# Is the Toxic Substances Control Act Sufficient to Monitor the Sustainable Use of Nanoscale Zero-Valent Iron for Groundwater Detoxification?

by Susan A. Fuchs

Susan A. Fuchs is a May 2010 LL.M. Candidate, Biotechnology and Genomics, Sandra Day O'Connor College of Law.

*Editors' Summary*

Proponents of nanoscale zero-valent iron maintain that this cutting-edge technology shows promise for removing 90% of groundwater toxins. Its detractors point to short-sighted profit interests that do not take into account the total potential economic, social, health, and environmental costs of cleaning up the cleanups; hence, government oversight is necessary. EPA has the unenviable task of promulgating TSCA rules that both define and anticipate the unique properties and challenges of these nanoscale particles. EPA's information-gathering and enforcement authority must balance protecting the public from the potential toxic effects of an otherwise beneficial nanotechnology.

Development is sustainable when society is able to meet its present needs without hindering the ability of future generations to meet theirs.[1] It is a compromise or balance among human development, economic, and environmental values by looking at long-range solutions on a global scale.[2] This necessarily involves cooperation between governmental and nongovernmental entities.[3]

The process of regulating the innovative use of nanoscale zero-valent iron (nZVI) to clean up contaminated groundwater wastes touches on all of these sustainability factors. Proponents of nZVI maintain that this cutting-edge technology shows promise for removing 90% of groundwater toxins. Its detractors point to short-sighted profit interests that do not take into account the total potential economic, social, health, and environmental costs of cleaning up the cleanups; hence, the necessity for government oversight. The U.S. Environmental Protection Agency (EPA) has the unenviable task of promulgating Toxic Substances Control Act (TSCA)[4] rules that both define and anticipate the unique properties and challenges of these nanoscale particles.

This Article examines the extent to which EPA's information-gathering and enforcement authority under TSCA balances protecting the public from the potential toxic effects of an otherwise beneficial nanotechnology. It grapples with the intrigue of uncovering whether nZVI or its macroscale counterpart, ZVI (elemental iron), are on either EPA's yet-to-be-published or unpublished, confidential, TSCA chemical substance inventory lists; EPA's stance on whether nZVI is a TSCA new chemical substance; and the necessity of and requirements for filing a significant new use or premanufacture notice for nZVI. This analysis concludes by proposing policy recommendations with steps for meaningful legal reforms.

## I. The Promise and Risks of nZVI

### A. *ZVI Versus nZVI*

Site project managers have used ZVI and other metal particles to clean up groundwater contaminated with chlorinated

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1. World Comm'n on Env't & Dev., Our Common Future 8 (1987).
2. Robert W. Kates et al., *What Is Sustainable Development? Goals, Indicators, Values, and Practice*, Env't: Sci. & Pol'y for Sustainable Dev., Apr. 2005, at 8, 19-20.
3. Michael D. Lemonick, *Top 10 Myths About Sustainability*, Sci. Am. (Special Ed.), Mar. 2009.
4. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.

hydrocarbons (chlorinated solvents) for almost 20 years.[5] ZVI seeks chemical reactions that allow it to donate electrons. Under aerobic conditions, oxygen is usually the electron acceptor.[6] Under anaerobic conditions, as when workers release ZVI into groundwater contaminated with toxic chlorinated solvents, the ZVI degrades the solvents into nontoxic end products.[7]

Typically, workers release the ZVI into the groundwater by filling a trench with ZVI granules creating a permeable reactive barrier (PRB), essentially an iron mesh wall.[8] They construct the wall perpendicular to and downgradient to the flow of a contaminated groundwater plume. The iron particle mesh must be permeable enough to allow the water to passively flow through the wall while maintaining sufficient ZVI contact to allow the ZVI to degrade or capture the contaminant from the water.[9]

A new variant of ZVI, nZVI,[10] appears to be both more effective and cheaper than its macroscale counterpart for groundwater contamination cleanup. Although the chemical reaction with nZVI is the same as with ZVI[11], nZVI and other nanoscale particles have less volume and greater surface area due to their microscopic size. This makes nano-sized particles more chemically reactive than the same particles that are macro-sized.[12] Studies indicate that nanoscale particles' greater reactivity may be the reason why nZVI is able to decontaminate higher concentrations of a broader range of chlorinated hydrocarbon and other contaminants than its macro-sized version.[13]

Scientists who used nZVI to clean up the Nease Chemical Superfund site chose the nano-sized version because it produced more favorable results at a lower cost and in a wider range of geological sites than macro-sized ZVI.[14] Unlike ZVI, nZVI is effective even when it cannot be injected directly into the groundwater. Sometimes, the only access to a groundwater aquifer or well that contains contaminants is through dense nonaqueous phase liquid (DNAPL). ZVI cannot penetrate DNAPL. However, the site worker can successfully inject nZVI into that DNAPL.[15] Furthermore, it is easier to inject finer nZVI particles into soil than coarser ZVI particles.[16] The Nease Chemical Superfund site contained DNAPL with chlorinated contaminants within bedrock groundwater, too dense for ZVI effectiveness.[17]

### *B. Cleanup Efficacy*

Chlorinated solvents, such as perchloroethylene (PCE) and trichloroethylene (TCE), were widely used as cleaning and degreasing agents. Lead, chromium, and arsenic also have a number of industrial uses.[18] nZVI can effectively remediate all of these hazardous wastes, common to many cleanup sites. The net result is that nZVI reduces groundwater contaminants into forms that are usually less hazardous and less mobile.[19]

In a 2005 pilot-scale test in Passaic, New Jersey, scientists injected nZVI into groundwater contaminated with TCE. They monitored the site weekly during the first month and then monthly. Their results indicated that the nZVI removed 90-100% of the TCE contaminants.[20]

That same year, in another New Jersey site in Hamilton Township, researchers injected nZVI in varying amounts to clean up four chlorinated solvents: TCE, tetrachloroethane (TCA), dichloroethylene (DCE), and dichloroethane (DCA). Subsequent groundwater monitoring revealed that nZVI removed 90% of these contaminants.[21]

The findings of a U.S. Navy research study at a third New Jersey site in Lakehurst cautions against short-term moni-

