

# THE PRECAUTIONARY PRINCIPLE: MORE THAN A CAMEO APPEARANCE IN UNITED STATES ENVIRONMENTAL LAW?

PHILLIP M. KANNAN\*

*Sing me no song! Read me no rhyme!  
Don't waste my time; Show me!*<sup>1</sup>

## INTRODUCTION

At its core, the precautionary principle is a risk management theory that elaborates on the simple command “show me.” It decides whether the regulator or the regulated must be “shown.” It decides whether “show” means proof to a scientific certainty or scientific consensus, a scintilla of evidence, a wild hunch, or some other standard. It decides when the showing is to start, when it must be completed, what the consequences of not showing are, what roles the regulators and the regulated have in the process of showing, whether minimizing false positives<sup>2</sup> or false negatives<sup>3</sup>

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\* Distinguished Lecturer and Legal-Scholar-in-Residence, Colorado College.

<sup>1</sup> ALAN JAY LERNER & FREDERICK LOEWE, *Show Me, in MY FAIR LADY* (1956).

<sup>2</sup> The definition of “false positive” used for medical tests is: “A test result that indicates that a person has a specific disease or condition when the person actually does not have the disease or condition.” National Cancer Institute, Dictionary of Cancer Terms, Definition of False-Positive Test Result, [http://www.cancer.gov/Templates/db\\_alpha.aspx?CdrID=340929](http://www.cancer.gov/Templates/db_alpha.aspx?CdrID=340929) (last visited Mar. 1, 2007). By analogue, a false positive in governmental matters is a decision by a governmental body based on judgment, data, and policy to control a phenomenon, product, or process when the phenomenon, product or process actually does not cause the harm the governmental body seeks to manage. False positives are also called type I errors or alpha errors. See National Water Quality Laboratory, United States Geological Service, Long-Term Method Detection Level and Laboratory Reporting Level Information: Glossary, <http://nwql.usgs.gov/Public/ltmdl/glossary.html> (last visited Mar. 1, 2007).

<sup>3</sup> The definition of “false negative” used for medical tests is: “A test result that indicates that a person does not have a specific disease or condition when the person actually does have the disease or condition.” National Cancer Institute, Dictionary of Cancer Terms, Definition of False-Negative Test Result, [http://www.cancer.gov/Templates/db\\_alpha.aspx?CdrID=340928](http://www.cancer.gov/Templates/db_alpha.aspx?CdrID=340928) (last visited Mar. 1, 2007). By analogue, a false negative in governmental matters is a decision by a governmental body based on judgment, data, and policy not to control a phenomenon, product, or process when the phenomenon, product or process actually does cause the harm the governmental body seeks to manage. False negatives

is to be the goal of the showing, and whether showing should protect the public interest primarily under a liability model or a preventive model.

The elaboration on "show me" will take place in an atmosphere of uncertainty: health and environmental risks will not be fully understood, economic impacts will not be clear, and political fallout will be uncertain. Moreover, the answer to all the questions that the process poses will take place in a contentious mix of competing values: environmental, economic, developmental, religious, and political.

Consider the question of whether the federal government should prohibit logging of old growth forests in the Pacific Northwest in order to protect the northern spotted owl. The Forest Service issued proposed management guidelines for protecting this habitat.<sup>4</sup> However, neither the timber industry nor environmentalists were satisfied with them.<sup>5</sup> Industry claimed the guidelines would eliminate thousands of jobs, while environmentalists argued that the guidelines could cause the extinction of the owl in twenty-five years.<sup>6</sup> The studies that had been performed could not determine with scientific certainty the number of acres of old growth forest each pair of owls required.<sup>7</sup> The Forest Service was faced with the dilemma of whether to side with industry and allow unrestricted logging while further data were collected or to restrict logging while further scientific studies were completed.<sup>8</sup> The former choice could well lead to data, but no owls.<sup>9</sup>

## I. REGULATING RISK

At least conceptually, the regulation of risk is broken into two steps: risk assessment and risk management.<sup>10</sup> The goal of risk assessment is

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are also called type II errors or beta errors. See National Water Quality Laboratory, *supra* note 2.

<sup>4</sup> CHARLES F. WILKINSON, CROSSING THE NEXT MERIDIAN: LAND, WATER, AND THE FUTURE OF THE WEST 160-67 (1992).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* at 164.

<sup>8</sup> See *id.* at 164-65.

<sup>9</sup> *Id.*

<sup>10</sup> COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 2-3 (1983) [hereinafter RISK ASSESSMENT IN THE FEDERAL GOVERNMENT] (stating that one objective of the study on public health risks was "[t]o assess the merits of separating the analytic function of developing risk assessment from the regulatory functions of making policy decisions").

to measure the overall magnitude of the risk taking into account probability of harm, pathways of causing harm, and size of at-risk population.<sup>11</sup> Risk assessment is based on scientific inquiry, but almost inevitably there is insufficient data to assess the risk to a scientific certainty. This will lead to the introduction of personal and professional judgments into the assessment process.<sup>12</sup> For example, if the only data available about the relationship between the dose of a particular chemical to the response it causes are high doses administered to mice, judgments must be made regarding how to translate that data into a dose-response curve for humans and how to extrapolate from high doses to low doses.<sup>13</sup> The assessment process can result in either a quantitative measure of the risk or a qualitative description, such as substantial risk or high risk, depending on the purpose of the assessment and the availability of data.<sup>14</sup>

Once the risk assessment has been completed or has progressed to a point that raises public or special interest concern, governments are faced with the question of how to respond. For example, the government faced a question of this nature when data showed that eighty-seven deaths had been caused by the deployment of airbags as of November 1, 1997.<sup>15</sup> The government could have responded by: requiring the disclosure of the number of deaths, leaving it up to automobile manufacturers, buyers, and owners to devise responses; taking no position and leaving

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<sup>11</sup> *Id.*

<sup>12</sup> At each risk assessment step,

a number of decision points (*components*) occur where risk to human health can only be inferred from the available evidence. Both scientific judgments and policy choices may be involved in selecting from among possible inferential bridges, and we have used the term risk assessment policy to differentiate those judgments and choices from the broader social and economic policy issues that are inherent in risk management decisions.

