

# Beyond Chemicals: The Lessons that Toxic Substance Regulatory Reform Can Learn from Nanotechnology

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## INTRODUCTION

Nanotechnology is a revolution in applied science. By manipulating molecules on the scale of billionths-of-a-meter, scientists have created materials that exhibit “almost magical feats of conductivity, reactivity, and optical sensitivity, among others.”<sup>1</sup> Nanotechnology also has the potential to drive an economic revolution. Retailers already sell over 300 products that incorporate nanotechnology,<sup>2</sup> and according to one estimate, nanotechnology will be a trillion-dollar-a-year industry by 2015.<sup>3</sup> In congressional testimony, Ray Kurzweil, Chairman and Chief Executive Officer of Kurzweil Technologies, asserted that nanotechnology would result in the pervasive miniaturization of all human industry by the middle of the twenty-first century.<sup>4</sup> Part I of this Article describes the emerging field of nanotechnology and its applications.

The tremendous economic benefit of nanotechnology, however, will come at a price. Nanotechnology applications present novel, serious, and possibly irreversible threats to human health and the environment. Recently, the field of nanotoxicology has been developed to characterize and quantify these threats.<sup>5</sup> Part II of this Article discusses the early research demonstrating health and environmental dangers associated with nanotechnology.

Because of nanotechnology’s mixed blessing, the United States government must select a strategy to maximize nanotechnology’s economic potential while containing its health and environmental dangers. Part III of this Article argues that the best strategy is to incorporate nanotechnology regulation into a general-purpose toxic substances statute, such as by amending the Toxic Substances Control Act (TSCA), which is intended to regulate all chemical substances at the point of manufacture.<sup>6</sup>

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1. Ernie Hood, *Nanotechnology: Looking as We Leap*, 112 ENVTL. HEALTH PERSP. A740, A741 (2004).

2. SCI. POLICY COUNCIL, ENVTL. PROT. AGENCY, NANOTECHNOLOGY WHITE PAPER 4 (2007), available at <http://epa.gov/ncer/nano/publications/whitepaper12022005.pdf>. Consumer products that contain nanotechnology include socks, cosmetics, and toothpaste. *Id.* at 11.

3. M.C. Roco, Overview of the National Nanotechnology Initiative (Sept. 10, 2003), [http://www.nsf.gov/crssprgm/nano/reports/nni\\_overview\\_rdii.pdf](http://www.nsf.gov/crssprgm/nano/reports/nni_overview_rdii.pdf).

4. *The Societal Implications of Nanotechnology: Hearing Before the H. Comm. on Science*, 108th Cong. 58 (2003) (statement of Ray Kurzweil), available at [http://commdocs.house.gov/committees/science/hsy86340.000/hsy86340\\_of.htm](http://commdocs.house.gov/committees/science/hsy86340.000/hsy86340_of.htm) [hereinafter Statement of Kurzweil].

5. See, e.g., Günter Oberdörster, Eva Oberdörster & Jan Oberdörster, *Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles*, 113 ENVTL. HEALTH PERSP. 823 (2005), available at <http://www.ehponline.org/members/2005/7339/7339.pdf>.

6. Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601–2692 (2006).

Part IV of this Article provides background on toxic substances law, and Part V proposes changes to United States toxic substances law to address nanotechnology's threat. Two laws figure heavily into this discussion: TSCA and the European Union directive, known as Registration, Evaluation, and Authorisation of Chemicals (REACH).<sup>7</sup> REACH is modeled to a large degree on TSCA, but addresses many of TSCA's perceived shortcomings. Congress is considering revising TSCA based on REACH, which would essentially create a third-generation toxic substances statute.<sup>8</sup> Part V explains that proposed amendments to TSCA based on REACH do an incomplete job of addressing the threats posed by nanotechnology and makes suggestions.

#### I. NANOTECHNOLOGY IS A HETEROGENEOUS GROUP OF TECHNOLOGIES

The United States Environmental Protection Agency (EPA) defines nanotechnology as:

research and technology development at the atomic, molecular, or macromolecular levels using a length scale of approximately one to one hundred nanometers [i.e., billionths of a meter] in any dimension; the creation and use of structures, devices and systems that have novel properties and functions because of their small size; and the ability to control or manipulate matter on an atomic scale.<sup>9</sup>

This definition covers both nanomaterials, which are materials with at least one dimension on a scale of nanometers, and nanotechnology processes, which describes the direct manipulation of atoms, molecules, or nanomaterials for human purposes.<sup>10</sup>

Because the EPA's definition is so broad, the reader may find some concrete examples of nanotechnology to be helpful. In 2007, the EPA Nanotechnology White Paper described four existing categories of nanotechnology (all of which are nanomaterials):

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7. Council Regulation No. 1907/2006, Registration, Evaluation, and Authorisation of Chemicals (REACH) (EC), *available at* <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1907:EN:NOT>.

8. *See infra* Part IV.C.