5. U.S. EPA, Publ'n No. EPA 542-F-08-008, Nanotechnology for Site Remediation Fact Sheet 2 (2008) [hereinafter Nanotechnology Fact Sheet], *available at* http://www.epa.gov/tio/download/remed/542-f-08-009.pdf.
6. H.M. Gaber et al., *Vadose Zone Processes and Chemical Transport: Metolachlor Dechlorination by Zerovalent Iron During Unsaturated Transport*, 31 J. Envtl. Quality 962, 962 (2002).
7. *Id.*; Interstate Tech. Regulatory Council, Permeable Reactive Barriers: Lessons Learned/New Directions 8 (2005), *available at* http://www.frtr.gov//pdf/prb-4.pdf.
8. Arun Gavaskar et al.,Naval Facilities Eng'g Command, Publ'n No. CR-05-007-ENV, Nanoscale Zero-Valent Iron Technologies for Source Remediation ii (2005), *available at* http://www.clu-in.org/download/remed/cr-05-007-env.pdf; Nanotechnology Fact Sheet, *supra* note 5, at 2; U.S. EPA, Publ'n No. EPA 100/B-07/001, Nanotechnology White Paper 22 (2007).
9. Andrew D. Henderson & Avery H. Demond, *Long-Term Performance of Zero-Valent Iron Permeable Reactive Barriers: A Critical Review*, 24 Envtl. Engineering Sci. 401, 401-02, 404 (2007); Federal Remediation Technologies Roundtable, 4.40 Passive/Reactive Treatment Walls, http://www.frtr.gov/matrix2/section4/4-41.html (last visited Mar. 11, 2010).
10. There is no set legal or industry standard for what constitutes nanoscale or nanotechnology. For the purposes of this Article, the author defines nanotechnology using the National Nanotechnology Initiative (NNI) definition. Each nanometer unit is one billionth of a meter. "Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications." NNI, What Is Nanotechnology?, http://www.nano.gov/html/facts/whatIsNano.html (last visited Mar. 11, 2010).
11. Interstate Tech. Regulatory Council, *supra* note 7, at 88.
12. U.S. EPA, Publ'n No. EPA 905K07001, Proceedings of the Nanotechnology Site Remediation Workshop 7 (2007) [hereinafter Nanotechnology Workshop]; Nanotechnology Fact Sheet, *supra* note 5, at 1-2.
13. Nanotechnology White Paper, *supra* note 8, at 22-23. nZVI is not only an effective agent for dechlorination; it also immobilizes lead, arsenic, and chromium. Jo Anne Shatkin, Nanotechnology: Health and Environmental Risks 87 (2008).
14. Nanotechnology Workshop, *supra* note 12, at 7.
15. Nanotechnology Fact Sheet, *supra* note 5, at 1; Nanotechnology White Paper, *supra* note 8, at 22-23.
16. Gavaskar et al., *supra* note 8, at ii.
17. Nanotechnology Workshop, *supra* note 12, at 6-7.
18. Shatkin, *supra* note 13, at 87; Nanotechnology White Paper, *supra* note 8, at 38-39.
19. Shatkin, *supra* note 13, at 87.
20. Nanotechnology Fact Sheet, *supra* note 5 at 11.
21. *Id.*

toring of nZVI-treated sites.[22] The study found that initial nZVI efficacy at removing these contaminants can be misleading if the site monitoring does not continue until the dissolved oxygen returns to pretreatment levels.[23] If the nZVI injection slurry contains too much water, the nZVI becomes oxygenated and cannot break down contaminants.[24] The added water from the slurry can then dilute the plume so that, at first, it appears to have less contaminants.[25] After several weeks, the contaminant level can begin to rise again along with the dissolved oxygen.[26] Thus, the study's authors recommend that once the dissolved oxygen levels completely rebound, the site manager continue to monitor the aquifer to make sure that it maintains its initial declines in contaminants.[27]

### *C. How nZVI Removes Toxins*

nZVI is mixed with water to create an iron-water slurry that is then injected into the contaminated water or DNAPL within an aquifer.[28] Since nZVI is not very mobile, it must be injected into closely spaced treatment zone wells.[29] When nZVI is injected into these sites, it destroys contaminants by oxidation reduction reactions (a process similar to rusting) while reducing chlorinated contaminant compounds into carbon dioxide.[30] In order for this process to work correctly, the site worker needs to ensure that slurry water that is mixed with the nZVI is minimal or deoxygenated, and that the worker injects a sufficient amount of nZVI to create the necessary abiotic reduction conditions.[31]

After the nZVI injections, dissolved iron increases as it eliminates dissolved oxygen in the treated water.[32] According to the Navy's site remediation studies, the low dissolved oxygen levels increase as nZVI levels reduce.[33] Once the dissolved oxygen levels completely rebound, much of the remaining iron particles dissolve or settle out of the groundwater. This causes groundwater-dissolved iron to increase while it eliminates dissolved oxygen.[34]

### *D. Sustainability Concerns*

nZVI technology offers considerable groundwater decontamination benefits. In order for nZVI use to enhance global sustainable development, nZVI's advantages must be balanced against any environmental, health, and economic burdens to present and future generations. One Superfund project manager downplays any increased nanoscale particle risks associated with nZVI use by reasoning that nZVI naturally occurs in groundwater, surface water, and soil.[35] Scientist Jo Anne Shatkin maintains that no zero-valent iron naturally occurs in the environment. Instead, Shatkin points out that the iron comprising approximately 5% of the earth's crust is generally in the form of iron sulfides and iron oxides.[36]

#### 1. Risks During nZVI Production and Application Processes

The nZVI production and application processes pose health and other environmental risks. The nZVI production process begins with heating iron pentacarbonyl, a flammable substance.[37] Oxygen from the air can turn nanoscale iron into iron oxide or rust; the speed of that reaction can cause an explosion.[38] In order to keep the iron from coming into contact with oxygen during the manufacturing process, the iron nanoparticles must be continually surrounded by argon gas and cooled with liquid nitrogen. The argon gas also keeps the nanoscale iron from aggregating into macroscale iron particles.[39] The resulting nanoscale iron powder is packed into an airtight container with nitrogen-diffused water that deoxygenates the water.[40] At the treatment site, the site worker mixes the nZVI with a dispersing agent prior to injecting it through airtight wells.[41]

An nZVI explosion from contact with oxygen can cause human and environmental damage resulting from flying debris, fire, and exposure to airborne nanoparticles.[42] This can occur during the nZVI manufacturing process or in packaging (exposing workers), or in transport or on site (exposing all in the vicinity, once nZVI becomes airborne).[43]

#### 2. After Application Risks

The Nease Chemical Superfund Project Manager, Mary Logan, postulates that the nZVI-treated water will stay within the aquifer by either collecting into a mass or settling to the bottom of the aquifer, but does not offer supporting data for that theory.[44] Researchers have found nZVI in groundwater up to one year after its use.[45] Dr. Shatkin warns of downstream environmental exposure risks, concluding: "The behavior of iron nanoparticles in ground water remains a key area of uncertainty . . . ."[46]

22. Nanotechnology Workshop, *supra* note 12, at 5-6.
23. *Id.* at 6.
24. Gavaskar et al., *supra* note 8, at 34.
25. *Id.* at 34, 37.
26. *Id.* at 34.
27. *Id.* at 42.
28. Nanotechnology Workshop, *supra* note 12, at 7.
29. *Id.* at 9.
30. Shatkin, *supra* note 13, at 87.
31. Gavaskar et al., *supra* note 8, at 34, 42. An abiotic atmosphere is more important with nZVI than with ZVI.
32. Nanotechnology Workshop, *supra* note 12, at 7.
33. Gavaskar et al., *supra* note 8, at 39.
34. Nanotechnology Workshop, *supra* note 12, at 7. The Navy found a two to four times increase in dissolved iron at several of its nZVI hazardous waste cleanup sites. The site results did not discuss the fate of nondissolved nZVI within or beyond the contamination plume. Gavaskar et al., *supra* note 8, at 39.
35. Nanotechnology Workshop, *supra* note 12, at 8.
36. Shatkin, *supra* note 13, at 88.
37. *Id.* at 109.
38. *Id.*
39. *Id.*
40. *Id. See also* Gavaskar et al., *supra* note 8, at 42.
41. Shatkin, *supra* note 13, at 109.
42. *Id.* at 109-10.
43. *Id.*
44. Nanotechnology Workshop, *supra* note 12, at 8.
45. Shatkin, *supra* note 13, at 88.
46. *Id.* at 110.