*Id.*

<sup>13</sup> *Id.* at 4 (illustrating inference guidelines with the following example: “a guideline might specify the mathematical model to be used to estimate the effects of exposure at low doses on the basis of the effects of exposure at high doses”).

<sup>14</sup> See Food and Drug Administration, Risk Assessment for Food Terrorism and Other Food Safety Concerns (Oct. 7, 2003), <http://www.cfsan.fda.gov/~dms/rabtact.html> (discussing the difference between quantitative and qualitative risk assessment and stating that “[t]he agency has determined that [a] qualitative risk assessment, which discusses prior incidents of food contamination and available unclassified information on prior acts of food sabotage, is appropriate to the circumstances”).

<sup>15</sup> Air Bag On-Off Switches, 62 Fed. Reg. 62,406 (Nov. 21, 1997) (stating that “current air bags [have] saved about 2,620 drivers and passengers, as of November 1, 1997[;] [h]owever, those air bags had also caused the death of 87 people in low speed crashes, as of that same date”).

it up to products liability litigation; requiring a redesign of airbags to eliminate the risk; requiring an on-off switch for airbags; or by taking no action until further studies enabled more reliable estimates of the risk. Each alternative is clouded by uncertainty concerning the cost and the number of lives to be lost or saved with any response. The choice of response, like all risk management decisions, is heavily influenced by the values the government decides to protect.<sup>16</sup>

There are many theories or principles, including the precautionary principle, that can be applied to risk management decisions. In each, the decision maker attempts to integrate a broad spectrum of interests and values, including scientific, economic, political, and social concerns, into the risk management regime, particularly when there is significant uncertainty or significant risk of irreversible harm. The various risk management principles are determined by the relative weights assigned to the competing interests and values.<sup>17</sup>

The Supreme Court's opinions in *Rapanos v. United States*<sup>18</sup> illustrate how risk management is controlled by assigning different weights to competing values. The risk posed in *Rapanos* was to "the chemical, physical, and biological integrity of the Nation's waters" caused by the destruction

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<sup>16</sup> *Id.* The final rule allowed vehicle owners to petition the National Highway Traffic Safety Administration for a letter approving the installation of an on-off switch for air bags. *Id.* Without such a determination, on-off switches cannot be installed. *Id.* See also National Highway Traffic Safety Administration, Air Bag On-Off Switch, <http://www.nhtsa.dot.gov/cars/testing/ncap/airbags/pages/FAQsABOnOff.htm> (last visited Mar. 1, 2007); Centers for Disease Control and Prevention, *Notice to Readers: Approval of Installation of Air Bag On-Off Switches For Certain Motor-Vehicle Owners*, 46 MORBIDITY & MORTALITY WKLY. REP. 1098, 1098-99 (1997), available at <http://ftp.cdc.gov/pub/publications/mmwr/wk/mm4646.pdf> (summarizing and expressing approval of the final rule).

<sup>17</sup> See, e.g., *Massachusetts v. U.S. Env'tl. Prot. Agency*, 415 F.3d 50, 58 (D.C. Cir. 2005), cert. granted, 126 S. Ct. 2960 (2006). In this case, the Court of Appeals for the D.C. Circuit explained that:

Congress does not require the Administrator to exercise his discretion solely on the basis of his assessment of scientific evidence. What the *Ethyl* court called policy judgments also may be taken into account. By this the court meant the sort of policy judgments Congress makes when it decides whether to enact legislation regulating a particular area.

*Id.* (citation omitted). For a critique of the application of this principle to the Environmental Protection Agency's ("EPA") refusal to regulate carbon dioxide emissions from vehicles, but not of the principle itself, see *D.C. Circuit Shields Environmental Protection Agency from Making Controversial Determination of Climate Endangerment*, 119 HARV. L. REV. 2620, 2620 (2006) (stating that "[b]y twisting the facts of the case and stretching precedent, the opinion effectively limits the EPA's accountability to both the public and Congress").

<sup>18</sup> 126 S. Ct. 2208 (2006).

of wetlands.<sup>19</sup> The Court considered whether four wetlands that are connected by ditches or drains to creeks that empty into a navigable river are navigable, and therefore protected, under the Clean Water Act.<sup>20</sup>

Justice Scalia, writing for the plurality, made it clear from the outset of his opinion that property rights were the predominate interest in his risk management analysis.<sup>21</sup> He likened the Army Corps of Engineers (“Corps”) to an “enlightened despot” exercising discretion over the development of “270-300 million acres of swampy lands” by considering “in general, the needs and welfare of the people.”<sup>22</sup> To further reduce the significance of the Corps, Justice Scalia framed the Corps’ regulation of these wetlands as “a significant impingement of the States’ traditional and primary power over land and water uses.”<sup>23</sup> For risk management regulation, this means that the expertise of the Corps will be ignored, the federal interest will be dismissed, and the interest of the public will count for little or nothing. Scalia elevated the interest of the landowner in this case by casting him in the role of the victim of an over-reaching government, stating that “for backfilling *his own* wet fields, Mr. Rapanos faced 63 months in prison and hundreds of thousands of dollars in criminal and civil fines.”<sup>24</sup> Not surprisingly, the plurality adopted a risk management rule that will under-protect the environmental conditions of the waters of the United States:

In sum, on its only plausible interpretation, the phrase “the waters of the United States” includes only those relatively permanent, standing or continuously flowing bodies of water “forming geographic features” that are described in ordinary parlance as “streams[,] . . . oceans, rivers, [and] lakes.” The phrase does not include channels through which water flows intermittently or ephemerally, or channels that periodically provide drainage for rainfall.<sup>25</sup>

The plurality’s risk management principle substitutes dictionary formalism for ecological reality. It does not permit even a case-by-case

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<sup>19</sup> *Id.* at 2215 (quoting 33 U.S.C. §1251(a) (2007)).

<sup>20</sup> *Id.* at 2219.

<sup>21</sup> *Id.* at 2214.

<sup>22</sup> *Id.* at 2214-15.

<sup>23</sup> *Id.* at 2224 (quoting *Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng’rs*, 531 U.S. 159, 174 (2001)).

<sup>24</sup> *Id.* at 2215 (emphasis added).