9. SCI. POLICY COUNCIL, *supra* note 2, at 5. Glenn Harlan Reynolds defines nanotechnology as "the science and technology of building from the bottom up—one atom or molecule at a time." Glenn Harlan Reynolds, *Nanotechnology and Regulatory Policy: Three Futures*, 17 HARV. J.L. & TECH. 179, 181 (2003). Scott Segal has described nanotechnology as being comprised of machines less than 100 nanometers in size. Scott H. Segal, *Environmental Regulation of Nanotechnology: Avoiding Big Mistakes for Small Machines*, 1 NANOTECHNOLOGY L. & BUS. 290, 291 (2004). Other commentators describe nanotechnology as a "heterogeneous family of technologies" without much further elaboration. *E.g.*, Diana M. Bowman & Graeme A. Hodge, *A Small Matter of Regulation: An International Review of Nanotechnology Regulation*, 8 COLUM. SCI. & TECH. L. REV. 1, 2 (2007).

10. *See* Nakissa Sadrieh & Parvaneh Espandiari, *Nanotechnology and the FDA: What Are the Scientific and Regulatory Considerations for Products Containing Nanomaterials?*, 3 NANOTECHNOLOGY L. & BUS. 339, 342 (2006) (distinguishing nanomaterials and nanotechnology processes).

1. Carbon-based materials including “hollow spheres, ellipsoids, and tubes.”<sup>11</sup> Carbon nanotubes can have enormous tensile strength and have been used to reinforce building materials.<sup>12</sup> Recently, scientists created a carbon nanotube structure that absorbed almost all visible light, making it the world’s “blackest” material.<sup>13</sup> The optical properties of nanotubes show promise in solar cell applications.<sup>14</sup>
2. Metal-based materials including quantum dots, which are tiny, closely-packed semiconductor crystals.<sup>15</sup> They show promise for use as “qubits” for quantum information processing in the next generation of computers.<sup>16</sup>
3. Dendrimers, which are tiny, branched structures.<sup>17</sup> They show promise as vectors for drug delivery. Recently, scientists have developed “nanobees” which deliver melittin, a toxin present in bee stings, directly to cancer cells within the human body.<sup>18</sup>
4. Composites of nanomaterials and conventional materials. By embedding nanotechnology in materials, researchers create new materials with enhanced physical or chemical properties.<sup>19</sup> One field involving composites is “nanobiotechnology,” which involves combining nanomaterials with naturally occurring molecules, including DNA.<sup>20</sup> These composites may be useful in treating disease through somatic gene therapy.<sup>21</sup>

The EPA predicts that scientists will rapidly create new categories of nanotechnologies. Future nanotechnology applications may include the following:

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11. SCI. POLICY COUNCIL, *supra* note 2, at 7.

12. B.G. Demczyk, Y.M. Wang, J. Cumings, M. Hetman, W. Han, A. Zettl & R.O. Ritchie, *Direct Mechanical Measurement of the Tensile Strength and Elastic Modulus of Multiwalled Carbon Nanotubes*, 334 MATERIALS SCI. & ENGINEERING APPLICATIONS 173, 173 (2002).

13. Helen Briggs, ‘Darkest Ever’ Material Created, BBC NEWS, Jan. 16, 2008, <http://news.bbc.co.uk/2/hi/science/nature/7190107.stm>.

14. *Id.*

15. SCI. POLICY COUNCIL, *supra* note 2, at 8.

16. See Daniel Loss & David P. DiVincenzo, *Quantum Computation with Quantum Dots*, 57 PHYSICAL REV. A 120, 120 (1998), available at [http://hep.princeton.edu/~mcdonald/examples/QM/loss\\_pra\\_57\\_120\\_98.pdf](http://hep.princeton.edu/~mcdonald/examples/QM/loss_pra_57_120_98.pdf).

17. SCI. POLICY COUNCIL, *supra* note 2, at 9.

18. *Tumors Feel the Deadly Sting of Nanobees*, SCI. DAILY, Aug. 10, 2009, <http://www.sciencedaily.com/releases/2009/08/090810174226.htm>.

19. SCI. POLICY COUNCIL, *supra* note 2, at 10.

20. Kevin Rollins, *Nanobiotechnology Regulation: A Proposal for Self-Regulation with Limited Oversight*, 6 NANOTECHNOLOGY L. & BUS. 221, 221 (2009).

21. *Id.* at 223.

1. Molecular assemblers. A molecular assembler is a device used to assemble bulk-scale materials molecule-by-molecule (that is, through a nanotechnology process).<sup>22</sup> In the future, molecular assembly may allow the assembly of large goods such as cars, airplanes and buildings molecule-by-molecule and without the assistance of human workers.<sup>23</sup>
2. Nanorobotics. Researchers are attempting to engineer robots on a nanometer scale.<sup>24</sup> These robots may be useful in performing surgery within the human body.<sup>25</sup>
3. Imaging technologies. Nanotechnology may lead to the next generation of television. Researchers are currently attempting to create holograms by manipulating molecules in the gas phase.<sup>26</sup>

## II. THE HEALTH AND ENVIRONMENTAL DANGERS OF NANOTECHNOLOGY

“Nanotoxicology” is defined as the “science of engineered nanodevices and nanostructures that deals with their effects in living organisms.”<sup>27</sup> Because nanotoxicology is a new field, detailed health and safety data for many nanotechnology applications is nonexistent.<sup>28</sup> However, existing nanotoxicology research suggests at least three themes that tend to make nanotechnology applications more dangerous than ordinary materials.