One research study revealed that when researchers used nZVI to dechlorinate more complex polychlorinated hydrocarbons, the reaction produced two toxic byproducts, biphenyl and trace amounts of benzene.[47] However, nZVI does degrade [carbon tetrachloride ($CCl_4$)] more quickly with less [chloroform ($CHCl_3$)] byproducts than its macro-version predecessor, ZVI.[48] Before opting to use nZVI to dechlorinate those more complex polychlorinated hydrocarbons, scientists should examine other containment and remediation options, including other types of nanometal particles.[49]

Some researchers have been experimenting with polymers and surfactants that help to stabilize nZVI, so that the particles will clump together less and disperse better in groundwater without adversely affecting nZVI's decontamination properties. Some of these products are already in commercial use.[50] Soil with high clay content appears to work as a natural stabilizer that enhances nZVI dispersion in contaminated water.[51] Methods that increase nZVI dispersal within the contamination plume are cheaper because they necessitate less nZVI injections for decontamination. However, the additives that enhance nZVI dispersal also increase the potential for nZVI to migrate beyond the contamination plume into drinking water wells or aquifers or into surface water.[52]

The prospect of enhanced nZVI migrating from contamination sites, flowing into surface water or drinking water wells and then entering water treatment plants, poses numerous health and environmental concerns.[53] Myopic profit motives do not address these potential long-term costs. Troy Benn and Paul Westerhoff conducted a study that, in part, investigated what happens to nanoparticles (nanosilver particles released from socks washed in water) once they enter the wastewater system.[54] They concluded that wastewater treatment plants have filters that adequately remove the majority of nano-sized particles. Those removed nanoparticles remain in the biosolids filtered from the water. The biosolids are then used on agricultural land for fertilizer.[55] The unfiltered nanoparticles that do pass through the wastewater treatment plants may migrate to biological ecosystems supported by surface water.[56]

Thus, if unused nZVI enters the waterways, nZVI may migrate to a water treatment plant; water treatment plants would filter the majority of nZVI from the water into biosolids, which might then become agriculture fertilizer, and finally into crops. Throughout this process, plants and animals have physical contact with the water and fertilizer. If the fertilizer is sprayed, the nZVI may enter the lungs of humans and other living creatures.[57] It is unknown how nZVI may affect plants that grow in nZVI-contaminated soil, or how it may affect species that eat those plants. Alternatively, the nZVI may pass through wastewater treatment plant filters and be ingested or support plant life. Using nZVI treated with dispersal enhancements produces myopic cost efficiencies that ignore the potential long-term sustainability costs for the environment and for cleaning up possible nZVI contaminations.

### 3. Human Exposure Health Risks

The manufacture, transport, handling, and application of nZVI and its precursor create additional exposure risks for humans. The iron pentacarbonyl used to manufacture nZVI is toxic to humans through inhalation and skin contact.[58] Once the production process converts it into nZVI, its small particle size allows the nanoparticles to cross biological barriers that block larger particles. Nanoparticles can be ingested or enter the body through blood, skin, and inhalation.[59] Although the effects of nanotechnology are still being investigated, the ability of nanoscale particles to infiltrate mostly impermeable barriers (blood-brain, dermal, lung cell) concerns researchers.[60]

Dr. Shatkin cautions that the type of nanoparticle, duration of exposure, and the dosage amount may all be factors that affect potential human and environmental toxicity. The effects of these factors on nanotechnology are the subject of current research.[61] However, she notes that one problem with nanoparticle research studies is that there are no nanomaterial reference standards. The same type of nanomaterial can vary considerably by particle shape, size, and concentration of nanoparticles to non-nanoparticles per batch. Particle consistency depends upon the batch manufacturer, differing chemical treatments, and varying levels of contaminants that affect toxicity.[62]

Another problem with many of the nanoparticle research studies is the paucity of animal and human studies. In vitro study samples do not contain immune and inflammatory cells, so the study results may not predict the toxic effects on the body's natural defense mechanisms.[63] Combinations of all of these issues make it difficult to interpret whether the results of the following studies can adequately predict the potential hazards of using nZVI.

47. Daniel Elliott et al., Novel Products From the Degradation of Lindane by Nanoscale Zero Valent Iron, Presentation at the 229th American Chemical Society National Meeting (Mar. 13, 2005).
48. *See supra* notes 14-15 and accompanying text.
49. Bi-metal nanoparticles (BNPs) may be more effective in some situations. BNPs are mostly iron or another metal mixed with a catalyst metal (palladium, gold, or nickel). Nanotechnology Fact Sheet, *supra* note 5, at 2, 4.
50. *Id.* at 10.
51. *Id.*
52. *Id.* "As the performance of NZVI is enhanced, its potential to migrate in the environment also increases." Shatkin, *supra* note 13, at 88.
53. *See supra* notes 44-45, 47-51 and accompanying text (human exposure risks); *see also supra* notes 44-45.
54. *See* Troy M. Benn & Paul Westerhoff, *Nanoparticle Silver Released Into Water From Commercially Available Sock Fabrics*, 42 Envtl. Sci. & Tech. 4133 (2008).
55. *Id.* at 4138.
56. *Id.* at 4133, 4138.
57. *See supra* notes 44-45, 47-51, 54-56.
58. Shatkin, *supra* note 13, at 110.
59. Nanotechnology Fact Sheet, *supra* note 5, at 10; Nanotechnology Workshop, *supra* note 12, at 22.
60. Nanotechnology Workshop, *supra* note 12, at 22. *See also* Shatkin, *supra* note 13, at 109.
61. Shatkin, *supra* note 13, at 65.
62. *Id.* at 70.
63. *Id.* at 68-69.

#### *a. Ingestion Exposure*

In one study, researchers injected silica-coated, magnetic rhodamine B isothiocyanate nanoparticles into the abdomens of mice over a four-week time period.[64] The nanoparticles penetrated into the spleens, hearts, lungs, uterus or testes, livers, and kidneys, and were able to pass through the blood-brain barrier to the brains of the mice.[65] The differing fluorescence of the nanoscale particles indicated that the earliest injected nanoparticles still remained within those organs after 28 days.[66] Even though the nanoparticles were able to pass through the blood-brain barrier, the particles produced no observable adverse brain affects or toxicity.[67]

#### *b. Dermal Exposure*

Dermal-sunscreen in vitro studies[68] show that nanoscale titanium oxide and zinc oxide penetration is possible in flexion areas or through hair follicles[69]; penetration is more certain through broken skin.[70] Some researchers theorize that nZVI may be able to enter human cells even more easily because they lack an electrical charge, but more research is needed to validate that hypothesis.[71] Once a nanoparticle penetrates the skin barrier, its entrance into red blood cells depends on its size, not its electrical charge.[72] Nanoparticles in red blood cells are able to pass through the blood-brain barrier.[73]

#### *c. Inhalation Exposure*

In a 2007 laboratory study,[74] researchers exposed human lung cell cultures to various levels of iron oxide[75] contained in silica nanoparticles.[76] They measured the lung cells' reactive oxygen species release to determine the degree of oxidative stress.[77] Whereas macroscale iron oxide dissolved, showing evidence of oxidative stress, nanoscale iron oxide neither dissolved nor exhibited evidence of oxidative stress.[78] The researchers surmise that there is a danger that the nanoscale iron oxide can cause prolonged cell damage, since those particles do not degrade.[79] Scientists at an EPA workshop reported that sensory neurons can directly transport inhaled nZVI particles into the brain, as can blood when nanoparticles pass through the blood-brain barrier.[80]

Even less is known about nanoparticle accumulation in the body from long-term exposures.[81] The common refrain in all of the above studies is that more research is needed to better assess nZVI health risks.[82] Despite the uncertainty as to the extent of nZVI harm, what is known warrants safe handling practices.[83]

Even though nZVI has distinct advantages over ZVI for groundwater site cleanups, a few companies have shied away from using it. DuPont has vetoed using nZVI for site remediation because of the above exposure concerns.[84] Additionally, Continental West Group insurance company policies temporarily excluded any damages or injuries arising from carbon nanotube (CNT) exposure.[85] If other insurance companies follow Continental West Group's lead, DuPont will not be alone in avoiding nZVI use.