<sup>25</sup> *Id.* at 2225 (citation omitted).

showing of ecological connection between a wetland and a navigable water when there is no relatively permanent, standing or continuous flow.<sup>26</sup> Its principle broadly accepts false negatives, and will therefore under-protect wetlands.

Justice Kennedy concurred in the plurality's judgment to vacate the court of appeals' judgment in favor of the United States and to remand, but he refused to join in the opinion of the plurality.<sup>27</sup> He rejected the weights assigned to the various interests by the plurality, and in doing so, stated a different risk management principle. First, Justice Kennedy rejected the excessive weight the plurality gave to Rapanos' property interests:

It bears mention also that the plurality's overall tone and approach—from the characterization of acres of wetlands destruction as “backfilling . . . wet fields,” to the rejection of Corps authority over “man-made drainage ditches” and “dry arroyos” without regard to how much water they periodically carry, to the suggestion, seemingly contrary to Congress' judgment, that discharge of fill material is inconsequential for adjacent waterways—seems unduly dismissive of the interests asserted by the United States in these cases.<sup>28</sup>

Justice Kennedy also gave more weight to the expertise of the Corps, but not to the same extent as the dissent.<sup>29</sup> He concluded that the Corps' categorical rule provided no assurance of an ecologic interconnection between wetlands adjacent to tributaries of navigable waters and those waters.<sup>30</sup> He recognized the Corps' authority, but advocated for a case-by-case scientific analysis:

Absent more specific regulations, however, the Corps must establish a significant nexus on a case-by-case basis when it seeks to regulate wetlands based on adjacency to non-navigable tributaries. Given the potential overbreadth of the Corps' regulations, this showing is necessary to avoid

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<sup>26</sup> *Id.*

<sup>27</sup> *Id.* at 2236 (Kennedy, J., concurring).

<sup>28</sup> *Id.* at 2246 (citations omitted).

<sup>29</sup> Compare *id.* at 2249, with *id.* at 2252 (Stevens, J., dissenting).

<sup>30</sup> *Id.* at 2249 (Kennedy, J., concurring).

unreasonable applications of the statute. Where an adequate nexus is established for a particular wetland, it may be permissible, as a matter of administrative convenience or necessity, to presume covered status for other comparable wetlands in the region.<sup>31</sup>

The four dissenting justices embraced a different risk management rule by assigning different weights to the competing values. First, they rejected the image of Rapanos as a helpless victim, pointing out that:

Rapanos then hired a wetland consultant, Dr. Frederick Goff. After Dr. Goff concluded that the land did in fact contain many acres of wetlands, “Rapanos threatened to ‘destroy’ Dr. Goff if he did not destroy the wetland report, and refused to pay Dr. Goff unless and until he complied.”<sup>32</sup>

Next, the dissent credited the Corps’ expertise and the authority of the executive branch of the federal government:

The Army Corps has determined that wetlands adjacent to tributaries of traditionally navigable waters preserve the quality of our Nation’s waters by, among other things, providing habitat for aquatic animals, keeping excessive sediment and toxic pollutants out of adjacent waters, and reducing downstream flooding by absorbing water at times of high flow. The Corps’ resulting decision to treat these wetlands as encompassed within the term “waters of the United States” is a quintessential example of the Executive’s reasonable interpretation of a statutory provision.<sup>33</sup>

The dissent’s risk management principle accepts the Corps’ categorical rule that all wetlands adjacent to a tributary of a navigable water are ecologically connected to that water and, thus, are protected by the federal government under the Clean Water Act.<sup>34</sup> This principle might be overprotective of wetlands, but it allows the Corps to judge whether the cost of false positives is outweighed by the overall benefit of the rule.

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<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at 2253 (Stevens, J., dissenting) (quoting the Application to Petition for Certiorari).

<sup>33</sup> *Id.* at 2252.

<sup>34</sup> *Id.*

A regulation based on a precautionary approach could accommodate Justice Kennedy's concerns as well as those of the dissent. Such a regulation would classify all wetlands adjacent to a tributary of a navigable water as navigable, but permit the owner of a particular wetland to prove by a preponderance of the evidence that it has no significant nexus to a navigable water. Shifting the burden of proof is one option to incorporate the precautionary approach in regulation.<sup>35</sup> The economic benefits of development of the property for the owner provide adequate justification and motivation for such an allocation of the burden of proof. In a situation similar to that in *Rapanos*, this version of a precautionary approach would provide more protection to wetlands than the plurality's rule because it would reduce the risk of false negatives. It would also provide more protection to property rights than the dissent's rule because it would yield fewer false positives.

## II. THE PRECAUTIONARY PRINCIPLE

There is no one precautionary principle. Versions of the precautionary principle have been incorporated in many recent international environmental agreements including: The 1996 Protocol to the London Convention of 1972,<sup>36</sup> the United Nations Framework Convention on Climate Change,<sup>37</sup> the Convention on Biological Diversity,<sup>38</sup> the Esbjerg

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<sup>35</sup> See *infra* Part II.B.

<sup>36</sup> In implementing this Protocol, Contracting Parties shall apply a precautionary approach to environmental protection from dumping of wastes or other matter whereby appropriate preventative measures are taken when there is reason to believe that wastes or other matter introduced into the marine environment are likely to cause harm even when there is no conclusive evidence to prove a causal relation between inputs and their effects.

1996 Protocol to the 1972 Convention on the Prevention of Marine Polluting by Dumping of Wastes and Other Matter art. 3, ¶ 1, Nov. 7, 1996, 36 I.L.M 1, available at <http://www.londonconvention.org/documents/lc72/PROTOCOL.pdf>.

<sup>37</sup> The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost . . . .

United Nations Framework Convention on Climate Change art. 3, ¶ 3, May 8, 1992, 31 I.L.M. 851, available at <http://unfccc.int/resource/docs/convkp/conveng.pdf>.

<sup>38</sup> "Where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid

Declaration of the North Sea Conference,<sup>39</sup> and the World Trade Organization (“WTO”) Agreement on the Application of Sanitary and Phytosanitary Measures.<sup>40</sup> The precautionary principle can also be found in the law of the European Union (“EU”).<sup>41</sup> While there are variations in the

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or minimize such a threat.” United Nations Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 822.

