tadashi Matsunaga et al., *Continuous-Sterilization System That Uses Photosemiconductor Powders*, 54 Applied. Envtl. Microbiol. 1330 (1988), *available at* http://aem.asm.org/cgi/reprint/54/6/1330.

155. Panafino is a deodorizing device which can be designed for such industrial applications as wastewater treatment and industrial waste treatment, using brookite TiO_2-based filters. *See* Showa Denko K.K., *Showa Denko K.K. (SDK) Subsidiary Develops TiO_2-Based Deodorizing Equipment*, JCN Newswire (Feb. 4, 2005), *available at* http://www.japancorp.net/Article.Asp?Art_ID=9324 (last visited Feb. 7, 2008).

156. *See* Altair Nanomaterials Inc., Annual Report (Form 10-K) 16 (2006), *available at* http://www.sec.gov/Archives/edgar/data/1016546/000101968707000697/altair_10k-123106.htm.

157. 40 C.F.R. §152.25(a).

158. *Id.*; *see also* OPPT, U.S. EPA, PR Notice 2000-1, Applicability of the Treated Articles Exemption to Antimicrobial Pesticides (2000), *available at* http://www.epa.gov/opppmsd1/PR_Notices/pr2000-1.pdf.

159. Jeff Kinney, *Silver-Infused Nanotech Closing Said to Kill Germs That Cause Cold, Flu*, 88 Daily Env't Rep. (BNA) A-5 (2007).

160. James C. Chen et al., ABA-SEER, The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/FIFRA.pdf [hereinafter ABA FIFRA Article].

161. 7 U.S.C.A. §136c(a). EPA regulations specify a variety of testing scenarios in which EUPs are presumed unnecessary. *Id.* §172.3(b) and (c).

162. *Id.* §172.4(b)(vi).

163. 7 U.S.C.A. §136c(d).

164. *Id.*

165. ABA FIFRA Article, *supra* note 160, at 8.

166. *See id.* at 7; *see also* 40 C.F.R. 172(c).

nano-antimicrobials are not normally considered pesticides (such as washing machines and clothes), the developer may not be aware that his or her product is classified as a pesticide, and thus will not apply for the permit. This should not be a major problem in the case of water purifiers because such technologies are explicitly listed as antimicrobial pesticides. Still, some confusion may arise where antimicrobial characteristics are not the primary expected use of the product.

Furthermore, as most tests on antimicrobial nanopesticides for water purification are likely to take place in the laboratory rather than in the field, as well as on waters that are not to be used for irrigation, drinking, bodily contact, or recreational activities, they will not be required to obtain EUPs. If, however, some of the nanotechnologies for groundwater remediation would be classified as pesticides, than the treatability tests under EPA cleanup programs would probably be required to obtain EUPs.

Overall, with some clarifications and minor amendments, the EUP program can generate and collect risk data on nanopesticides at the premanufacture stage. Early understanding of the risks involved with the product may allow developers to find ways to avoid or mitigate those risks, and to make informed decisions about whether to continue investment in the product. It is important to keep in mind, however, that these risk data are mainly for environmental exposure during the testing of the product and are not likely to provide much insight on the human and environmental exposure during an ordinary use of the product. Therefore, the next section discusses FIFRA's registration program where more extensive risk data can be generated, collected, and verified.

c. The Pesticides Registration Program

Similar to TSCA, FIFRA also distinguishes between new pesticides and existing pesticides for regulatory purposes. The FIFRA registration program aims to examine any new pesticide or new active ingredient for unreasonable adverse effects on humans, the environment, and nontarget species.[167] The primary question is, therefore, whether the pesticide is new. For existing pesticides, a supplemental statement is enough to add the nanoscale ingredient to the registration, and a separate risk assessment is not required.[168]

 New Pesticides. A pesticide is considered new and subject to registration if its claims or composition differ substantially from claims made for, or the composition of, a registered pesticide.[169] Given the unique characteristics of nanomaterials, nanopesticides are unlikely to have the same composition as their counterpart registered macro version. Nanomaterials also allow many new applications; therefore, it is unlikely that nanopesticides would have the same claims as registered macro pesticides. For example, Showa Denko K.K. claims that "[c]ompared with the conventional anatase TiO_2, Nano Titania NTB shows a high level of photocatalyst activity in response to weak light."[170] EPA can also take the position that the substitution of a nanoscale ingredient for its macro counterpart constitutes a change in composition per se because of the change in product chemistry and toxicity.[171]

EPA has separate registration processes for three categories of pesticides: (1) antimicrobials; (2) biopesticides; and (3) conventional pesticides.[172] Throughout the registration process, EPA may require applicants to generate scientific data on toxicity and behavior in the environment necessary to address concerns of potential adverse human health effects and the environmental fate of each pesticide.[173] Nevertheless, current data requirements for product composition, certified limits, and physical and chemical characteristics do not address information regarding some of the key unique properties of nanomaterials.[174] For example, the regulation does not require either identifying or testing of surface area, shape, and aggregation of particles, all of which can modify cellular uptake, protein binding, translocation from portal of entry to the target site, and the potential for causing tissue injury. Likewise, the regulation defines the limits threshold by mass concentration rather than surface area[175] and does not require data on the impurities of toxicological significance associated with inert ingredients.[176]