First, because of their small size, nanotechnology applications can pass through the protective membranes of the human body, including the cell membranes of the skin, gastrointestinal tract, and lungs.<sup>29</sup> Nanomaterials have even been shown to cross the blood/brain barrier in rats, which is regarded as the body’s tightest junction.<sup>30</sup> Once nanomaterials penetrate the body’s outer defenses, they can migrate to the blood stream or lymph system, circulate throughout the human body, and deposit in organs, tissues, and cells, where they bioaccumulate.<sup>31</sup>

Second, nanotechnology applications have higher chemical activity than ordinary materials. This higher activity is due to the fact that small objects (such as

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22. See Reynolds, *supra* note 9, at 185.

23. See *id.* at 186.

24. See SCI. POLICY COUNCIL, *supra* note 2, at 12.

25. Oberdörster et al., *supra* note 5, at 824 (discussing the use of nanorobots for targeted drug delivery).

26. Christopher R. Moon, Lalia S. Mattos, Brian K. Foster, Gabriel Zeltzer & Hari C. Manoharan, *Quantum Holographic Encoding in a Two-Dimensional Electron Gas*, 4 NATURE NANOTECHNOLOGY 167 (2009).

27. Oberdörster et al., *supra* note 5, at 824.

28. See, e.g., *id.* at 828.

29. *Id.* at 829–35 (summarizing research on how nanoparticles infiltrate and circulate through the body).

30. G. Oberdörster, Z. Sharp, V. Atudorei, A. Elder, R. Gelein, W. Kreyling & C. Cox, *Translocation of Inhaled Ultrafine Particles to the Brain*, 16 INHALATION TOXICOLOGY 437, 441 (2004) (showing translocation of nanoparticles into the brains of rats).

31. Oberdörster et al., *supra* note 5, at 829.

nanomaterials) have much higher surface area per unit volume than large objects (such as conventional materials).<sup>32</sup> Because chemical reactions usually occur at exposed surfaces, nanomaterials are much more chemically reactive, and thus more toxic, than ordinary materials.<sup>33</sup> For example, as a result of its high surface area, inhaled nanoscale titanium dioxide, which is used in sunscreens, has been shown to generate a greater inflammatory response than ordinary titanium dioxide.<sup>34</sup>

Third, nanotechnology applications behave in unpredictable (even “magical”) ways because the laws of quantum mechanics, as opposed to Newtonian physics, become increasingly important with diminishing size.<sup>35</sup> As a result, nanomaterials are toxic by different mechanisms than their bulk-scale counterparts. For example, a study found that nanoscale iron oxide was extremely toxic by an unknown mechanism.<sup>36</sup> In summary, nanomaterials may infiltrate the body in higher-than-expected numbers, reach unexpected parts of the body, bioaccumulate throughout the body, be more toxic than expected, and cause toxic effects of a completely different character than those associated with ordinary substances of the same chemical identity.

Future nanotechnology applications also will present other dangers. Currently, toxicological data only exists for “first generation” nanotechnology applications, which generally consist of small particles.<sup>37</sup> The EPA predicts that by 2015 it may be possible to design nanosized robots.<sup>38</sup> Eric Drexler has expressed concern that uncontrolled self-replication of nanorobots could result in uncontrolled molecular nanotechnology chewing the world down to “grey goo.”<sup>39</sup> Of course, no one knows if this could actually happen. However, the “grey goo” hypothetical does illustrate that higher-generation nanotechnologies will present novel risks.

### III. THE CASE FOR AMENDING TSCA TO REGULATE NANOTECHNOLOGY

Several commentators have argued that Congress should pass a nanotechnology-specific law.<sup>40</sup> This Part argues that nanotechnology should be regulated under a general-purpose toxic substances law, such as TSCA, for two reasons: first, because the subject matter of a “nanotechnology” statute may be difficult or impossible to define;

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32. *Id.* at 825 tbl.2 (illustrating the relationship between diameter and surface area).

33. *Id.* at 823.

34. *Id.* at 826.

35. See SCI. POLICY COUNCIL, *supra* note 2, at 13.

36. Tobias J. Brunner, Peter Wick, Pius Manser, Philipp Spohn, Robert N. Grass, Ludwig K. Limbach, Arie Bruinink & Wendelin J. Stark, *In Vitro Cytotoxicity of Oxide Nanoparticles: Comparison to Asbestos, Silica, and the Effect of Particle Solubility*, 40 ENVTL. SCI. & TECH. 4374, 4379 (2006).

37. See SCI. POLICY COUNCIL, *supra* note 2, at 12–13 (explaining the need for the EPA to have the flexibility to adjust to changing generations of nanotechnology).

38. *Id.* at 13.

39. K. ERIC DREXLER, *ENGINES OF CREATION* 171–90 (1986).

40. See, e.g., J. CLARENCE DAVIES, *MANAGING THE EFFECTS OF NANOTECHNOLOGY* 10 (2006), available at [http://www.wilsoncenter.org/index.cfm?fuseaction=news.item&news\\_id=165552](http://www.wilsoncenter.org/index.cfm?fuseaction=news.item&news_id=165552) (proposing a nanotechnology-specific law); Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 391–407 (2007) (proposing a new law requiring that manufacturers of certain nanotechnologies post environmental bonds).

and second, because passing a law to regulate nanotechnology alone might leave the EPA unable to regulate future technologies.