## III. EPA Oversight Through TSCA

### *A. Chemical Substance*

The U.S. Congress' purpose in enacting TSCA is to protect against an unreasonable risk of health or environmental injury from certain chemical substances by both collecting information and, when necessary, regulating those substances.[86] TSCA's regulatory authority is front-loaded; it regulates those chemical substances before, during, and after the substances have entered into commerce. TSCA defines chemical substances that are subject to its regulation as organic and inorganic substances that have a "particular molecular identity."[87] These include an element or uncombined radical, as well as combinations that occur in nature or that are at least partially the result of a chemical reaction.[88] Although Congress passed TSCA in 1976, before the advent of engi-

64. *See* Jun Sung Kim et al., *Toxicity and Tissue Distribution of Magnetic Nanoparticles in Mice*, 89 Toxicological Sci. 338 (2006).
65. *Id.* at 341.
66. *Id.* at 340.
67. *Id.*
68. This author found no evidence of nanoparticle dermal animal studies. *See also* Shatkin, *supra* note 13, at 71-73.
69. Nanotechnology Workshop, *supra* note 12, at 22. *See also* Shatkin, *supra* note 13, at 73.
70. Nanotechnology Workshop, *supra* note 12, at 22; Stephan T. Stern & Scott E. McNeil, *Nanotechnology Safety Concerns Revisited*, 101 Toxicological Sci. 4, 8 (2008).
71. Nanotechnology Workshop, *supra* note 12, at 22. Generally, opposite charges attract each other and same charges repel each other.
72. *Id.*
73. *Id. See also supra* notes 61-62, 67-69 and accompanying text.
74. This in vitro study used spherical iron oxide nanoparticles. Ludwig K. Limbach et al., *Exposure of Engineered Nanoparticles to Human Lung Epithelial Cells: Influence of Chemical Composition and Catalytic Activity on Oxidative Stress*, 41 Envtl. Sci. & Tech. 4158, 4159 (2007). The nanoparticle inhalation animal studies have focused on carbon nanotubes (CNTs), not on other types of nanometal particles. Shatkin, *supra* note 13, at 70-71.
75. Nanoscale iron oxide ($nFe_2O_3$) is not the same as nZVI. The latter is not an oxidized iron and has no electrical charge.
76. Limbach et al., *supra* note 74, at 4159.
77. *Id.*
78. *Id.* at 4160.
79. *Id.* at 4162.
80. Nanotechnology Workshop, *supra* note 12, at 22.
81. Nanotechnology White Paper, *supra* note 8, at 56.
82. These include: Nanotechnology Fact Sheet, *supra* note 5, at 10; Nanotechnology White Paper, *supra* note 8, at 29-31, 46-47, 49, 54-62, 65, 67, 76-80, 89, 92; Nanotechnology Workshop, *supra* note 12, at 22; Shatkin, *supra* note 13, at 73-74, 110; Stern & McNeil, *supra* note 70, at 9, 13-16.
83. *See supra* notes 44-82.
84. DuPont, Nanomaterial Risk Assessment Worksheet (2007), *available at* http://www.edf.org/documents/6554_nZVI_Summary.pdf (last visited Mar. 11, 2010).
85. Insurance Services Office, Inc., Nanotubes and Nanotechnology Exclusion, *available at* http://cwgins.com/mike/documents/CW33690608NanotubesExclusion.pdf (last visited Mar. 11, 2010).
86. 15 U.S.C. §2601 (2007).
87. TSCA §3(2)(A), 15 U.S.C. §2602(2)(A).
88. *See* 40 C.F.R. §720.30 (2009). TSCA does not regulate any mixtures; Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) chemicals; tobacco products; Atomic Energy Act source materials; any items taxable upon sale by §4181 of the Internal Revenue Code of 1954; items regulated by the Federal Food, Drug, and Cosmetic Act (FDA); and poultry, meat, and egg products defined in Poultry Products Inspection Act, Federal Meat Inspection Act, and Egg Products Inspection Act. TSCA §3(2)(B), 15 U.S.C. §2602(2)(B).

neered nanotechnology, its definition of chemical substances is broad enough to encompass those containing nano-sized particles. EPA interprets TSCA's language to generally include nanoscale chemical substances.[89]

ZVI and nZVI, its nanoscale equivalent, are different sizes of iron particles. Since iron is a chemical element, it has a particular molecular identity under TSCA §3. Despite ZVI's and nZVI's particular molecular identities, they can only be TSCA-defined chemical substances if they do not fall within any TSCA exclusions. Neither iron particle fits within those exclusion categories or is regulated under the Food and Drug Administration (FDA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[90] or under other TSCA-excluded agencies.[91] Thus, both ZVI and nZVI are TSCA-defined chemical substances.[92]

### *B. Inventory List*

TSCA §8 requires the EPA Administrator to publish an updated inventory list of all TSCA chemical substances manufactured or processed within the United States that EPA has reviewed for toxicity under TSCA regulations (Inventory List).[93] TSCA §5 imposes different obligations depending upon whether the substance is an existing one (if it is on the Inventory List) or a new one (if it is not on the Inventory List).

#### 1. New Chemical Substance

A TSCA-defined chemical substance that is not on the Inventory List is a TSCA §5(a) new chemical substance.[94] The National Technical Information Service (NTIS) is the only official, regularly updated EPA source that catalogs the chemical substances that are on the Inventory List; it is not a free publication.[95] Even if one pays to view the NTIS Inventory List, it does not include TSCA-reviewed chemical substances that are confidential.[96]

If ZVI is on the Inventory List, does its listing also include its nanoscale version, nZVI? In January 2008, EPA stated that TSCA distinguishes each chemical substance based on its molecular identity, not on its particle size.[97] ZVI has historically been used for site cleanup in the United States,[98] so it is conceivable that it may already be on the Inventory List. If so, one might presume that EPA also considers that nZVI, its nano counterpart, is also on the Inventory List.[99]

Although EPA announced that it intends to continue to generally treat identical chemical substances with varying molecular sizes as the same chemical, it has carved out several exceptions.[100] EPA is required to give a processor, manufacturer, or importer of a TSCA chemical substance (submitter) fair notice of how it intends to treat nanoparticle-sized chemical substances. In an analogous context, an administrative law judge refused to grant EPA a summary judgment. The judge ruled that EPA's separate entries on the Inventory List for isotopes of compound A are not enough to put the submitter on sufficient notice that an isotope of compound B is a new chemical substance.[101]

If EPA subsequently determines that nZVI is a TSCA-defined new chemical substance distinct from ZVI, an nZVI manufacturer must first file a premanufacture notice (PMN).[102] EPA recommends that the submitter file a Bona Fide Intent to Manufacture or Import Notice to receive a written EPA determination of its Inventory List status.[103] This can be an important protection for the submitter. According to *In re E.I. DuPont de Nemours & Co.*,[104] the fact that a submitter unnecessarily filed a PMN does not cure the submitter's inaccurate information contained in the PMN. EPA can hold the submitter of a superfluous PMN liable for any of its PMN deficiencies.