To close these gaps, EPA can use its authority under FIFRA §3(c)(2)(A) to publish guidelines for the kinds of information needed to support nanopesticides registration. EPA can modify the existing general guidance to incorporate data requirement tailored to nanoscale properties, or it can publish a nanopesticides-specific guideline, as it did with biochemical and microbial pesticides.[177] EPA may also revise its proposed regulation for antimicrobial pesticides to address specifically aspects of nanoscale materials. Overall, EPA has ample tools to require risk data generation and submission before the commercialization of nanopesticides. Based on the data, EPA should be able to determine whether the benefits of nanopesticides outweigh their risks, and where data gaps exist. EPA also has discretion to determine the conditions under which these products may be registered so as to limit their potential risks.

After registration, EPA is required to review each pesticide every 15 years or less,[178] and may require nanopesticides registrants to develop new data if "additional data are required to maintain in effect an existing registration of a

167. 7 U.S.C.A. §136a; 40 C.F.R. 172(C).

168. *Id.*

169. 7 U.S.C.A. §136j(a)(1)(B) and (C).

170. Showa Denko K.K., *supra* note 155.

171. ABA FIFRA Article, *supra* note 160, at 11.

172. The application review process and data requirement of antimicrobial pesticides, including water purifiers, differ somewhat from those of other pesticides. FIFRA §3(h) and EPA guidance set forth the requirements and the process to streamline and expedite the application review process of antimicrobial pesticides. *See* 7 U.S.C.A. §136a(h); *see also* OPPT, U.S. EPA, Guidance for Antimicrobials Division Review of Applications for New Chemicals, New Uses, and Major Amendments (2001), *available at* http://www.epa.gov/oppad001/sopstrategy011.htm and Registration Requirements for Antimicrobial Pesticide Products and Other Pesticide Regulatory Changes: Proposed Rule, 63 Fed. Reg. 50672 (Sept. 17, 1999).

173. *See* FIFRA §3(c)(2)(A), 7 U.S.C.A. §136a(c)(2)(A) and relevant regulation in 40 C.F.R. §158; U.S. EPA, *Pesticides Regulations, Registration, Data Requirements*, http://www.epa.gov/pesticides/regulating/data.htm (last visited Feb. 7, 2008).

174. 40 C.F.R. §§158.155, 158.175, 158.190.

175. *Id*. §158.175(b).

176. *Id*. §158.155(e).

177. *Id*. §§158.68, 158.690, 158.740; *see also* ABA FIFRA Article, *supra* note 160, at 12.

178. FIFRA §3(g)(1)(A), 7 U.S.C.A. §136a(g)(1)(A).

pesticide[.]"[179] In addition, FIFRA requires each pesticide registrant to notify EPA of "additional factual information regarding unreasonable adverse effects on the environment of the pesticide[.]"[180] Finally, based on sufficient evidence, EPA may cancel or suspend registration, and issue stop sale, use, or removal orders for pesticides.[181]

B. Media-Based Approach

Unlike product-based regulation, which focuses on the technology itself, media-based regulation traditionally focuses on the waste stream from the manufacture process of the technology. Yet, as mentioned above, when nanotechnologies are intentionally released into water, either to absorb or degrade contaminants, media-based regulation may serve as a watchdog for the performance and use of these technologies. This category of law includes laws regulating wastewater discharges into surface water, drinking water quality, and groundwater remediation. The next sections discuss how each of these laws can oversee the performance and use of nanotechnologies for water treatment and groundwater remediation.

1. Surface Water Protection: The CWA

The CWA was enacted "to restore and maintain the chemical, physical and biological integrity of the Nation's waters."[182] One of the declared policies to achieve this objective is "that a major research and demonstration effort be made to develop technology necessary to eliminate the discharge of pollutants into navigable waters."[183] Although not directly funding it, the CWA encourages research, development, and deployment of innovative technologies, such as nanotechnologies, to control and detect pollutants in industrial effluent waste streams or in wastewater treatment plants.

More specifically, the CWA requires EPA to develop two sets of standards to control the discharge of pollutants into the nation's water. One set applies to water quality-based limitations, based on the water quality of each receiving water body covered by the Act, taking into consideration its designated uses.[184] The other set applies to technology-based limitations based on available pollution control technologies for an industrial category.[185] Consequently, the use of technology-based limitations creates a built-in incentive for the development of new pollutant control technologies, including nanotechnologies, by essentially guaranteeing a market for technological improvements.[186]

Yet, since the CWA regulation focuses on specifically listed pollutants, EPA usually does not take into consideration whether a treatment technique may result in increase risk due to unintended byproducts of unregulated pollutants. EPA's *Pollution Prevention (P2) Guidance Manual for the Pesticide Formulating, Packaging, and Repackaging Industry*, for example, explains that EPA is concerned about reaction byproducts that may be generated during wastewater treatment operations; however, these concerns focus on byproducts that are already regulated and not on those for which the potential risk is unknown.[187]

Furthermore, even if EPA voluntarily tests the technologies it lists as best available technology (BAT) under the effluent guidelines, the regulated facility may choose to implement other equivalent technologies, which can meet the same permit limits.[188] While some would argue that EPA can close this loophole by mandating best management practices (BMPs)[189] and then would have the ability to test the technology before mandating it, §304(e) only authorized EPA to mandate BMPs for the control of toxic pollutants and hazardous substances from ancillary industrial activities. Simply put, as long as the technology "fixes" the problem under the spotlight, it can be implemented at the regulated facility without conducting additional testing for process byproducts.