*A. The Trouble with Defining Nanotechnology*

Nanotechnology has proven difficult to define for regulatory purposes.<sup>41</sup> As discussed, the EPA's definition of nanotechnology is so broad that it fails to communicate a concrete definition of what nanotechnology is.<sup>42</sup> In addition, it contains ambiguities. For example, are naturally occurring structures, such as pollen or the scales on butterfly wings considered nanotechnology? What about nanosized structures that are covered by another scientific discipline, such as peptides (biotechnology) or tiny transistors (computer science)?

Commentators have advanced many definitions of nanotechnology.<sup>43</sup> But these definitions are all problematic because they are either too narrow to cover the full range of what is considered nanotechnology or too broad to concretely convey what nanotechnology is.<sup>44</sup> No one yet has defined nanotechnology in a way that is both broad and specific.

However, defining the precise bounds of "nanotechnology" would not be necessary if nanotechnology regulation was incorporated into a broader toxic substances statute, such as TSCA. Part V of this Article argues that Congress should amend TSCA to allow the EPA to regulate all novel materials as unique substances, without requiring the EPA to make the finding that the materials are a form of nanotechnology. As a result, this approach completely avoids the thorny issue of defining nanotechnology.

*B. Limiting a Statute Only to Nanotechnology Would Fail to Protect Society Against Future Technologies*

Passing environmental reform is a politically expensive proposition. Congress has not passed a significant new environmental law since the environmental decade from 1970 to 1980.<sup>45</sup> Thus, to adequately protect the public, Congress should pass toxic substances reform that is flexible enough to regulate future technologies. A

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41. See DAVIES, *supra* note 40, at 8 ("The answer to the definitional question—whether regulators and those regulated will be able to make a clear demarcation between what is and what isn't considered [nanotechnology]—will depend on the details of the definition and the technical capability for applying it.").

42. See *supra* Part I.

43. See *supra* note 9.

44. For example, Scott Segal defines nanotechnology as machines that are less than 100 nanometers in size. Segal, *supra* note 9, at 291. This definition is too narrow because it ignores currently existing nanotechnology applications such as nanocomposites as well as potential future nanotechnologies such as molecule-by-molecule assemblers. See *supra* Part I. By contrast, other commentators describe nanotechnology as a "heterogeneous family of technologies" without further elaboration. Bowman & Hodge, *supra* note 9, at 2. Such a definition does not convey any definite idea of what nanotechnology is.

45. See John S. Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 13, 72 (2002).

nanotechnology-specific law would not provide protection against future regulatory gaps.

For example, imagine that scientists develop an economically promising but dangerous technology called “xenotechnology.” Scientists agree that xenotechnology is not nanotechnology, but it has characteristics that make it difficult to regulate under existing toxic substances law. In this case, a nanotechnology-specific law would not be adequate to protect society from xenotechnology. Part V of this Article proposes reforms to general toxic substances law that are adequate to deal with future technologies.

#### IV. FROM TSCA TO REACH AND BACK AGAIN: RECENT DEVELOPMENTS IN TOXIC SUBSTANCES LAW

This Part provides background on current toxic substances law. In particular, it describes the complicated relationship between TSCA and the European Union directive known as REACH.

##### A. TSCA and Its Discontents

TSCA is the most important toxic substances law in the United States because it regulates chemicals at the point of manufacture.<sup>46</sup> The core of TSCA is its section 5 requirement that manufacturers of a chemical substance submit a pre-manufacture notice (PMN) to the EPA ninety days before producing a “new chemical substance.”<sup>47</sup> If the EPA objects to the manufacture of the substance, section 6 of TSCA gives the EPA the power to issue a rule preventing or limiting the manufacture.<sup>48</sup> TSCA also gives the EPA the power to limit the distribution or use of a chemical substance at any point in the chain of commerce, require the use of warnings on the packaging of the chemical substance,<sup>49</sup> or require manufacturers of a new or existing chemical to perform testing to generate health or environmental data.<sup>50</sup> In summary, TSCA would seem to grant the EPA far-reaching powers to regulate chemical substances.

Nonetheless, TSCA has been an underachiever among U.S. environmental laws. TSCA requires the EPA to expend considerable resources before it can take any regulatory action. For example, to place restrictions on a chemical under section 6, the burden is on the EPA to demonstrate that a chemical is an “unreasonable risk.”<sup>51</sup> Federal courts have interpreted the unreasonable risk standard to require the agency to perform a wide-ranging cost-benefit analysis before regulating even the most dangerous chemicals.<sup>52</sup> In fact, the EPA has used its section 6 authority only four times

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46. See 15 U.S.C. § 2604 (2006) (requiring notice prior to manufacture). By comparison, media-based statutes, such as the Clean Water Act and Clean Air Act, and use-based statutes, such as the Federal Insecticide, Fungicide, and Rodenticide Act are much narrower in scope. DAVIES, *supra* note 40, at 14–15.

47. 15 U.S.C. § 2604(a).