<sup>39</sup> “The Ministers AGREE that the objective is to ensure a sustainable, sound and healthy North Sea ecosystem. The guiding principle for achieving this objective is the precautionary principle.” Esbjerg Declaration of the Fourth International Conference on the Protection of the North Sea art. 3, para. 17, June 8-9, 1995, <http://www.seas-at-risk.org/Images/1995%20Esbjerg%20Declaration.pdf>. Article 17 calls for the cessation of emissions and losses of hazardous substances into the North Sea in twenty five years. *Id.* Substances that are toxic, persistent and liable to bioaccumulate are assumed to fall in the category of hazardous substances that are to be eliminated. *Id.* paras. 19, 22. The explicit inclusion of the precautionary principle means that these substances are to be prohibited even if the scientific evidence that their presence in the North Sea is causing significant harm is inconclusive or absent.

<sup>40</sup> After requiring that members’ trade measures are based on scientific risk assessment, this treaty states that:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

Agreement on the Application of Sanitary and Phytosanitary Measures art. 5, ¶ 7, Apr. 15, 1994, Marrakesh Agreement Establishing the WTO annex 1A, 1867 U.N.T.S. 493, 496-97, available at [http://www.wto.org/English/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm).

<sup>41</sup> The precautionary principle should be informed by three specific principles:

- implementation of the principle should be based on the fullest possible scientific evaluation. As far as possible this evaluation should determine the degree of scientific uncertainty at each stage;
- any decision to act or not to act pursuant to the precautionary principle must be preceded by a risk evaluation and an evaluation of the potential consequences of inaction;
- once the results of the scientific evaluation and/or the risk evaluation are available, all the interested parties must be given the opportunity to study of [sic] the various options available, while ensuring the greatest possible transparency.

Europa, Activities of the European Union: The Precautionary Principle, <http://europa.eu/scadplus/leg/en/lvb/l32042.htm> (last visited Mar. 1, 2007) (summarizing a February 2000 communication from the Commission of the European Communities on the precautionary principle). See also Sarah Lively, *The ABCs and NTBs of GMOs: The Great European*

several versions, they all share the normative assumption that when a government is balancing and integrating scientific, economic, political, and social values for the purpose of risk management, environmental protection is to be a paramount value.<sup>42</sup> The various versions of the precautionary principle are distinguished by the levels of risk and uncertainty necessary to invoke the principle, the relative weights assigned to the competing interests and values (i.e. what level of precaution to take and at what cost), and the rights and obligations of the regulated party vis-à-vis the government.<sup>43</sup>

A formulation of the precautionary principle similar to that in the Convention on Biological Diversity,<sup>44</sup> which calls for actions to minimize or avoid harm when there is a lack of *full scientific certainty*, would effectively make a precautionary approach the norm because there will often be a lack of full scientific certainty.<sup>45</sup> If, in such a version of the precautionary principle, the required response is “to take cost effective measures as deemed appropriate,” requiring such measures would be the norm because “the dominate analytic difficulty [in risk assessment] is pervasive uncertainty.”<sup>46</sup> If, in such a version, the required response is to shift the burden of proof regarding causation of harm to the proponent of proposed activity, the norm would be an almost universal reversal of the usual rule regarding the placement of the burden of proof.<sup>47</sup> If the trigger is the lack of full scientific certainty, a version that goes beyond shifting the burden of proof and actually bans the activity, similar to the approach in the Esbjerg Declaration of the North Sea Conference for toxic, persistent and bioaccumulative substances, would be an even more categorical approach achieving environmental protection through excessive caution.<sup>48</sup>

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*Union-United States Trade Debate—Do European Restrictions on the Trade of Genetically Modified Organisms Violate International Trade Law?*, 23 N.W. J. INT'L L. & BUS. 239, 246-48 (2002) (explaining the use of the Precautionary Principle in the EU).

<sup>42</sup> See *supra* notes 36-41.

<sup>43</sup> See *supra* notes 36-41.

<sup>44</sup> United Nations Convention on Biological Diversity, *supra* note 38, at 822.

<sup>45</sup> See, e.g., RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 10, at 11 (noting that “there is often great uncertainty in estimates of the types, probability, and magnitude of health effects associated with a chemical agent, of the economic effects of a proposed regulatory action, and of the extent of current and possible future human exposures”).

<sup>46</sup> *Id.* See also *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993) (stating that “[s]cientific conclusions are subject to *perpetual revision*”) (emphasis added).

<sup>47</sup> See *infra* notes 88-89 and accompanying text.

<sup>48</sup> See, e.g., Esbjerg Declaration, *supra* note 39, at art. 19.

Applications of the precautionary principle have been separated into two categories: pre-emptive precautionary approaches and risk-based precautionary approaches.<sup>49</sup> Strategies that shift the burden or proof or ban an activity altogether constitute pre-emptive precautionary approaches.<sup>50</sup> The precautionary principle embraced by the EU is much more balanced; it is clearly a risk-based precautionary principle. “According to the Commission the precautionary principle may be invoked when the potentially dangerous effects of a phenomenon, product or process have been identified by a scientific and objective evaluation, and this evaluation does not allow the risk to be determined with sufficient certainty.”<sup>51</sup> If this measured standard indicates that a precautionary principle should be applied, the EU guidelines call for a response that is tailored to the risk.<sup>52</sup> They require a response be developed that reflects “proportionality between the measures taken and the chosen level of protection; non-discrimination in application . . . ; consistency . . . with . . . similar situations; examination of the benefits and costs . . . ; review of the measures in the light of scientific developments; [and] the burden of proof.”<sup>53</sup> Thus, the EU approach stresses science and requires judgments based on individual risks.

The one federal court that was presented with a pre-emptive version of the precautionary principle rejected it. In *New Mexico v. General Electric*, a case involving groundwater contamination, New Mexico offered a declaration from a leading proponent of the precautionary principle.<sup>54</sup> In analyzing this statement the court stated that: “[o]ne parses the Teitelbaum Declaration in vain, searching for specific facts supporting Plaintiffs’ sweeping and oft-repeated assertion that the groundwater contamination at South Valley is permanent, or that this resource has been ‘rendered useless for all time.’”<sup>55</sup> The court refused to give any weight to Dr. Teitelbaum’s analysis, demonstrating its view that the precautionary principle must be risk-based in order to be enforceable.<sup>56</sup>

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<sup>49</sup> Bernard D. Goldstein & Russel S. Carruth, *Implications of the Precautionary Principle for Environmental Regulation in the United States: Examples from the Control of Hazardous Air Pollutants in the 1990 Clean Air Act Amendments*, 66 LAW & CONTEMP. PROBS. 247, 249-50 (2003).