Thus, when developing effluent guidelines based on innovative technologies such as nanotechnologies, EPA should examine reaction byproducts which may occur even if their risk is currently unknown. Likewise, when a facility chooses to use an equivalent treatment method that uses nanotechnology, EPA should require certification that such treatment does not generate negative reaction byproducts. Such certification may be acquired under EPA's Environmental Technology Verification (ETV)[190] Program, discussed in more details in the next section, from the nanotechnology developer or manufacturer, or by screening the wastewater effluent with appropriate techniques.[191]

2. Drinking Water Quality: The SDWA

The SDWA was enacted "to assure that the public is provided with safe drinking water."[192] This Act governs both surface water and groundwater designated for drinking use. The Act directs EPA's consideration of treatment technologies for the national primary drinking water regulations, and influences water utilities' selection of treatment technologies for regulatory compliance.[193] For a new technology to be considered by either EPA or a water utility, it must have advantages such as lower costs, higher efficiency, improved treated water quality, or less waste production compared to

179. FIFRA §3(c)(2)(B), 7 U.S.C.A. §136a(c)(2)(B).

180. FIFRA §6(a)(2), 7 U.S.C.A. §136d(a)(2). EPA regulations further specify what information is required to be submitted. 40 C.F.R. §159.

181. FIFRA §§6(b)-(c), 13(a), 7 U.S.C.A. §§136d(b)-(c), 136k(a).

182. CWA §101(a), 33 U.S.C.A. §1251(a) (2007).

183. CWA §101(a)(6), 33 U.S.C.A. §1251(a)(6).

184. CWA §303, 33 U.S.C.A. §1313.

185. CWA §301, 33 U.S.C.A. §1311.

186. *See* The Clean Water Act Handbook 19 (Mark A. Ryan eds., ABA, 2d ed. 2003).

187. "The control/permitting authority should evaluate the possible impacts on local limitations from specific chemical byproducts that may form during treatment operations. The presence of these byproducts may require additional treatment, or may require a different primary treatment technology to be used in specific instances." OPPT, U.S. EPA, Pollution Prevention (P2) Guidance Manual for the Pesticide Formulating, Packaging, and Repackaging Industry: Implementing the P2 Alternative 138 (1998) (EPA-821-B-98-017), *available at* http://www.epa.gov/waterscience/guide/p2/pdf/p2guide.pdf.

188. *See id.*

189. *See* CWA §304(e), 33 U.S.C.A. §1314(e).

190. EPA Environmental Technology Verification Program website, http://www.epa.gov/etv/index.html (last visited Feb. 7, 2008).

191. *See* Oberdörster et al. 2007, *supra* note 19, at 17.

192. 42 U.S.C. §§300f to 300j-26, ELR Stat. SDWA §§1401-1465.

193. *See* Drinking Water Regulation and Health 381 (Fredrick W. Pontius eds., Wiley & Sons, Inc. 2003).

traditional treatment processes.[194] Furthermore, to be accepted and implemented on a large municipal scale it typically has to go through several stages of demonstration, implementation, and operation at a smaller scale plant.[195] Nevertheless, once accepted and approved by the regulatory agencies, a market for the technology's deployment is guaranteed. Thus, similar to the CWA, the SDWA can create incentive for nano-based technological development and innovation.

More specifically, the Act directs EPA to set a non-enforceable maximum contaminant level goal (MCLG) and national primary drinking water regulation (NPDWR) for contaminants that EPA decides to regulate. The MCLG should be set "at the level at which no known or anticipated adverse effects on health of persons occur and which allows an adequate margin of safety."[196] EPA, then, to set an enforceable standard determining either an MCL or a treatment technique, at a level "which is as close to the maximum contaminant level goal as is feasible," using best technology, treatment techniques, or other means available.[197] For each MCL, EPA must list the technology, treatment techniques, and other means available to meet the standard.[198]

For example, in the 2006 Disinfectants and Disinfection Byproducts Rule, EPA listed nanofiltration with a molecular weight and cutoff of 1,000 Daltons or less as BAT for achieving the MCL for total trihalomethanes (TTHM) and Haloacetic acids (five) (HAA5).[199] In an earlier rulemaking for arsenic removal, however, EPA noted that "[it] did not consider nanofiltration a likely compliance technology because of high costs relative to other technologies and decreased removal efficiency when operated to constrain production of waste streams."[200] This means that relative to other available technologies, nanofiltration is not found to be cost-effective at large metropolitan water systems. Nevertheless, water utilities could choose to use nanofiltrations as equivalent technologies even though they are not listed if they can achieve the MCL,[201] unless they seek a variance, and then they must agree to install a BAT.[202]

Thus, cost-effective technologies that can meet the MCL or are recommended in lieu of the MCL, and that have gone through all demonstration pilots, are taken as safe and appropriate to use at water utility plants. However, the traditional evaluation process cannot guarantee that innovative technologies will not cause new risks, unless developers or technology verifiers will specifically address these risks.