48. 15 U.S.C. § 2605(a) (2006).

49. *Id.* § 2605(a)(2)–(3).

50. 15 U.S.C. § 2603 (2006).

51. 15 U.S.C. § 2605(a).

52. See, e.g., *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1223 (5th Cir. 1991).

to limit the use of chemicals and has never successfully used its section 6 authority to ban the manufacture of a chemical.<sup>53</sup>

For example, consider the EPA's efforts to regulate asbestos. The history of asbestos regulation has special relevance to current efforts to regulate nanotechnology. In fact, if it were developed today, asbestos likely would be considered nanotechnology because asbestos consists of nanoscale ceramic fibers.<sup>54</sup> And like modern nanotechnology applications, asbestos was the "miracle material" of its day. In the mid-twentieth century, asbestos was prized for its fire-resistance and was widely used in applications including insulation, brake pads, and fire blankets.<sup>55</sup> By the 1960s, strong evidence existed that corocidolite asbestos was a potent carcinogen.<sup>56</sup> Today, the World Health Organization estimates that currently, 125 million individuals are occupationally exposed to asbestos.<sup>57</sup>

The EPA studied the health effects of asbestos for ten years, conducted over one hundred human health studies, and issued a TSCA section 6 rule banning the use of asbestos.<sup>58</sup> Despite the EPA's exhaustive investigation, the Fifth Circuit struck down most of the EPA's rule because the court determined that the EPA had not demonstrated that asbestos causes an "unreasonable risk."<sup>59</sup> The court found that the EPA failed to consider regulatory alternatives to a total ban, failed to consider the toxicity of products that would be used to replace asbestos, and failed to follow TSCA's procedural provisions.<sup>60</sup>

In addition, TSCA is ineffective at gathering information about the chemicals it regulates. The EPA must meet the burden of demonstrating that a chemical "may present an unreasonable risk" before it can order testing.<sup>61</sup> This puts the EPA in a catch-22: the agency is required to produce information it does not have to learn what it does not know. A 1984 study found that no toxicity data was available for more than eighty percent of toxic chemicals in commerce and that toxicity data were available for only twenty-two percent of high volume chemicals.<sup>62</sup>

The EPA has relied on voluntary programs because of the high evidentiary standard imposed by TSCA. In 2008, the EPA launched the Nanotechnology Materials Stewardship Program to learn about the types of nanoscale materials under development, develop risk management practices, encourage the development of health and environmental test data, and encourage the responsible development of

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53. LYNN L. BERGESON, TSCA: TOXIC SUBSTANCES CONTROL ACT 48–49 (2000).

54. Brunner et al., *supra* note 36, at 4379–80. For this reason, asbestos fibers are often used as a positive control in *in vitro* nanotoxicology studies. *See, e.g., id.*

55. EPA, Asbestos: Basic Information, <http://www.epa.gov/asbestos/pubs/help.html>.

56. P.W.J. Bartrip, *History of Asbestos Related Disease*, 80 POSTGRADUATE MED. J. 72, 72 (2004), available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1742940>.

57. WORLD HEALTH ORG., ELIMINATION OF ASBESTOS-RELATED DISEASES I (2006), [http://www.who.int/occupational\\_health/publications/asbestosrelateddiseases.pdf](http://www.who.int/occupational_health/publications/asbestosrelateddiseases.pdf).

58. John S. Applegate, *Bridging the Data Gap: Balancing the Supply and Demand for Chemical Information*, 86 TEX. L. REV. 1365, 1386 (2008).

59. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1222–23 (5th Cir. 1991).

60. *Id.* at 1214–30.

61. 15 U.S.C. § 2603(a)(1)(A)(i) (2006).

62. John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 ECOLOGY L.Q. 721, 734–36 (2008).



nanotechnologies.<sup>63</sup> Unfortunately, companies have been selective in reporting information to the program. The program's 2009 Interim Report states that the EPA has received very little health and safety data about nanomaterials.<sup>64</sup> This failure suggests that voluntary programs alone will be inadequate to address the threats posed by nanotechnology.

### B. REACH as a Reaction to TSCA

In 2006, the European Union enacted the directive known as REACH, which provides a comprehensive framework for the regulation of chemicals throughout Europe.<sup>65</sup> REACH was written as a response to the regulatory paralysis created by TSCA,<sup>66</sup> as well as more uniquely European concerns, such as reducing animal testing and harmonizing European toxic substances law.<sup>67</sup>

REACH explicitly incorporates the precautionary principle.<sup>68</sup> Fundamentally, a "precautionary approach" to regulation requires that technologies with an uncertain impact on human health or the environment be restricted until the uncertainty is resolved.<sup>69</sup> It reflects the normative belief that protection of human health and environmental concerns trump concerns about economic efficiency.<sup>70</sup> It also reflects the factual assumption that "new technologies will create novel, severe, and irreversible . . . harms to human health and the environment" unless preventive measures are taken.<sup>71</sup>

REACH's data gathering provisions reflect this precautionary approach. REACH places the burden of producing health and environmental data on prospective chemical manufacturers.<sup>72</sup> Prospective manufacturers must submit dossiers of health and environmental data for any chemical to be manufactured in an amount greater than ten metric tons.<sup>73</sup> Recent EU policy guidance makes clear that the report must include information on all known uses of the chemical, including the conversion of the

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63. U.S. ENVTL. PROT. AGENCY, CONCEPT PAPER FOR THE NANOSCALE MATERIALS STEWARDSHIP PROGRAM UNDER TSCA 1-2 (2008), available at <http://www.epa.gov/opptintr/nano/nmsp-conceptpaper.pdf>.