<sup>50</sup> *See id.*

<sup>51</sup> *See Europa, supra* note 41.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *New Mexico v. General Elec.*, 335 F. Supp. 2d 1185, 1220 (D. N.M. 2004).

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

A. *A Prominent Example of the Precautionary Principle: Principle 15 of the Rio Declaration*

Perhaps the most widely accepted version of the precautionary principle in international law can be found in the Rio Declaration,<sup>57</sup> which states:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.<sup>58</sup>

Principle 15 of the Rio Declaration is far from a rigid obligation to apply the precautionary principle in many cases. First, this is a declaration, not a treaty; thus, it has been signed, but has not been through the ratification processes of the signatory nations.<sup>59</sup> Second, it is stated as a precautionary approach, rather than a requirement.<sup>60</sup> Third, its application will vary with the capabilities of the parties.<sup>61</sup> Finally, the signatories only agree that it will be “widely applied” rather than applied in every case.<sup>62</sup>

In addition to these ambiguities concerning when the principle must be applied, there are ambiguities within the principle itself. The Rio Declaration leaves several questions unanswered, including what level of scientific uncertainty justifies the application of precaution, how

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<sup>57</sup> For a summary of the broad acceptance of the Rio Declaration and the limited reservations expressed by the United States, see *Rio Declaration*, EARTH NEGOT. BULL., June 3-14, 1992, at part III, available at <http://www.iisd.ca/vol02/0213032e.html>.

<sup>58</sup> U.N. Conference on Environment and Development: Rio Declaration on Environment and Development princ. 15, June 13, 1992, 31 I.L.M. 874 [hereinafter Rio Declaration].

<sup>59</sup> See United Nations Treaty Collection, Treaty Reference Guide, <http://untreaty.un.org/English/guide.asp#treaties> (last visited Mar. 1, 2007).

<sup>60</sup> Rio Declaration, *supra* note 58, princ. 15. Principle 15 would present a stronger obligation if phrased as a requirement than as a broad approach with few explicit guidelines.

<sup>61</sup> The principle specifically acknowledges that it is to be applied by states “according to their capabilities.” *Id.* This is an example of the principle of common but differentiated responsibilities that is prevalent in modern environmental treaties. See Christopher D. Stone, *Common but Differentiated Responsibility in International Law*, 98 AM. J. INT'L L. 276 (2004) (surveying and discussing recent examples).

<sup>62</sup> Rio Declaration, *supra* note 58, princ. 15.

the term “cost effective” should be understood, and what level of precaution should be imposed.<sup>63</sup>

These questions concerning the ambiguities in Principle 15 could apply to all articulations of the precautionary principle because the precautionary principle is more of a creed than a commandment. It expresses an acceptance of environmental protection as a paramount value. Thus the precautionary principle creates the obligation to follow through in succeeding steps with specific actions in particular cases to pursue that goal.

When considering the precautionary principle as a creed, it can be analogized to the concept of sustainable development, the broadly accepted meaning of which is “development that meets the needs of the present without compromising the ability of future generations to meet their own needs.”<sup>64</sup> This definition also rests on vague concepts.<sup>65</sup> What is meant by “needs?” Do all people have the same needs? Is this to be determined on an individual or group basis? What is necessary for a generation to “meet” their needs? For example, can the present generation continue to use oil under the assumption that new technologies will be available in the future to provide a substitute? These ambiguities do not make sustainable development a useless concept, however.<sup>66</sup> Charles Wilkinson has analyzed sustainability as a principle that exists at two levels:

First, sustainability has great appeal as a broad societal objective—as a symbol, as a statement of some of the fundamental values we hold as a people. Sustainability has

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<sup>63</sup> *Id.* See also Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 COLUM. J. TRANSNAT'L L. 323, 332 (2002) (noting that “neither [the Rio Declaration nor the Convention on Biodiversity] addresses the question as to what level of risk and which kind of prima facie evidence triggers the application of the precautionary principle”); Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 278 (2000) (stating that “[t]he precautionary principle effectively shifts the burden of proving safety to producers of a potentially environmentally damaging risk when there is some undefined level of scientific uncertainty”).

<sup>64</sup> WORLD COMM'N ON ENV'T AND DEV., OUR COMMON FUTURE 43 (1987). The World Commission on Environment and Development is commonly referred to as the Brundtland Commission. See, e.g., S. Jacob Scherr & R. Juge Gregg, *Johannesburg and Beyond: The 2002 World Summit on Sustainable Development and the Rise of Partnerships*, 18 GEO. INT'L ENVTL. L. REV. 425, 429 (2006).

<sup>65</sup> See Bosire Maragia, *The Indigenous Sustainability Paradox and the Quest for Sustainability in Post-Colonial Societies: Is Indigenous Knowledge All that is Needed?*, 18 GEO. INT'L ENVTL. L. REV. 197, 198 (2006) (explaining that “[s]ustainable development . . . has been widely criticized as an ambiguous concept”).

<sup>66</sup> *Id.* at 198.

this appeal because it combines the philosophical and moral force of fairness to future generations with the practical edge of being necessary to our economic and social well-being. In this broad, symbolic sense, sustainability embodies a shared national goal in much the same way that freedom and equality do. Such broad formulations—idealistic and never fully attainable, yet undeniable in their essential verity—are critical for setting an agreed-upon context for making public choices on difficult and contentious issues. . . .

Yet the truest way to understand what sustainability means comes . . . from seeing how sustainability has actually been implemented in real places. It is through real-world efforts that you best understand and define sustainability and how it differs from traditional approaches.<sup>67</sup>

Wilkinson then discusses the Northwest Forest Plan as an embodiment of sustainability in “a concrete, working policy” in which logging interests, forest preservation interests, and wildlife preservation interests were balanced under the constraint that future generations had rights which needed protection.<sup>68</sup> It was this explicit consideration of the rights of future generations and their role in guiding the compromise that was notable.