Traditionally, EPA has determined feasibility based on regional and large metropolitan water systems, but the technical demands and costs associated with such technologies often make these technologies inappropriate for small systems. Thus, in 1996 Congress amended the SDWA to require EPA to specifically list small system compliance technologies for meeting each MCL or the Surface Water Treatment Rule (SWTR) requirements.[203] These lists may be updated at any time to include new or innovative treatment technologies,[204] but they are not product-specific and cannot certify that a specific technology is safe, because specific product review is beyond EPA's purview.[205]

The amendment created market demand for low-cost technologies that can achieve the same MCL in a more effective way. Nanotechnologies promise to do exactly that, and thus attract interest and research funding. What they can not guarantee, however, is not to create "new" risks. While EPA may determine that certain nanotechnologies are not cost-effective at large municipal plants, which can implement other well-proven technologies, for small systems, which do not have as many choices, the same technologies may be cost-effective. This situation may put small communities at greater risk of unknown health effects than the rest of the population.

In 1998, EPA announced the small system compliance technology lists for existing national primary drinking water regulations.[206] Nanofiltration, for example, was found to qualify as BAT to meet the MCLs for asbestos, arsenic, and synthetic organic chemicals (SOCs), as well as to comply with the SWTR requirements.[207] Therefore, while EPA determined that nanofiltration is not cost-effective for treating arsenic at large municipal plants, it found it to be cost-effective in small systems. It might be that technological limitations make it more effective on a smaller scale than on a larger scale, but it is also possible that costs do not allow small systems to implement better technologies, thus requiring compromise on the final results.

Furthermore, compliance technologies or treatment techniques sometimes can result in degradation byproducts, of which toxicological properties are unknown. Some byprod-

194. Issam Najm et al., *New and Emerging Drinking Water Treatment Technologies*, *in* IDENTIFYING FUTURE DRINKING WATER CONTAMINANTS 220 (National Academy Press 1999).

195. New technologies must be: (1) successfully demonstrated in another field; (2) tested and developed at bench- and pilot-scale levels (1 to 50 gallons per minute (gpm)); (3) verified at demonstration-scale level (>100 gpm); (4) installed and operated successfully at multiple small full-scale level (0.5 to 5 million gallons per day); and (5) implemented at a large-scale municipal water treatment plant. *See id.*

196. *See* SDWA §300g-1(b)(4)(A), 42 U.S.C.A. §1412(b)(4)(A).

197. *Id*. §300g-1(b)(4)(B) and (D), 42 U.S.C.A. §1412(b)(4)(B) and (D). If EPA determines that it is not economically or technologically feasible to ascertain the level of the contaminant, it is authorized to require the use of a treatment technique in lieu of establishing MCLs. *See* SDWA §300g-1(b)(7)(A), 42 U.S.C.A. §1412(b)(7)(A) (2007); *see e.g.*, National Primary Drinking Water Regulations; Filtration, Disinfection; Turbidity, Giardia lamblia, Viruses, Legionella, and Heterotrophic Bacteria; Final Rule, 54 Fed. Reg. 27486 (June 29, 1989).

198. SDWA §300g-1(b)(4)(E)(i), 42 U.S.C.A. §1412(b)(4) (E)(i).

199. *See* National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule, 71 Fed. Reg. 387, 413 (Jan. 4, 2006).

200. National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. 6975, 7039 (Jan. 22, 2001).

201. SDWA §300g-1(b)(4)(E)(i), 42 U.S.C.A. §1412(b)(4) (E)(i).

202. DRINKING WATER REGULATION AND HEALTH, *supra* note 193, at 382.

203. SDWA §300g-1(b)(4)(E)(ii)-(v), 42 U.S.C.A. §1412(b)(4)(E)(ii)--(v). EPA cannot include in the list any point-of-use (POU) treatment technology to achieve compliance with a MCL for a microbial contaminant.

204. SDWA §300g-1(b)(4)(E)(iv), 42 U.S.C.A. §1412(b)(4)(E)(iv).

205. DRINKING WATER REGULATION AND HEALTH, *supra* note 193, at 384.

206. Announcement of Small System Compliance Technology Lists for Existing National Primary Drinking Water Regulations and Findings Concerning Variance Technologies, 63 Fed. Reg. 42032 (Aug. 6, 1998); *see also* OFFICE OF WATER, U.S. EPA, SMALL SYSTEM COMPLIANCE TECHNOLOGY LIST FOR THE NON-MICROBIAL CONTAMINANTS REGULATED BEFORE 1996 (1998) (EPA 815-R-98-002), *available at* http://www.epa.gov/safewater/standard/tlstnm.pdf; OFFICE OF WATER, U.S. EPA, SMALL SYSTEM COMPLIANCE TECHNOLOGY LIST FOR THE SURFACE WATER TREATMENT RULE AND TOTAL COLIFORM RULE (1998) (EPA-815-R-98-001), *available at* http://www.epa.gov/safewater/disinfection/pdfs/compliancelist_tcr-swtr_smallsystem.pdf.