64. See U.S. ENVTL. PROT. AGENCY, NANOSCALE MATERIALS STEWARDSHIP PROGRAM INTERIM REPORT 9 (2009), available at <http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf> [hereinafter INTERIM REPORT].

65. Applegate, *supra* note 62, at 723.

66. *Id.* ("[T]he Commission's *White Paper* can be read as an extended critique of TSCA, and REACH as the legislative product of that critique.").

67. *Id.* at 741.

68. Council Regulation No. 1907/2006, *supra* note 7, art. 1, para. 3. ("This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.").

69. Applegate, *supra* note 45, at 13.

70. *Id.*

71. *Id.*

72. Applegate, *supra* note 62, at 743.

73. Council Regulation No. 1907/2006, *supra* note 7, art. 10.

chemical into nanomaterials.<sup>74</sup> Thus, REACH is expected to generate a large amount of health and environmental data about chemicals.

REACH's provisions for the authorization of chemical manufacture also reflect the precautionary principle. The precautionary approach is strongest in the case of chemicals that are designated to be of Very High Concern (VHC) because of carcinogenic, mutagenic, or bioaccumulative properties.<sup>75</sup> In the case of VHC chemicals, the manufacturer must receive express permission to begin or continue production.<sup>76</sup> To receive this permission, the manufacturer must demonstrate that no safer chemical exists and present a research plan to find alternatives.<sup>77</sup> Furthermore, if the release of the chemical into the environment cannot be "adequately controlled" the manufacturer must demonstrate that the benefits of producing the chemical outweigh the costs.<sup>78</sup>

In the case of non-VHC chemicals, REACH takes a somewhat less precautionary approach. Article 69 states that a chemical will be restricted if the "dossier demonstrates that action on a Community-wide basis is necessary."<sup>79</sup> Thus, the text of REACH does not clearly allocate the burden of proving safety between the agency and the manufacturer. However, the procedure for restricting a chemical is very complicated, and compliance places a substantial burden on the agency.<sup>80</sup>

### C. The Movement for REACH-Based Reforms to TSCA

TSCA reform, based on REACH, is a realistic prospect in near future. In February 2009, the House Subcommittee on Commerce Trade and Consumer Protection held a hearing entitled "Revisiting the Toxic Substances Control Act of 1976."<sup>81</sup> The subcommittee discussed TSCA's well-known problems, including the "unreasonable risk" standard for chemical regulation, its ineffectiveness at collecting information, and its procedural complexity.<sup>82</sup> Regulatory reform based on REACH was discussed as a way to correct these shortcomings.<sup>83</sup> Part V of this Article discusses the implications of REACH-based reform for nanotechnology regulation.

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74. EUROPEAN COMM'N, FOLLOW-UP TO THE 6TH MEETING OF THE REACH COMPETENT AUTHORITIES FOR THE IMPLEMENTATION OF REGULATION (EC) 1907/2006 (REACH) 6 (2008), available at <http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf>.

75. See Applegate, *supra* note 62, at 742–73 (citing Council Regulation No. 1907/2006, *supra* note 7, arts. 55–66).

76. *Id.*

77. *Id.*

78. Council Regulation No. 1907/2006, *supra* note 7, at art. 60, paras. 2, 4; see also Applegate, *supra* note 62, at 742–73.

79. Council Regulation No. 1907/2006, *supra* note 7, at art. 69 para. 3.

80. Applegate, *supra* note 58, at 746–47.

81. *Revisiting the Toxic Substances Control Act of 1976: Hearing Before the H. Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 111th Cong. (2009), available at [http://energycommerce.house.gov/index.php?option=com\\_content&task=view&id=1505&Itemid=95](http://energycommerce.house.gov/index.php?option=com_content&task=view&id=1505&Itemid=95).

82. *Id.* (statement of John Stephenson, U.S. Gov't Accountability Office), available at [http://energycommerce.house.gov/Press\\_111/20090226/testimony\\_gao.pdf](http://energycommerce.house.gov/Press_111/20090226/testimony_gao.pdf).

83. See, e.g., *id.* at 4.

## V. REGULATION OF NANOTECHNOLOGY: IMPLICATIONS OF REACH-BASED REFORM TO TSCA

This Part discusses both the strengths and weaknesses of REACH-based reform to TSCA and discusses ways in which a third-generation toxic substances statute could be written to meet the health and environmental challenges posed by nanotechnology.