*B. Elements of the Precautionary Principle*

Principle 15 and other articulations of the precautionary principle will serve “as a symbol, as a statement of some of the fundamental values we hold as a people.”<sup>69</sup> While symbols are important to inspire action, concrete plans are necessary for achieving success. This subsection will focus on practical means for reaching the goals of the precautionary principle.

The precautionary principle or approach is generally understood to include three elements: “fully assessing possible impacts of an action, shifting the burden of proof to those whose activities pose a threat to the environment, and not acting if there is significant uncertainty or risk of

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<sup>67</sup> CHARLES F. WILKINSON, *THE EAGLE BIRD* 109-11 (rev. & updated ed. 1999).

<sup>68</sup> *Id.* at 111.

<sup>69</sup> *Id.* at 109.

irreversible harm.”<sup>70</sup> The first two elements are procedural, and the third is substantive.

The first element, environmental impact assessment, enables but does not guarantee environmental protection or caution. Without such assessments, environmental values may not be given much weight in the decision-making process. Judge Wright, speaking for the court, recognized this in one of the first cases interpreting the National Environmental Policy Act of 1969 (“NEPA”),<sup>71</sup> the law requiring environmental impact assessments before certain federal actions. Judge Wright stated that “Congress did not establish environmental protection as an exclusive goal; rather, it desired a reordering of priorities, so that environmental costs and benefits [would] assume their proper place along with other considerations.”<sup>72</sup> This ensures “[an environmentally] informed decision-making process.”<sup>73</sup> Environmental impact assessments enable an informed decision to be made and enable precaution regarding the environment to assume its proper place in the decision-making process.<sup>74</sup>

NEPA could be expanded to include all of the elements of the precautionary principle, rather than just the first. One European treaty provides a model of this type of policy. Under the auspices of the United Nations Economic Commission for Europe (“UNECE”),<sup>75</sup> European states

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<sup>70</sup> Charmian Barton, *The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine*, 22 HARV. ENVTL. L. REV. 509, 515 (1998). Participants at the Wingspread Conference explained the elements of the precautionary principle in a similar manner:

Where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public bears the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic, and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action.

Wingspread Statement on the Precautionary Principle, Jan. 23-25, 1998, <http://www.gdrc.org/u-gov/precaution-3.html>.

<sup>71</sup> National Environmental Policy Act of 1969, Pub. L. No. 91-190, 83 Stat. 852 (1969) (codified at 42 U.S.C. §§ 4321-70f (2007)).

<sup>72</sup> *Calvert Cliffs' Coordinating Comm. v. U.S. Atomic Energy Comm'n*, 449 F.2d 1109, 1112 (D.C. Cir. 1971).

<sup>73</sup> *Id.* at 1115.

<sup>74</sup> Information disclosure requirements can serve this same function. *See infra* notes 113-17 and accompanying text.

<sup>75</sup> For general information about the UNECE, see United Nations Economic Commission for Europe, UNECE in a Nutshell, <http://www.unece.org/oes/nutshell/introduction.htm> (last visited Mar. 1, 2007).

have negotiated a treaty that combines environmental impact assessment with a substantive provision.<sup>76</sup> This combination is aimed at reducing transboundary environmental pollution.<sup>77</sup> The Convention on the Environmental Impact Assessment in a Transboundary Context requires the party of origin to: (1) prepare an environmental impact assessment before a decision to authorize any of a broad list of activities likely to cause significant transboundary environmental harm,<sup>78</sup> and (2) give notice to states likely to be affected.<sup>79</sup> Together these procedural steps enable the state of origin and the affected states to take precautionary measures to mitigate environmental harm. The Convention also includes a substantive provision which requires each party to “take all appropriate and effective measures to prevent, reduce and control significant adverse transboundary environmental impact from proposed activities.”<sup>80</sup> It is this type of provision that could be added to NEPA to incorporate the substantive element of the precautionary principle.

There are two ways for the second element of the precautionary principle, the burden of proof, to affect the level of precaution in environmental decision making: (1) mandating which party has the burden of proof, and (2) establishing what level of proof is required.<sup>81</sup> The least precautionary rule would be one that placed the burden of proof on the party opposed to a proposed action and required scientific certainty in order to satisfy that burden. The most protective rule would require the same level of proof but place the burden on the party proposing the action.

In between these extremes is the rule applied by the Supreme Court in *Missouri v. Illinois*.<sup>82</sup> In this case, Missouri sued Illinois to enjoin the state from allowing Chicago to dump its untreated human waste into a river that is a tributary to the Mississippi River from which St. Louis took its drinking water.<sup>83</sup> Missouri claimed this pollution was causing increased mortality from typhoid.<sup>84</sup> The Court placed the following burden of proof on Missouri: “[b]efore this court ought to intervene

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<sup>76</sup> Convention on Environmental Impact Assessment in a Transboundary Context, Feb. 25, 1991, 30 I.L.M. 802, available at [http://www.unece.org/env/eia/documents/convention\\_textenglish.pdf](http://www.unece.org/env/eia/documents/convention_textenglish.pdf).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.* art. 2, para. 3.

<sup>79</sup> *Id.* art. 2, para. 4.

<sup>80</sup> *Id.* art. 2, para. 1.

<sup>81</sup> See Barton, *supra* note 70, at 519-20.

<sup>82</sup> 200 U.S. 496 (1906).

<sup>83</sup> *Id.* at 496.

<sup>84</sup> *Id.*

the case should be of serious magnitude, clearly and fully proved, and the principle to be applied should be one which the court is prepared deliberately to maintain against all considerations on the other side.”<sup>85</sup> Because there was conflicting scientific evidence<sup>86</sup> and Missouri allowed its cities to dump untreated human waste in the Mississippi River, the Court held that Missouri had not met the high burden of proof required,<sup>87</sup> and the pollution continued. A precautionary approach would have recognized the serious harm and the credible, but disputed, scientific evidence that this harm was caused by Chicago’s waste. It could have placed the burden on Illinois to prove by clear and convincing evidence that it was not causing the harm. A less protective version of the precautionary principle could have required that Illinois meet a preponderance of the evidence standard.