In order to clarify ZVI's and nZVI's inventory status, this author contacted the EPA Office of Prevention, Pesticides, and Toxic Substances[105] Upon referral to Jim Alwood, this author learned that iron, including zero-valent iron, is already on the Inventory List.[106] Mr. Alwood confirmed that nZVI is neither on the NTIS new chemical substance Inventory List nor the confidential Inventory List.[107]

The only nanoparticles listed in the *Federal Register* that are on the nonconfidential Inventory List are different types

89. U.S. EPA, TSCA Inventory Status of Nanoscale Substances—General Approach 6 (Jan. 23, 2008) [hereinafter TSCA Inventory], *available at* http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf.
90. 7 U.S.C. §§136-136y, ELR Stat. FIFRA §§2-35.
91. *See id.*
92. TSCA §3(2)(A), 15 U.S.C. §2602(2)(A).
93. TSCA §8(b)(1), 15 U.S.C. §2607(b)(1).
94. TSCA §5(a)(1)(A), 15 U.S.C. §2604(a)(1)(A). *See also* 40 C.F.R. §720.22.
95. U.S. EPA, New Chemicals Program: What Is the TSCA Chemical Substance Inventory?, http://www.epa.gov/oppt/newchems/pubs/invntory.htm (last visited Mar. 17, 2010). For the first time, beginning March 15, 2010, EPA began offering the updated nonconfidential Inventory List online. *Id.* Prior to that date, it cost between $2,100.00 and $11,200.00 per year, depending on the number of full-time equivalent employees the subscribing organization has. National Technical Reports Library, IP Subscription Access Registration Form (Apr. 2009), http://www.ntis.gov/pdf/ntrl-form200904-fillable.pdf (last visited Mar. 11, 2010).
96. See 40 C.F.R. §720.25, for a discussion of confidential substances not on the Inventory List.
97. TSCA Inventory, *supra* note 89, at 6.
98. *See supra* notes 6-19 and accompanying text.
99. TSCA Inventory, *supra* note 89, at 5-7.
100. *Id.* See *infra* notes 111-24 and accompanying text, for a more in-depth discussion of EPA's intent, including reviewing nanotechnology on a case-by-case basis.
101. In re Concord Trading Corp., No. TSCA-94-H-19, 1997 WL 738014 (EPA July 24, 1997).
102. *See generally* 40 C.F.R. pt. 720 (2009).
103. U.S. EPA, New Chemicals Program: How Can I Formally Find Out if a Substance Is on the TSCA Inventory?, http://www.epa.gov/oppt/newchems/pubs/findsubs.htm (last visited Mar. 11, 2010); TSCA Inventory, *supra* note 89, at 7. 40 C.F.R. §§720.25 and 721.11 discuss this process.
104. No. TSCA-III-731, 1998 WL 220032 (EPA Mar. 30, 1998).
105. Telephone Conversation with Jim Alwood, Environmental Protection Specialist, U.S. EPA Chemical Control Division; Project Manager, EPA Nanoscale Materials Stewardship Program, Jan. 12, 2010.
106. Telephone Conversation and E-mail Communication with Jim Alwood, Environmental Protection Specialist, U.S. EPA Chemical Control Division; Project Manager, EPA Nanoscale Materials Stewardship Program, Jan. 12, 2010. Mr. Alwood is an Environmental Protection Specialist at EPA's Chemical Control Division. *See* 72 Fed. Reg. 38083 (July 12, 2007). He also serves as the Project Manager for EPA's Nanoscale Materials Stewardship Program and is on the advisory board of the International Council on Nanotechnology.
107. Telephone Conversation and E-mail Communication with Jim Alwood, *supra* note 106.

of CNTs.[108] CNTs differ from macroscale carbon particles by more than particle size.[109] In contrast, nZVI is physically distinct from ZVI only by its particle size. It is unlikely that EPA will determine that nZVI is a new chemical substance given EPA's January 2008 stance that particle size is insufficient under TSCA to distinguish the nanoscale version of an Inventory List chemical from its macroscale version. Alternatively, EPA may determine that nZVI is a TSCA significant new use (SNU) from the Inventory List chemical, ZVI.

### 2. SNU of a Substance on the Inventory List

Under §5, TSCA has the authority to review an SNU of a chemical on the Inventory List.[110] EPA considers a variety of factors to determine if a chemical substance (like nZVI) is an SNU of an existing chemical substance on its Inventory List (like ZVI).[111] These factors include changes in use that increase human or environmental exposure or changes in the type of that exposure considering the manufacture, process, distribution, and disposal of the target substance.[112] One could argue that nZVI may increase the amount or type of human or environmental exposure caused by ZVI.[113]

The *Code of Federal Regulations* lists SNU rules (SNURs) for 995 specific chemical substances that EPA determines have SNUs.[114] None of the 995 SNURs are for nZVI, ZVI, or any other iron-containing chemical substance. Their absence from the SNURs is significant because it indicates that nZVI is not currently an SNU chemical substance.[115] Thus, without new SNURs, EPA cannot legally require a current nZVI submitter to file an SNU notice.[116]

EPA is not likely to add all nanoscale versions, like nZVI, of its macroscale Inventory List chemicals, like ZVI, to its *Code of Federal Regulations* list of TSCA §5(a) SNURs. EPA indicated in February 2007 that it *may* review nanoscale versions of its macroscale Inventory List chemicals as SNUs; while in January 2008, EPA asserted that its policy *may not be* to do so.[117] EPA's January 2008 statement clarified that it will review each nanoscale substance submission that has a macroscale counterpart on a case-by-case basis to determine its inventory status.[118] EPA did not specify whether this case-by-case analysis will require an SNUR notice or a PMN.[119] Then in October and November 2008, EPA added two of those 995 SNURs for siloxane nanoparticles.[120] Thus, despite EPA's contradictory rhetoric, its actions indicate that it plans to review these nanoscale submissions on a case-by-case basis. nZVI is in the beginning stages of that review process. In January 2009, EPA revealed that their Office of Research and Development plans to test nZVI and six other nanomaterials to assess their environmental risks and benefits.[121]

EPA's intent in all of its waffling may be to provide itself some wiggle room to restrict the manufacture of a nanoscale chemical substance that EPA believes may be toxic to humans or to the environment. However, EPA's lack of clarity may do the opposite unless accompanied by additional SNURs. In General Electric Co. v. United States Environmental Protection Agency,[122] the court held that EPA must give fair notice to a regulated entity of EPA's regulatory interpretation, so that a reasonable submitter would understand what the Agency expects of it. The American Bar Association cautions, with regard to a similar TSCA nanotechnology issue:

> EPA is well aware that significant changes in existing policies (e.g., through interpretive rulemakings) generally require that the public be provided with prior notice and an opportunity for comment, as do substantive rulemakings.[123]

## *C. Notice Requirements*

### 1. SNUR Notice Versus PMN

The same TSCA §5(e) environmental and health-risk analysis applies to both §5(a) SNUR notices and PMNs. EPA uses the same form for an SNUR notice and a PMN. Thus, the distinction between a new and an existing TSCA chemical substance is less important than the threshold question of whether either a PMN or SNUR notice is required for a particular substance.[124] What is crucial in this case, as in other