207. *See id.*

ucts may be more toxic than their parent compounds.[208] To address this problem, the SDWA authorizes EPA to set an MCL at other than the feasible level if the treatment method used to determine the feasible level would lead to an increase in health risk by increasing the concentration of other contaminants or by interfering with the treatment processes used to comply with other SDWA regulations.[209] In such cases, the standard or the treatment technique must minimize the overall health risk, and not just those posed by a specific contaminant.[210] Here again, the focus is on increased risks from listed contaminants and not from those for which risk is currently unknown. Thus, while EPA's authority to consider overall risk reduction allows it to mitigate some of the negative effects of these technologies, the MCL mechanism is clearly insufficient to ensure that nano-based water treatments will not cause increased risks of unknown adverse health effects.

Although voluntary, EPA's ETV Program may be a supplemental oversight mechanism worth considering. ETV is a voluntary public/private testing partnership created to accelerate the entrance of new environmental technologies into the domestic and international marketplace. Its main focus is to develop testing protocols and to verify the performance of innovative technologies that have the potential to improve protection of human health and the environment.[211] As in other pollution prevention areas, the ETV program can assist in verifying the performance of water treatment technologies. A 2006 survey carried by the Association of State Drinking Water Administrators (ASDWA) showed that 29 states recognize and use ETV reports in policymaking, permitting decisions, and/or reducing pilot testing; yet, only Utah makes formal reference to the ETV reports in its regulations.[212]

Numerous EPA offices and state programs are being supported by ETV technology testing results. Still, EPA's media-based programs do not encourage more robust and systematic verification of new technologies. Although the program does not rank, label, or list technologies as acceptable or unacceptable, determine BAT, or approve or disapprove technologies,[213] its flexibility allows it to adapt the testing protocols to address issues of specific concerns related to the unique properties of nanoscale materials. Therefore, the program may provide direct answers to the potential risks of a specific technology. According to Dr. George Gary, Assistant Administrator at EPA's Office of Research and Development, as of September 2007, the ETV has not received any requests to verify nanotechnology applications.[214] It is highly recommended that EPA finds ways to incorporate ETV reports into the regulatory process as well as to extend its scope to initiate technology verifications, rather than only verify technologies that are brought to it by various vendors.

3. Groundwater Remediation: The Resource Conservation and Recovery Act/The Comprehensive Environmental Response, Compensation, and Liability Act

Nanotechnology applications for groundwater remediation are most likely to involve releasing of free nanoparticles into the environment; therefore, their potential risks for human health and the environment are of most concern. The following section discusses EPA cleanup programs and how they can play a role in overseeing the performance of nanotechnologies for groundwater remediation. It is argued that with minimal amendments, EPA's current verification process of innovative technologies can verify the performance of nanotechnologies as well.

Groundwater remediation may be handled under either Resource Conservation and Recovery Act (RCRA)[215] or Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)[216] cleanup programs which take a similar approach. Under both programs, before choosing a cleanup method, a range of alternatives is analyzed and evaluated for advantages and disadvantages relative to site-specific conditions, including long-term effectiveness.[217] Within the stage of RCRA's facility investigation/corrective measure study (RFI/CMS), or the remedial investigation/feasibility study (RI/FS) under CERCLA, cleanup managers develop and screen alternative remedies. During this process, information is reviewed on existing and innovative remedial technologies applicable to the problems at the site.[218] If data is missing to support the remedy selection process, the applicable alternative technologies go through laboratory or field tests (treatability studies) to collect the necessary data.[219] Generally, technologies are first evaluated at the laboratory screening level and only then progress through the bench-scale level to the pilot-scale testing level.[220] However, based on available data on the technology and site-specific factors, a technology may enter at the second or third level as appropriate.[221]

208. Long D. Nghiem et al., *Critical Risk Points of Nanofiltration and Reverse Osmosis Processes in Water Recycling Applications*, 187 DESALINATION 303, 304 (2006), *available at* http://www.desline.com/articoli/6979.pdf.

209. SDWA §300g-1(b)(5), 42 U.S.C.A. §1412(b)(5).

210. EPA may balance the risk from the contaminant and the risk from other contaminants, the concentration of which may be affected by the use of a treatment technique or process that would be employed to attain the MCL. *See id.*

211. U.S. EPA, *What Is the ETV Program?*, http://www.epa.gov/etv/index.html, (last visited Feb. 7, 2008).

212. NSF International, *Survey of ASDWA Members Use of NSF Standards and ETV Reports March 2006*, at 3, http://www.nsf.org/business/water_distribution/pdf/ASDWA_Survey_2006.pdf (last visited Sept. 6, 2007).