### A. Strengths of REACH-Based Reform to TSCA

#### 1. REACH's Precautionary Approach Is Appropriate for Nanotechnology

Preliminary research into the health and environmental effects of nanotechnology supports the precautionary principle's factual assumptions that new technologies create novel, severe, and irreversible harms. The physical and chemical properties of nanotechnology are novel because they are different than the properties of existing materials with the same chemical composition.<sup>84</sup> The high-surface area and resulting high chemical reactivity of nanomaterials leads to severe health and environmental consequences.<sup>85</sup> Finally, the tendency of nanomaterials to bioaccumulate throughout the body (and the possibility of uncontrolled self-replicating nanotechnologies) supports the conclusion that nanotechnology contamination is irreversible.<sup>86</sup>

Furthermore, society's experience with asbestos should be taken into account because, as discussed, asbestos shares characteristics with nanotechnology.<sup>87</sup> Asbestos has characteristics that are both "magical" and dangerous. During the first half of the twentieth century, industry moved full-speed ahead because of the potential for economic gain, but, by the later half of the twentieth century, society learned that the use of asbestos resulted in a net loss. Thus, society's experience with asbestos suggests that the precautionary approach taken by REACH is appropriate for nanotechnology.

#### 2. REACH's Mandatory Information Gathering Provisions are Appropriate for Nanotechnology

Very little is known about the health and environmental risks of most nanotechnology applications for at least two reasons. First, the EPA has only limited information about the types of nanotechnologies under development by private industry. At the present time, EPA knowledge is limited to the voluntary submissions of sixteen companies under the auspices of the Nanotechnology Stewardship Program.<sup>88</sup> Second, the EPA has very limited health and safety information regarding known nanotechnology applications. Even companies participating in the Stewardship Program have not provided the EPA health and environmental data.<sup>89</sup>

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84. *See supra* Part II.

85. *See supra* Part II.

86. *See supra* Part II.

87. *See supra* Part IV.A.

88. INTERIM REPORT, *supra* note 64, at 9.

89. *Id.* at 11.

TSCA is inadequate to close these data gaps for at least two reasons. First, TSCA's PMN requirement applies only to "new" and not "existing" chemicals.<sup>90</sup> The EPA treats a chemical as existing if it is listed on TSCA's Chemical Substance Inventory.<sup>91</sup> As a result, nanotechnology versions of chemicals that are already listed on the Inventory are not subject to the PMN requirement.<sup>92</sup> Thus, the EPA is not informed when a novel nanotechnology application is manufactured if it is manufactured from an existing chemical. Second, even if the EPA was informed about the existence of a novel nanotechnology application, it would be unable to require health and environmental testing because of TSCA's demanding evidentiary requirements.<sup>93</sup>

REACH provides much better tools to close the nanotechnology data gap. As discussed, REACH requires prospective manufacturers to submit dossiers disclosing any nanotechnology uses of manufactured chemicals.<sup>94</sup> Furthermore, manufacturers must produce health and safety data regarding those uses.<sup>95</sup> Thus, REACH-based reform of United States toxic substances law would result in the generation of much-needed health and environmental data regarding nanotechnology.

### 3. TSCA Provides Flexibility in Regulating Chemicals

As discussed in Part I, nanotechnology is extremely heterogeneous. Future applications of nanotechnology will be as diverse as processes for the molecule-by-molecule assembly of large-scale consumer goods (such as vehicles),<sup>96</sup> implants that will allow the human brain to interface with external technology,<sup>97</sup> and tiny machines that will be able to remediate toxic waste sites.<sup>98</sup> This diversity suggests that the EPA should have the authority to assess nanotechnology applications on a case-by-case basis and take whatever action is appropriate to protect the public.

TSCA's strength is its flexibility. As discussed, TSCA provides the EPA with a wide selection of actions to restrict chemicals at any point in the chain of commerce.<sup>99</sup> (Of course, EPA's power to take these actions is undercut by TSCA's lack of precaution, which is a separate issue.)<sup>100</sup> A third-generation toxic substances statute should maintain TSCA's flexibility of response to effectively regulate diverse forms of nanotechnology.

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90. U.S. ENVTL. PROT. AGENCY, TSCA INVENTORY STATUS OF CHEMICAL SUBSTANCES—GENERAL APPROACH 1–2 (2008), available at <http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf> [hereinafter General Approach].

91. *Id.*

92. *Id.*

93. *See supra* Part IV.A.

94. *See supra* Part IV.B.

95. *See supra* Part IV.B.

96. *See* Reynolds, *supra* note 9, at 181.

97. *See* Statement of Kurzweil, *supra* note 4, at 34–36.

98. Pratim Biswas & Chang-Yu Wu, *Nanoparticles and the Environment*, 55 J. AIR & WASTE MGMT. ASS'N 708, 710 (2005).

99. *See supra* Part IV.A.

100. *See supra* Part IV.A.