108. EPA generally considers that CNTs are new chemicals substances; if a specific CNT is not on the Inventory List, it requires a PMN. 73 Fed. Reg. 64946-02 (Oct. 31, 2008). EPA's rationale is that CNTs, as well as carbon fullerenes, do not have non-nanoscale versions that are larger particles of the same thing. Unlike other nanoscale chemical substances, CNTs and carbon fullerenes are physically distinct from larger carbon particles other than just by their size. Thus, CNTs and carbon fullerenes have different molecular identities from other carbon particles. Their different molecular identities means that these nanoparticles are TSCA-defined different chemical substances that require PMNs. *See* TSCA Inventory, *supra* note 89, at 4-6.
109. TSCA Inventory, *supra* note 89, at 4-6.
110. TSCA §5(a), 15 U.S.C. §2604(a) (2007).
111. TSCA §5(a)(1)(B), (a)(2), 15 U.S.C. §2604(a)(1)(B), (a)(2). For the purposes of this discussion, this author is presuming that ZVI is on the Inventory List.
112. TSCA §5(a)(2), 15 U.S.C. §2604(a)(2).
113. *See supra* notes 44-87 and accompanying text.
114. *See* 40 C.F.R. pt. 721, Subpart E (2009).
115. 40 C.F.R. pt. 721, Subpart E, contains an extensive list of 995 significant new uses for specific chemical substances. No element or compound containing iron is on that list.
116. TSCA §5(a), 15 U.S.C. §2604(a). 40 C.F.R. §721.5 only requires manufacturers, importers, or processers of significant new uses for chemical substances listed in 40 C.F.R. pt. 721, Subpart E, to file an SNUR notice.
117. *See supra* notes 101-02 and accompanying text.
118. TSCA Inventory, *supra* note 89, at 2.
119. However, as noted in *In re Concord Trading Corp.*, *supra*, those actions are insufficient notice. *See supra* note 102 and accompanying text.
120. 40 C.F.R. §§721.10119 (tight fitting respirators or continuous flow hoods in workplace for siloxane-modified silica nanoparticles), 721.10120 (tight fitting respirators or continuous flow hoods in workplace for siloxane-modified alumina nanoparticles). EPA has also proposed SNURS for single-walled and multi-walled CNTs defining their SNUs as when those nanotubes are used without the workplace protections required by their TSCA §5(e) consent orders with EPA. The proposed SNURs require advance notice to EPA prior to manufacturing or processing. 74 Fed. Reg. 57430 (Nov. 6, 2009).
121. U.S. EPA, Nanoscale Materials Stewardship Program: Interim Report 29-30 (2009) [hereinafter NMSP], *available at* http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf.
122. 53 F.3d 1324, 1328-30, 25 ELR 20982 (D.C. Cir. 1995). This is consistent with 40 C.F.R. §721.5. *See supra* note 102 and accompanying text.
123. Am. Bar Ass'n, Regulation of Nanoscale Materials Under the Toxic Substances Control Act 12 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf.
124. *Id.* at 12. *See also* 40 C.F.R. §721.25. It states that the notice requirements for significant new uses of chemical substances are the same as for PMNs in Part 720 of the same C.F.R. chapter (except when Part 720 is inconsistent with Part 721).

cases involving nanomaterials, is to determine if EPA will require either of the TSCA notices for nZVI. As noted above, it is unclear, though unlikely, that EPA will determine that nZVI is a TSCA new chemical substance. The only certainty is that EPA does not currently consider either ZVI or nZVI to have an SNU because neither is the subject of an SNUR.

### 2. PMN Process

In the first part of the PMN[125] review, an EPA chemist decides if the submitter identified the chemical substance accurately in accordance with the Chemical Abstracts Service Inventory Expert Service nomenclature.[126] Once the submitter resolves any nomenclature issues, EPA determines if the submission is a "chemical substance," as defined by the statute. If it is not, the PMN process ends.[127] Similarly, if EPA concludes that a target TSCA chemical substance is already on the Inventory List,[128] the PMN review halts.[129] If the target substance is either not a TSCA chemical substance or is already on the Inventory List,[130] TSCA does not require a PMN (or SNUR notice) before the submitter manufactures, processes, or imports the chemical substance.

A TSCA-defined chemical substance that is not on the Inventory List is, by default, a new chemical substance.[131] Only at that point will the EPA chemist examine the PMN submitter's Chemistry Report for the EPA's health and environmental risk assessment.[132] The examiner compares the submitter's product testing data on physical and chemical properties; health, ecological and environmental effects; and monitoring from human and environmental exposures to scientific literature, past submissions of similar chemicals, and less polluting alternatives.[133]

Often, the submitter uncovers little human and environmental toxicity data to include in the PMN report. When confronted with a lack of data specific to the new chemical substance, the EPA scientist looks at toxicology data from previously tested substances that have analogous structures to the target substance.[134] This analysis will not work when applied to nanotechnology. Nanotechnology products, such as nZVI, have chemical structures that may be the same as their macroscale versions, such as ZVI. However, nanomaterials have distinct sizes, surface area to volume measurements, shapes, and dimensions that give them unique properties that distinguish them from their macro-sized counterparts that have identical chemical structures.[135]

Scientists know little about nZVI's toxicity, though most health and environmental concerns stem from its nanoscale-sized particles.[136] If EPA requires a PMN (if EPA determines that nZVI is a new chemical) or an SNUR notice (if EPA decides that nZVI is an SNU of ZVI), EPA has the power to limit or restrict nZVI's production and use. TSCA §5(e) gives EPA broad authority to regulate a TSCA chemical substance if EPA has insufficient information available to evaluate unreasonable risks of injury to the environment or to health.[137]

## *D. Information-Gathering and Enforcement*

EPA may not have been clearer about its intentions to regulate nanoscale chemical substances due to its inability to adequately define and assess any risks posed by nanoparticles such as nZVI. TSCA §§5, 6, and 8 provide EPA with broad authority to gather the information that the Agency needs to determine at what point the particle's size, concentration, and dimensions create an unreasonable risk of health or environmental injury.[138] In order to require compliance to collect this information, EPA would have to adequately define what constitutes nanoparticles, the very information it seeks to collect.[139] This is, at best, a Herculean task.[140]

### 1. Section 5

If a PMN or SNUR notice is required for nZVI or any other TSCA chemical substance under TSCA §5(a), EPA may determine that it has insufficient information "to permit a reasoned evaluation" of the target substance's health and environmental effects.[141] The lack of this information must either "present an unreasonable risk of injury to health or the environment" at some point in the life cycle of the chemical

125. References in this part to PMN also refer to SNUR notice, since PMN and SNUR notice review processes are the same.
126. U.S. EPA, Publ'n No. EPA 744-R-97-003, Chemistry Assistance Manual for Premanufacture Notification Submitters 8, 15 (1997) [hereinafter Chemistry Assistance Manual].
127. *Id.* at 15-16.
128. This assumes that the target chemical substance is not an SNU of a substance on the Inventory List. In order for the target chemical substance to be an SNU, there must be an SNUR that requires the submitter of the target chemical substance to submit an SNU notice. *See supra* notes 115-17 and accompanying text.
129. Chemistry Assistance Manual, *supra* note 126, at 15-16.
130. This again presumes that it is not an SNU of a substance on the Inventory List.
131. *See supra* notes 95-110 and accompanying text. This only applies to a PMN, not an SNUR notice.
132. Chemistry Assistance Manual, *supra* note 126, at 16.
133. *Id.* at 20-21, 25. TSCA does not require the submitter to provide testing data if the submitter properly identifies the data's previous nonconfidential submission. 40 C.F.R. §720.50 (2009). *See also* TSCA §5(b), 15 U.S.C. §2604(b) (2007).
134. Chemistry Assistance Manual, *supra* note 126, at 27-28.
135. *See supra* note 11.
136. *See supra* notes 44-87 and accompanying text.
137. EPA exercised that authority when it entered into a consent order with Thomas Swan & Co. Ltd. during its CNT PMN process. The order required the manufacturer to conduct a 90-day CNT inhalation toxicity study in rats. Press Release, Thomas Swan & Co. Ltd., Swan Pioneers Nanomaterial Controls With EPA (Sept. 15, 2009), *available at* http://www.thomas-swan.co.uk/ASP/News_Events/News_Events.asp?Type=News&ID=195&Arc=Yes&DLT=Swan%20pioneers%20nanomaterial%20controls%20with%20EPA; *see also* U.S. EPA, Confidential Consent Order and Determinations Supporting Consent Order (PMN No. P-08-0177), *available at* http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf.
138. EPA is in the process of developing a proposed rule under TSCA §4 that would require manufacturers or processors of nanomaterials to do health and environmental testing. U.S. EPA, Existing Chemicals: Enhancing EPA's Chemical Management Program, http://www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html (last visited Feb. 5, 2010).
139. In its SNURs of generic siloxane-modified silica nanoparticles and siloxane-modified alumina nanoparticles, EPA did not define at which size or dimensions those particles become nanoparticles other than that the SNUR notice requirements take effect when concentrations reach 1%. Those nanoparticle SNURs may be difficult to enforce.
140. *See supra* note 11.
141. TSCA §5(e)(1)(A)(i), 15 U.S.C. §2604(e)(1)(A)(i) (2007).