When a precautionary approach shifts the burden of proof, a three-step process typically results.<sup>88</sup> First, the government assembles scientific evidence that indicates, but perhaps does not prove with scientific certainty or even by a preponderance of the evidence, that a substance can cause harm to humans or the environment. Next, the government issues a regulation banning the substance unless the proponent of its use can prove that the substance presents a risk less than a standard stated in the regulation. Finally, the proponent is offered an administrative or judicial forum to demonstrate that the substance presents a risk less than the standard. This approach will justifiably inspire many critics if the risk standard is so strict that it effectively forces the proponent prove that the risk is zero.<sup>89</sup>

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<sup>85</sup> *Id.* at 521.

<sup>86</sup> *Id.* at 523.

<sup>87</sup> *Id.* at 525-26.

<sup>88</sup> For example, California’s Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, took this approach. Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Proposition 65 (1986), *available at* [http://www.oehha.ca.gov/prop65/law/pdf\\_zip/P65LAW72003.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/P65LAW72003.pdf). This law prohibits persons from knowingly discharging “a chemical known to the state to cause cancer or reproductive toxicity” into any source of drinking water unless the discharger shows that no significant amount will enter drinking water. CAL. HEALTH & SAFETY CODE § 25249.5 (2007). It also prohibits persons “in the course of doing business” from “knowingly and intentionally expos[ing] any individual to a chemical known to the state to cause” such harm, unless the person gives adequate warning or can show that the chemical poses no significant risk. CAL. HEALTH & SAFETY CODE § 25249.6.

<sup>89</sup> See Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 853 (1996) (noting that some versions of the precautionary principle “require[] ‘proof of harmlessness’ before an activity is allowed”). Cross uses the following example to point out that this approach can actually increase risk:

The third element of the precautionary principle requires a proposed action to be blocked if there is significant uncertainty or risk of irreversible harm.<sup>90</sup> This element represents the normative judgment that the proper role of the government is to protect against potential harms in addition to those established by scientific certainty. Ambiguity in the meanings of "significant" and "irreversible" may provide flexibility in the application of this element.

### III. THE PRECAUTIONARY PRINCIPLE IN UNITED STATES LAW

There are at least three routes by which the precautionary principle could be included in the law of the United States:

- (1) Through integration of customary international law;
- (2) Through obligations assumed by the United States in binding treaties; and
- (3) Through specific statutes, regulations, or policies that either by their express terms or as interpreted by court decisions impose a precautionary approach for the particular conduct that is the subject of the statute.

This Part will briefly discuss the first two strategies. However, the third of these approaches is the primary focus of the Article and is analyzed in Part IV.

#### A. *Customary International Law as a Source of the Precautionary Principle in United States Law*

In *The Paquete Habana*<sup>91</sup> the Supreme Court recognized that customary international law<sup>92</sup> can become a part of domestic law:

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A family of sweeteners called cyclamates was removed from the market in the late 1960s, when evidence arose regarding their potential carcinogenicity. Saccharin rushed in to meet the market demand for artificial sweetening. The FDA then proposed to ban saccharin because of evidence of carcinogenicity. Congress, which overturned the ban, let saccharin off with a warning.

*Id.* at 863-64.

<sup>90</sup> See *supra* note 70 and accompanying text.

<sup>91</sup> 175 U.S. 677 (1900).

<sup>92</sup> Customary international law is based on state practice which states engage in because they believe they are legally bound to do so. This second element of the doctrine of

International law is part of our law, and must be ascertained and administered by the courts of justice of appropriate jurisdiction, as often as question of right depending upon it are duly presented for their determination. For this purpose, where there is no treaty, and no controlling executive or legislative act or judicial decision, resort must be had to the customs and usages of civilized nations . . . .<sup>93</sup>

To prove that the precautionary principle has become domestic law as customary international law, one would have to demonstrate first that it was the practice of all or nearly all states and second that these states applied it because they believed they were legally bound to do so.<sup>94</sup> Although the precautionary principle has been embraced by all the States that are party to the Rio Declaration<sup>95</sup> and by many states in several environmental treaties,<sup>96</sup> it is unlikely that it has become customary international law because its indefiniteness and the ambiguity regarding its scope of application would make it impossible to enforce. The one United States Court of Appeals that has considered this question held that the principle had not been integrated into customary international law.<sup>97</sup> The court explained its conclusion as follows:

[The plaintiff] fail[ed] to show that [the precautionary principles stated in The Rio Declaration and other treaties] enjoy universal acceptance in the international community. The sources of international law cited by [the plaintiff] and the *amici* merely refer to a general sense of environmental responsibility and state abstract rights and liberties devoid of articulable or discernable standards and regulations to identify practices that constitute international environmental abuses or torts.<sup>98</sup>

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customary international law is called the *opinio juris* requirement. *See infra* note 94 and accompanying text.

<sup>93</sup> *The Paquete Habana*, 175 U.S. at 700.

<sup>94</sup> PHILIPPE SANDS, *PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW* 143-47 (2d ed. 2003); MARK W. JANIS & JOHN E. NOYES, *INTERNATIONAL LAW: CASES AND COMMENTARY* 96 (2001).

<sup>95</sup> *See supra* notes 57-58 and accompanying text.

<sup>96</sup> *See supra* notes 36-40 and accompanying text.

<sup>97</sup> *Beanal v. Freeport-McMoran, Inc.*, 197 F.3d 161, 167 (5th Cir. 1999).

<sup>98</sup> *Id.*

The Fifth Circuit rejected the factual position that the precautionary principle is actually followed by all states and the legal position that those states believe they are legally bound to do so.<sup>99</sup> Both conclusions appear to reflect international reality. As the precautionary principle is new, in a formative stage, and potentially sweeping in its application, it is hardly reflective of customary international law at this time.<sup>100</sup>

*B. Treaty Obligations as a Source of the Precautionary Principle in United States Law*

Even if the precautionary principle has not become a part of United States law via customary international law, the government has the authority under the Constitution to incorporate the principle into domestic law through its treaty powers.<sup>101</sup> At this time there does not appear to be an example of a treaty in which the United States has committed itself to abide by a precautionary principle or to enact legislation to do so. However, there is one example that illustrates how such an importation could occur. The United States is a party to the United Nations Framework Convention on Climate Change, which has entered into force.<sup>102</sup> Article 3 of that convention states, in part:

The Parties *should* take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty *should* not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change *should* be cost-effective so as to ensure global benefits at the lowest possible cost.<sup>103</sup>

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<sup>99</sup> *Id.*

<sup>100</sup> The Dispute Settlement Body of the World Trade Organization implicitly reached the same conclusion. See Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R (Jan. 16, 1998), available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds26\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm) (follow “Appellate Body Report” hyperlink).