213. U.S. EPA, *ETV Fact Sheet*, http://www.epa.gov/etv/pdfs/fs/600f07005compliant.pdf.

214. Remarks by Dr. George Gary, Assistant Administrator, EPA Office of Research and Development (Pollution Prevention Through Nanotechnology Conference, Sept. 25-26, 2007).

215. 42 U.S.C. §§6901-6992k, ELR STAT. RCRA §§1001-11011.

216. 42 U.S.C. §§7401-7671q, ELR STAT. CERCLA §§101-618.

217. *See* OFFICE OF SOLID WASTE & EMERGENCY RESPONSE (OSWER), U.S. EPA, RCRA ORIENTATION MANUAL 2006: CORRECTIVE ACTION TO CLEAN UP HAZARDOUS WASTE CONTAMINATION III/126 (2006), *available at* http://www.epa.gov/epaoswer/general/orientat/rom39.pdf; OSWER, U.S. EPA, DIRECTIVE 9283.1-2, GUIDANCE ON REMEDIAL ACTIONS FOR CONTAMINATED GROUND WATER AT SUPERFUND SITES 6/1-5 (1988), *available at* http://www.epa.gov/superfund/resources/remedy/pdf/540g-88003-s.pdf.

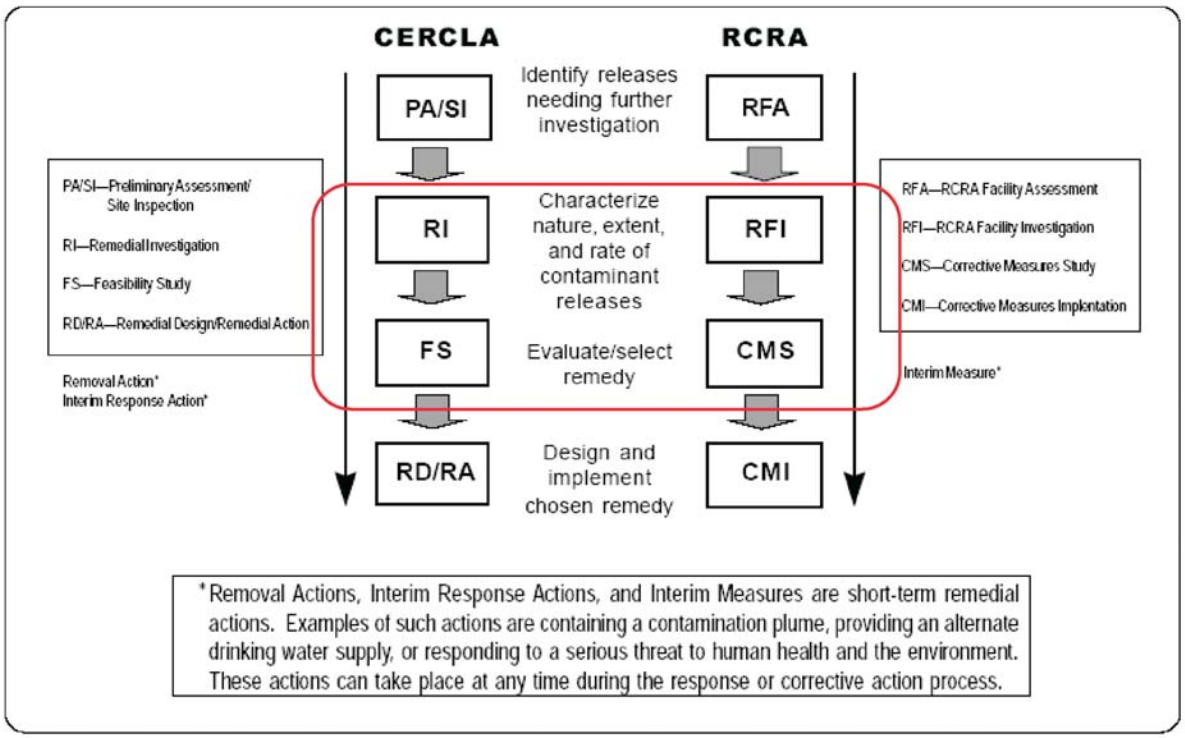
218. OSWER, U.S. EPA, DIRECTIVE 9355.3-01, GUIDANCE FOR CONDUCTING REMEDIAL INVESTIGATIONS AND FEASIBILITY STUDIES UNDER CERCLA 5/3 (1988), *available at* http://www.epa.gov/superfund/policy/remedy/pdfs/540g-89004-s.pdf; OSWER, U.S. EPA, DIRECTIVE 9902.3-2A, RCRA CORRECTIVE ACTION PLAN 41 (1994), *available at* http://www.epa.gov/correctiveaction/resource/guidance/gen_ca/rcracap.pdf.

219. *See id.*

220. OSWER, U.S. EPA, DIRECTIVE 9380.3-10, GUIDANCE FOR CONDUCTING TREATABILITY STUDIES UNDER CERCLA 8-10 (1992), *available at* http://www.epa.gov/superfund/resources/remedy/pdf/540r-92071a-s.pdf; DIRECTIVE 9902.3-2A, *supra* note 218.