substance, or present a risk of significant quantities or human exposure of the substance.[142]

If EPA makes that determination, TSCA has the authority under §5(e) to regulate the target substance if it is produced in "substantial quantities" by volume. This measurement may be a barrier to regulating nanotechnology since it is inherently low volume.[143] This health and environmental risk authority extends throughout the life of the target substance, from manufacture through disposal.[144] EPA can issue an order to ban or limit the target substance throughout the substance's life cycle.[145] EPA's authority to ban or limit the nZVI and ZVI gives EPA the authority to demand health and environmental information and testing in order for their submitters to avoid those consequences.

### 2. Section 6

EPA also has the authority to gather quality control information if the manner of manufacturing or processing of a chemical substance, including nZVI and ZVI, unintentionally causes or will cause unreasonable health or environmental risks of injury.[146] However, the requirements for EPA to promulgate a rule under TSCA §6(a) are quite strict. In 1991, the U.S. Court of Appeals for the Fifth Circuit ruled that §6(a) limits EPA's rulemaking authority "to the extent necessary to protect adequately against such risk *using the least burdensome requirements*."[147] This makes it almost impossible for EPA to pass new regulations.

TSCA §6(b) authorizes EPA to order the submitter to file its quality control procedures for EPA assessment.[148] EPA can order an nZVI or ZVI submitting company to remedy the quality control deficiencies, to give notice to the public and to others who have exposure risks, and to issue an nZVI and ZVI product recall.[149] Even though there is no TSCA §6(a) limitation for EPA to use "the least burdensome requirements" for a §6(b)(1) non-rulemaking function, EPA has never successfully done so.

### 3. Section 8

#### *a. Section 8(a)*

TSCA §8(a) requires EPA to create regulations that compel chemical substance submitters to maintain records and to file EPA reports.[150] EPA has broad authority to reasonably require those reports from all who propose to or who already manufacture and process chemical substances like nZVI and ZVI. EPA's §8(a) information-gathering authority exempts small manufacturers and processors,[151] and small amounts of chemical substances solely for scientific experimentation, analysis for research, or analysis for product development purposes.[152] However, TSCA clarifies that EPA still has permissive authority to regulate small manufacturers' and processors' information disclosures under §§4, 5(b)(4), or 6.[153]

Therefore, even though the volume of a nanoscale substance like nZVI may be small, EPA still must require recordkeeping reports if the nanosubstance is not produced or processed by an EPA-defined small manufacturer or processor for one of the above scientific or research purposes.[154] Under §8(a), EPA exercises this authority without showing any §5(e) propensity for, or §6(b) lack of data, regarding health or environmental risk. Furthermore, EPA is required to collect this information, so EPA's authority is less subject to legal challenges than its permissive authority in the prior two TSCA sections.

EPA is in the process of exercising its information-gathering authority by developing several proposed rules. Under §4, EPA plans to require nanotechnology manufacturers to conduct health and environmental testing.[155] Under §8(a), EPA also intends to require those companies to report the results of that testing to EPA, along with additional information on nanoscale "existing uses, production volumes, specific physical properties, chemical and structural characteristics, methods of manufacture and processing, [and] exposure and release information. . . ."[156]

#### *b. Section 8(c)*

EPA must require any manufacturer, processor, or distributor in commerce of a chemical substance, such as nZVI or ZVI, to maintain records of significant health or environmental adverse reactions allegedly caused by the substance. For 30 years after the first allegation, the manufacturer, processor, or distributor must collect and maintain records on adverse reactions to its employees' health. Records for nonsignificant adverse reactions need only be maintained for five years. These allegations include all reports of adverse reactions emanating from any source. EPA has the permissive authority to request that manufacturers, processors, and distributors submit those records to EPA.[157]

#### *c. Sections 8(d) and 8(e)*

Even without §8(c) allegations of chemical substance-caused health or environmental adverse reactions, EPA has mandatory authority to require submitters to file a list of health and safety studies.[158] These are studies that the submitter has ini-

142. TSCA §5(e)(1)(A)(ii), 15 U.S.C. §2604(e)(1)(A)(ii).
143. TSCA §5(e)(1)(A), 15 U.S.C. §2604(e)(1)(A).
144. TSCA §5(e)(1)(A)(ii), 15 U.S.C. §2604(e)(1)(A)(ii).
145. TSCA §5(e)(1)(A), 15 U.S.C. §2604(e)(1)(A).
146. TSCA §6(b), 15 U.S.C. §2605(b).
147. Corrosion Proof Fittings v. U.S. Envtl. Prot. Agency, 947 F.2d 1201, 1215, 22 ELR 20304 (5th Cir. 1991) (emphasis added).
148. TSCA §6(b)(1), 15 U.S.C. §2605(b)(1).
149. TSCA §6(b)(2), 15 U.S.C. §2605(b)(2).
150. See TSCA §8(a)(2), 15 U.S.C. §2607(a)(2), for a list of the records and reporting that EPA may require under TSCA §8 (a)(1), 15 U.S.C. §2607(a)(1).
151. TSCA §8(a)(1)(A), 15 U.S.C. §2607(a)(1)(A).
152. TSCA §8(a)(1)(B)(ii), 15 U.S.C. §2607(a)(1)(B)(ii).
153. TSCA §8(a)(3), 15 U.S.C. §2607(a)(3).
154. TSCA §8(a)(3)(A), 15 U.S.C. §2607(a)(3)(A).
155. U.S. EPA, *supra* note 137. *See supra* note 145.
156. U.S. EPA, *supra* note 137; NMSP, *supra* note 121, at 28.
157. TSCA §8(c), 15 U.S.C. §2607(c).
158. TSCA §8(d), 15 U.S.C. §2607(d); 40 C.F.R. §716.30(a).

tiated that are either completed or that are ongoing.[159] They also include any known or reasonably ascertained health and safety studies of nZVI, ZVI, or other chemical substances to EPA.[160] Under §8(e), the manufacturer, processor, or distributor of a TSCA substance who obtains any reasonable information of the substance's risk of substantial health or environmental injury has an independent obligation to transmit the information to EPA.[161] However, those studies are not "known" to the submitter unless the person that the submitter assigns to keep that information has a record of that information where such information is usually kept.[162] EPA has no §8(d) authority to require submitting companies to do any health and safety studies, so its mandatory authority is limited to studies in which the submitter has chosen to participate. Unless EPA determines that the submission of a list of such studies is sufficient,[163] the entity must send a copy of the actual studies.[164]