*B. Problems with REACH-Based reform of TSCA*

## 1. Definition of Subject Matter

Both TSCA and REACH define their subject matter in a way that would make it difficult to regulate nanotechnology. TSCA defines “chemical substances” to mean “any organic or inorganic substance *of a particular molecular identity . . .*”<sup>101</sup> The EPA interprets “molecular identity” to mean “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.”<sup>102</sup> In other words, under TSCA, “chemical substances” are defined in terms of “molecules,” which are arrangements of atoms. Unfortunately, nanotechnology applications are often defined by arrangements of molecules—that is, arrangements at a higher structural level than the definition of chemical substances in TSCA can capture.<sup>103</sup>

As a result, many nanomaterials are not recognized as “new chemical substances” subject to PMN reporting. For example, consider nanoscale titanium dioxide. Titanium dioxide is an “existing” chemical for purposes of TSCA.<sup>104</sup> Therefore, a producer of nanoscale titanium dioxide is not required to give premanufacture notice. This is true even though nanoscale titanium dioxide is used in sunscreens precisely because of its novel physical and chemical properties.<sup>105</sup>

In a handful of cases, the EPA has stretched the meaning of “chemical substances” to include structures that, like nanotechnology, are organized above the atomic level. For example, the EPA has asserted that the definition of chemical substances is broad enough to cover microorganisms, which can hardly be described as molecules.<sup>106</sup> This broad approach is also found in EPA’s definition of Class 2 chemical substances, which are defined as having a chemical composition that “cannot be fully represented by a complete, specific chemical structure diagram.”<sup>107</sup>

However, these designations have not been challenged in court. If they were, they might be struck down. Courts typically review agency definitions of terms in statutes with *Chevron*<sup>108</sup> deference.<sup>109</sup> Under *Chevron* deference, the reviewing court will typically uphold the agency’s interpretation unless it is counter-textual.<sup>110</sup> However, in this case, the plain language of the statute, which requires substances to be “of a

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101. 15 U.S.C. § 2602(2)(A) (2006) (emphasis added).

102. GENERAL APPROACH, *supra* note 90, at 3.

103. *See id.* at 4.

104. *See* U.S. ENVTL. PROT. AGENCY, NANOMATERIAL CASE STUDIES: NANOSCALE TITANIUM DIOXIDE IN WATER TREATMENT AND IN TOPICAL SUNSCREEN 1-5 to 1-6 (2009).

105. *Id.* at 1-7.

106. *See* 40 C.F.R. §§ 700, 720–21, 723, 725 (1997) (“TSCA defines ‘chemical substance’ broadly and in terms which cover microorganisms as well as traditional chemicals.”).

107. 40 C.F.R. § 720.45(a)(1)(i) (2008).

108. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

109. *E.g.*, Timothy K. Armstrong, *Chevron Deference and Agency Self-Interest*, 13 CORNELL J.L. & PUB. POL’Y 203, 204–07 (2004).

110. *Id.*

particular molecular identity,”<sup>111</sup> is clearly a problem in the context of novel substances that are defined by more than the connectivity of their atoms.

Unfortunately, the definition of “substance” in REACH also lacks the scope to regulate most nanotechnology. “Substance” is defined to mean:

*a chemical element and its compounds in a natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.*<sup>112</sup>

A recent EU policy document is cryptic about whether this definition is sufficient to distinguish nanotechnology from ordinary materials.<sup>113</sup>

Thus, neither TSCA nor REACH contains a definition of subject matter that is adequate to regulate nanotechnology. The definition of subject matter in a third-generation toxic substances statute should avoid limiting language such as “of a particular molecular identity” or “a chemical element and its compounds.” A suggested definition for “substances” would be: any state of matter, combined or uncombined, as distinguished by any physical or chemical property, or any process for the production of such a state of matter.

## 2. Chemical Safety Reports Should Not Be Limited to High Volume Chemicals

As discussed in Part II, nanotechnology applications can be much more toxic per unit mass than ordinary chemicals. Thus, the assumption that low volumes of chemicals are not dangerous is not valid for nanotechnology. Unfortunately, both REACH and TSCA incorporate this assumption.

REACH contains an exemption for chemicals that are manufactured in amounts less than ten metric tons per year.<sup>114</sup> The EPA has also implemented a Low Volume Exemption under TSCA, which exempts manufacturers who produce less than 10 metric tons of chemical per year from PMN requirements.<sup>115</sup> A third-generation toxic substances statute should avoid incorporating the assumption that low volumes of chemicals will have a *de minimus* environmental impact.

## CONCLUSION

For many years reformers from the academic, regulatory, and environmental communities have been drawing up plans to improve or replace TSCA. In many ways,

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111. 15 U.S.C. § 2602(2)(A) (2006).

112. Council Regulation No. 1907/2006, *supra* note 7, at art. 3(1) (emphasis added).

113. EUROPEAN COMM’N, *supra* note 74, at 13 (“Overall, the Commission services recognise that those issues require further consideration with a view to getting a solid understanding of the current regulatory coverage of REACH and identifying any need for further review at a subsequent stage.”).

114. Council Regulation No. 1907/2006, *supra* note 7, at art. 14(1).

115. 40 C.F.R. § 723.50 (1995); *see also* EPA, Low Volume Exemptions, <http://www.epa.gov/oppt/newchems/pubs/backlvem.htm>.

the enactment of REACH was a victory for these reformers. Understandably, they want to seize the momentum and make similar changes to toxic chemicals regulation in the United States.

But nanotechnology is a game-changer. Nanotechnology challenges the very definition of what chemicals are. Furthermore, many of the ideas that reformers have developed in the decades after the enactment of TSCA do not adequately take account of nanotechnology. As a result, proposed reforms need to be reevaluated. If this is done, the result will be a third-generation toxic substances statute that both overcomes TSCA's legacy of failure and looks forward to the technological future.