221. *See id.*

Figure 3



Under CERCLA, the applicable technologies go through detailed analysis and a remedy selection process.[222] During this process, each alternative technology is assessed against nine evaluation criteria: (1) overall protection of human health and the environment; (2) compliance with applicable or relevant and appropriate requirements (ARARs); (3) long-term effectiveness and permanence; (4) reduction of toxicity, mobility, or volume; (5) short-term effectiveness; (6) implementability; (7) cost; (8) state acceptance; and (9) community acceptance.[223]

This process could have been sufficient to ensure minimum risks from nanotechnologies for groundwater remediation, if all crucial questions were addressed. However, to date, EPA guidance only requires evaluating human health and environmental risks of controlled pollutants, and no investigation for additional risks due to treatment processes is required.[224]

Furthermore, to streamline the process, EPA developed the Presumptive Remedies: Policy and Procedures directive describing EPA's preferred technologies for common categories of sites.[225] However, the list describes categories of remedies and not specific technologies.[226] Thus one may assume that under the presumptive green light policy, nanotechnologies that fall under certain remedy categories, e.g., nano Fe_2O_3 and nano TiO_2 may fall under the chemical oxidation category, may escape the entire treatability studies process, since their advantages and disadvantages are assumed to be already known. It is recommended that EPA clarifies that nanotechnologies cannot be classified as presumptive technologies unless additional testing has been conducted.

Even if nanotechnologies are not classified as presumptive technologies, EPA still encourages their development so they can be used in unusual site-specific circumstances.[227] Furthermore, the national contingency plan (NCP) regulations direct explicitly consideration of innovative technology "when such technology offers the potential for comparable or superior treatment performance and implementability, fewer or lesser adverse impacts than other available approaches, or lower costs for similar levels of performance than demonstrated technologies."[228] Still, the innovative nanotechnologies would have to go through the long evaluation process.

In summary, the current evaluation process is a good start, but it is insufficient unless issues related to the unique properties of nanoscale materials are addressed. When evaluating nanotechnologies for groundwater remediation, it is necessary to address the possible increased human health

222. *See id.*

223. *See* DIRECTIVE 9355.3-01, *supra* note 218, at 6/1-15.

224. *See id*. at 6/9-11.

225. *See* OSWER, U.S. EPA, DIRECTIVE 9355.0-47FS, PRESUMPTIVE REMEDIES: POLICY AND PROCEDURES (1993), *available at* http://www.epa.gov/superfund/resources/presump/finalpdf/pol.pdf; *see also* OSWER, U.S. EPA, DIRECTIVE 9283.1-12, PRESUMPTIVE RESPONSE STRATEGY AND EX-SITU TREATMENT TECHNOLOGIES FOR CONTAMINATED GROUND WATER AT CERCLA SITES (1996), *available at*: http://www.epa.gov/superfund/resources/gwguide/gwfinal.pdf.

226. *See* DIRECTIVE 9283.1-12, *supra* note 225, apps. A3 and D1-D8.

227. *See* DIRECTIVE 9355.0-47FS, *supra* note 225, at 2.

228. 40 C.F.R. pt. 300.430(a)(1)(iii)(E) (2007).

and environmental risks resulting from the treatment process and from byproducts of the technology in question. Another critical point is that careful consideration should be given to the extent to which existing data on related technologies can be attributed to nanotechnologies. For instance, can data existing on ZVI performance in groundwater remediation be attributed to nZVI performance, eliminating the need for some levels of the treatability studies?[229]

C. Applicability and Adequacy Evaluation

There are various ways to evaluate the applicability and adequacy of existing laws to oversee the development and use of nanotechnologies for water treatment. Some evaluations may take a more theoretical approach, focusing entirely on the language of the statutes, while others would be more practical, taking into consideration factors such as adequate funding and human resources, as well as EPA's political will and experience in implementing the programs.

The following table summarizes the previous discussion. As a matter of principle it does not take into consideration EPA's funding and human resources for running the programs or its political will to oversee the development of nanotechnologies, both of which may have a significant impact on the effectiveness of the programs.[230] The criteria for evaluations in broad terms are: requirements for safety review of the technologies and data disclosure; the safety threshold and the administrative burden; and EPA discretion to approve and regulate the technology. Although the table does not provide a complete life-cycle analysis, it looks at the various stages of the development and implementation of the nanotechnologies in the water treatment sector. Finally, the scope of the program is also evaluated. Scores were given to each criterion in terms of "adequate," "mostly adequate," "inadequate," or "not available." It should be noted, however, that some of the scores were affected by the way EPA interprets its legal authority under the various programs, and those interpretations were considered to be applicable law. For example, had EPA taken a broader approach regarding the new chemical definition under TSCA, this would have affected the score given to the "program coverage" and "EPA approval discretion" criteria in the pre-market stage.