## IV. Sustainability Recommendations

The recommendations for legislative changes, below, will fulfill a valid sustainability goal to protect potable water for future generations. EPA should proceed with its nZVI research while it develops proposed rules under TSCA §§4 and 8(a) to increase nanotechnology information-gathering capabilities.[165] Congress should amend the following TSCA sections to clarify EPA's regulatory authority, so that the statute better addresses the unique challenges presented by nano-sized particles like nZVI:

- §3(2)(A)—once EPA garners enough nanotechnology information, below, redefine a chemical substance other than by its "particular molecular identity" to include nano-chemical substances;[166]
- §8(a)(2)—include data collection on particle size, including updates; give EPA authority to establish standards for how to measure particle size, so that the information EPA gathers is useful;[167]
- §6(a)—to give EPA the tools to enact new regulations requiring mandatory nanotechnology information-reporting, so that EPA can create nanotechnology-specific TSCA regulations.[168]

When Congress has amended §6(a), EPA should exercise its authority to enact regulations requiring each new PMN and SNUR notice submitter to file with EPA:

- Data on particle size, surface area to volume measurements, concentration, shape, and dimensions for each batch of a chemical substance;[169]
- Standard methods for establishing average sample batches to determine particle characteristics;[170] and
- Worker health and safety data that specifies the particle size categories to which the worker has been exposed.[171]

While EPA gathers and processes the above information, EPA should evaluate its existing nZVI information to balance its benefits against its known risks. Until EPA can adequately define distinctions between nZVI and ZVI, EPA should require the same restrictions for both products:

- Collect the same data, above, as for new PMNs and SNUR notices;[172]
- Ban or closely regulate use of nZVI and ZVI to dechlorinate more complex polychlorinated hydrocarbons that produce toxic byproducts, biphenyl and benzene;[173]
- Ban nZVI and ZVI dispersion enhancements to avoid having the products migrate beyond the contamination site where unused nZVI may potentially seep into drinking water aquifers or wells, or into surface water;[174]
- Mandate safe handling practices to minimize ingestion, inhalation, and skin contact:[175]
  - Encase manufacturing equipment to protect against explosion and fire hazards;[176]
  - Install fume hood ventilation in the manufacturing plant areas where workers handle nZVI's precursor, iron pentacarbonyl;[177]
  - To avoid explosions and human contact with nZVI, erect a protective anaerobic enclosure around manufacturing and packaging processes;[178]
  - Train workers[179] and wear protective clothing to minimize field risks; and

159. TSCA §8(d), 15 U.S.C. §2607(d); 40 C.F.R. §716.30(a).
160. TSCA §8(d), 15 U.S.C. §2607(d).
161. TSCA §8(e), 15 U.S.C. §2607(e).
162. 40 C.F.R. §§716.25, .30. The recordkeeper does not need to search for records dated earlier than 1977. §716.25.
163. TSCA §8(d)(1), 15 U.S.C. §2607(d)(1).
164. TSCA §8(d)(2), 15 U.S.C. §2607(d)(2).
165. *See supra* notes 122, 145, 162-63 and accompanying text.
166. *See supra* note 89 and accompanying text.
167. Dr. J. Clarence Davies, from the Woodrow Wilson International Center, testified at a recent hearing to encourage TSCA amendments that would give EPA better flexibility to address nanotechnology. No new legislation is imminent. *See Testimony of J. Clarence Davies Before the H. Subcomm. on Commerce, Trade, & Consumer Prot. of the Comm. on Energy & Commerce*, 111th Cong. (2009), *available at* http://energycommerce.house.gov/Press_111/20090226/testimony_davies.pdf.
168. *See supra* note 153-54 and accompanying text.
169. *See* TSCA §5(e), 15 U.S.C. §2604(e) (regarding insufficient health and environmental information).
170. *Id.*
171. *Id.*
172. *See* TSCA §5(e), 15 U.S.C. §2604(e), and TSCA §5(a), 15 U.S.C. §2604(a), for health and environmental effects in PMNs and SNUR notices.
173. TSCA §5(e), 15 U.S.C. §2604(e). This is especially true if a BNP is more effective for this use. *See supra* notes 49-51 and accompanying text. EPA may be able to avoid having to distinguish nZVI from ZVI if ZVI is not effective for dechlorinating these more complex polychlorinated hydrocarbons.
174. TSCA §5(e), 15 U.S.C. §2604(e); TSCA §8(a), 15 U.S.C. §2607(a).
175. TSCA §5(e), 15 U.S.C. §2604(e); TSCA §8(a), 15 U.S.C. §2607(a).
176. Shatkin, *supra* note 13, at 110.
177. *Id.* at 111.
178. *Id.*
179. *Id.*

- Require nZVI and ZVI product users to periodically test, measure, and report on these particles that users detect in water from downstream water treatment plants and from those plants' filtered biosolids.[180]

## V. Conclusion

nZVI shows great promise for its ability to efficiently decontaminate aquifers. Untreated with dispersion enhancers, it naturally dissolves or settles to the bottom of an aquifer without much risk of migrating beyond its treatment zone. Yet, without EPA oversight, the same technology that enhances decontamination range provides companies with short-term cost incentives to ignore increased nZVI safety risks. These include nZVI dispersion enhancements that risk increasing nZVI dispersal at the expense of contaminating crop fertilizers and drinking water with unused nZVI. Although most nZVI site remediation may be benign, nZVI dechlorination of complex hydrocarbons causes some toxic byproducts. All nZVI use poses the potential for ingested, dermal, and inhaled contact exposure risks for humans, particularly for workers who process or handle nZVI. EPA needs to have the flexibility to gather toxicology data and to demand additional testing, when necessary, to determine nZVI's risk potential in order to consider all of these possible costs.

Without a working definition for what constitutes a nanoparticle, EPA will probably only be successful in regulating nanoparticle shapes, as with CNTs, or a particular type of nanoparticle use. If EPA aggressively pursues its TSCA information-gathering authority to collect data on the relationships between health and environmental effects and particle size, EPA may be in a better position to define a nanoparticle in terms of its size, surface area to volume measurement, shape, concentration, and dimension. Congress can facilitate this effort by amending TSCA §8(a) to grant EPA specific authority to request this particle information, avoiding time-consuming legal challenges to EPA's authority.

Once EPA has a regulation in place defining nanoparticles, EPA will have sufficient authority to begin to regulate nZVI under TSCA, if necessary. Depending on the information that EPA's Office of Research and Development gathers during its current or subsequent nZVI inquiries, EPA can either halt its nZVI research, or review nZVI as an SNU while mandating SNUR restrictions on its use. Despite nZVI's promise for groundwater detoxification, hazards inherent with its use will probably necessitate further regulation. Otherwise, short-sighted profit interests, coupled with inexpert handling of nZVI, may burden future generations with a different type of toxic waste to clean up, nZVI particles.

180. TSCA §5(e), 15 U.S.C. §2604(e); TSCA §8(a), 15 U.S.C. §2607(a). *See supra* notes 139-41, 145-49 and accompanying text. EPA is in the process of developing a proposed rule under §8(a) that would require companies that manufacture or process nanomaterials to provide EPA with reports on their uses, volumes, characteristics, production methods; and information on health, environmental, and exposure effects. U.S. EPA, Existing Chemicals: Enhancing EPA's Chemical Management Program, http://www.epa.gov/oppt/existingchemicals/pubs/Existing.Chem.Fact.sheet.pdf (last visited Mar. 17, 2010).