Table 1

Requirements \ Regulation		Product-Based		Media-Based		
		FIFRA	TSCA	CWA	SDWA	RCRA/ CERCLA
R&D	Program coverage	+	–	–	–	–
	Safety review and data disclosure	++	–	–	–	–
	Safety threshold	+++	–	–	–	–
	Placing burden of proof on Industry	+++	–	–	–	–
Pre-market/ Pre-Implementation	Program coverage	++	+	+++	+++	+++
	Safety review and data disclosure	++	+	–	+	++
	Safety threshold	++	+	++	+++	++
	Placing burden of proof on Industry	+++	–	++	++	++
	EPA approval discretion	+++	+	+	++	+++
Market/ Implementation	Safety review and data disclosure	+++	++	–	–	–
	Early warning reporting	+++	+++	–	–	–
	Placing burden of proof on Industry	+++	–	–	–	–
	EPA regulation discretion	+++	+	–	–	–
Total average adequacy (0-3)		2.5	0.76	0.6	0.85	0.92

Index: Adequate (+++), Mostly adequate (++), Inadequate (+), N/A (–)

229. According to DuPont's assessment of nZVI for environmental remediation, "[t]here is presently no way to determine the degree to which most of the suppliers have collected health and environmental safety data, conducted an exposure analysis or determined what engineering controls and personal protective equipment they should employ." *See* DuPont, Nanomaterial Risk Assessment Worksheet: Zero Valent Nano-Sized Iron Nanoparticles (nZVI) for Environmental Remediation (2007), *available at* http://www.environmentaldefense.org/documents/6554_nZVI_Summary.pdf.

230. For general discussion on these issues, see Davies 2007, *supra* note 67, at 27-30.

V. Conclusion

Previous reviews of EPA programs reached different conclusions on whether they are applicable and adequate to address the EHS implications of nanotechnologies.[231] For the most part, these reviews examined legal provisions in general terms, looking either at nanoscale substances as the regulated products, or at nanoparticles as the regulated pollutants.

EPA has chosen to use TSCA as the main vehicle to regulate nanotechnologies. TSCA also will have a significant role in regulating water treatment applications that do not fall under FIFRA because they are not antibacterial. Yet, as this Article points out, TSCA's authority faces great challenges in regulating nanoscale substances. TSCA has long been criticized for its inadequacy to regulate unknown risks, but in the case of nanotechnologies, these challenges seem greater.

The strength of TSCA lies within its premanufacture program. However, focusing on the molecular identity of the substance rather than on other properties for PMN regulatory purposes ignores the fact that nanotechnologies aim to create substances with fundamentally different and novel properties, which may pose novel risks. Dismissing the new chemical definition issue by referring to the parallel SNUR track clearly underestimates its own limitations, as well as the fact that in many cases EPA will not be able to claim a significant new use. In addition, various exemptions from the premanufacture program make its coverage almost insignificant and EPA would have to amend these exemptions in order to regulate nanomaterials.

Nevertheless, relatively minor amendments to current regulations and guidelines may allow some progression through the uncertainty stage. If EPA amends its current rules under TSCA §8 to specifically require submission of data related to nanoscale materials, those amendments may help collect risk data already available and, in some cases, generate new data. Better clarity on real EHS risks would help TSCA regulatory provisions to be used in a more meaningful way.

Contrary to TSCA, FIFRA is much more suitable for the task. While some issues still require attention, under FIFRA, EPA is much better equipped to make the necessary clarifications. For example, EPA should clarify that the substitution of a nanoscale ingredient for its macro counterpart constitutes a new chemical for registration purposes. This would allow EPA to require additional testing tailored to the unique properties of nanoparticles. Under FIFRA, EPA's hands are not tied by the molecular identity definition and it can make this clarification based on a significant new claim or composition of the substance. Additionally, EPA should amend current data requirements for product composition, certified limits, and physical and chemical characteristics to address information regarding some of the key unique properties of nanomaterials, such as surface area, shape, and aggregation of particles. Finally, EPA should change the measurement basis for threshold limits across its regulatory framework from mass concentration to surface area.

Departing from product-based regulation, this Article offers a new perspective on the role media-based regulation can play in overseeing the performance of nanotechnologies for water treatment. For example, the Article suggests using RCRA and CERCLA cleanup programs, specifically the treatability studies mechanism, to further oversee potential risks of the innovative technologies for groundwater remediation. It also suggests that EPA use its discretion in determining BAT for CWA effluent guidelines or the SDWA MCLs to verify that the nanotechnologies listed as BAT will not pose additional risks. It specifically recommends that EPA look at reaction byproducts that may occur. Likewise, when a facility chooses to use an equivalent treatment method utilizing nanotechnology, EPA is encouraged to require verification that such equivalent treatment does not generate negative reaction byproducts. Finally, the Article encourages EPA to find ways to incorporate ETV reports into the regulatory process as well as to extend its scope to initiate technology verifications in this area.

231. *See* Environmental Law Institute, Securing the Promise of Nanotechnology: Is the U.S. Environmental Law Up to the Job? (2005), *available at* http://www.elistore.org/Data/products/d15_10.pdf; ABA-SEER Nanotechnology Project website at http://www.abanet.org/environ/nanotech/ (last visited Feb. 7, 2008); Davies 2007, *supra* note 67, at 24-27 (concluding that some laws are more adequate than others, but "[h]aving the legal authority to cover nano is not the same as providing adequate protection for the public . . . the program needs sufficient authority and technical capacity to perform certain necessary functions").