<sup>101</sup> U.S. CONST. art IV, cl. 2, (“This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land . . .”).

<sup>102</sup> United Nations Framework Convention on Climate Change, *supra* note 37.

<sup>103</sup> *Id.* art. 3 (emphasis added).

The use of “should” throughout Article 3 and the failure to set forth specific obligations, however, mean that the treaty does not actually require the United States to incorporate the precautionary principle into its climate policy and corresponding laws.<sup>104</sup>

The United States is also a party to the Montreal Protocol on Substances that Deplete the Ozone Layer (“Montreal Protocol”).<sup>105</sup> Though it does not directly mandate adherence to the precautionary principle, the parties to this treaty did not wait for scientific certainty that several chemicals were causing the depletion of the ozone layer before accepting binding obligations to eliminate their production and consumption.<sup>106</sup> In this way, the Montreal Protocol was able to implement the earlier decision by each party to apply the precautionary principle without any explicit mention of the term. The United States did enact legislation to carry out the obligations it had assumed under this treaty.<sup>107</sup>

One could view this sequence of events as the United States entering into a treaty that: (1) required it to enact a law adopting a precautionary approach, and (2) specified what that law would say, namely, that it would ban the production and consumption of the listed chemicals. Applying the language of Principle 15 of the Rio Declaration, entering into the Montreal Protocol reflects the decisions that: (1) ozone depleting chemicals were “threats of serious or irreversible damage,”<sup>108</sup> even though full scientific certainty was lacking,<sup>109</sup> (2) lack of full scientific certainty was not “a reason for postponing cost-effective measures to prevent environmental

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<sup>104</sup> This conclusion is contrary to that reached by another commentator regarding the obligations of Australia: “Australia has ratified the Convention on Biological Diversity and Framework Convention on Climate Change, both of which have entered into force. Therefore, Australia has international obligations under these Conventions to implement the precautionary principle domestically, in legislation relating to biodiversity and greenhouse emissions.” Barton, *supra* note 70, at 516-17 (citation omitted).

<sup>105</sup> Montreal Protocol on Substances That Deplete the Ozone Layer, Sept. 16, 1987, 26 I.L.M. 1550 (entered into force Jan. 1, 1989).

<sup>106</sup> For a history of the scientific uncertainty on the cause of the depletion of ozone in the stratosphere and the ultimate consensus, see National Oceanic and Atmospheric Administration, Reports to the Nation on Our Changing Planet: Our Ozone Shield, <http://www.ogp.noaa.gov/library/rtnf92.htm> (last visited Mar. 1, 2007).

<sup>107</sup> See 42 U.S.C. §§ 4671-71q (2007) (defining ozone-depleting substances and prohibiting their production); 26 U.S.C §§ 4681-82 (2007) (imposing a tax on ozone-depleting substances).

<sup>108</sup> Rio Declaration, *supra* note 58, princ. 15.

<sup>109</sup> *Id.*

degradation;”<sup>110</sup> and (3) banning production and consumption of certain chemicals was such a cost-effective measure.<sup>111</sup>

#### IV. UNITED STATES STATUTES, REGULATIONS, AND POLICIES THAT IMPLEMENT THE PRECAUTIONARY PRINCIPLE

The precautionary principle, which is a substantive policy, can be implemented primarily through either substantive or procedural requirements or both. Three procedural mechanisms have been used in United States laws, regulations, and policies as the primary methods for implementing the precautionary principle: (1) allocation of the burden of proof; (2) creation of rebuttable presumptions; and (3) certification of compliance requirements. Each of these procedures ultimately is linked to a substantive standard. The typical way in which the precautionary principle is implemented is for Congress or a regulatory agency to announce a substantive assumption, adopt a standard, allocate the burden of proof or create a rebuttable presumption, and create a procedure under which the assumption can be challenged in particular cases.<sup>112</sup>

In addition to statutes that require a precautionary approach, there are statutes that facilitate or enable agencies to implement the precautionary principle if they so choose. These statutes are agencies' seeing-eye dogs for potential environmental risks. Two examples of such laws are the National Environmental Policy Act (“NEPA”)<sup>113</sup> and the Emergency Planning and Community Right to Know Act (“EPCRA”).<sup>114</sup> The role of NEPA in facilitating the achievement of precautionary policies was considered above.<sup>115</sup> EPCRA can function in an analogous way. For example, by allowing for a precautionary approach in EPCRA, Congress was able to obtain the data necessary for identifying and controlling hazardous air pollutants.<sup>116</sup> Additionally, EPA has integrated the Toxics Release

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<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> See *supra* notes 88-89 and accompanying text.

<sup>113</sup> 42 U.S.C. §§ 4331-70(f) (2007).

<sup>114</sup> 42 U.S.C. §§ 11001-50 (2007).

<sup>115</sup> See *supra* notes 71-80 and accompanying text.

<sup>116</sup> See ROBERT V. PERCIVAL ET AL., ENVIRONMENTAL REGULATION: LAW, SCIENCE, AND POLICY 485-486 (4th ed. 2003) (“The TRI [Toxics Release Inventory] proved invaluable to Congress in specifying the 189 toxic chemicals required to be regulated as hazardous air pollutants in the 1990 Clean Air Act Amendments.”). For an extensive analysis of how the Toxics Release Inventory data mandated by EPCRA is used, see U.S. ENVTL. PROT. AGENCY, EPA-260-R-002-004, HOW ARE THE TOXICS RELEASE INVENTORY DATA USED? (2003), [http://www.epa.gov/triinter/guide\\_docs/2003\\_datausepaper.pdf](http://www.epa.gov/triinter/guide_docs/2003_datausepaper.pdf).

Inventory (“TRI”) database that is generated under EPCRA into its other enforcement and regulatory functions.<sup>117</sup>

The precautionary principle can become a part of United States environmental law as a statutory requirement or through the exercise of discretion by agencies implementing a statute. Because agencies’ implementation strategies can change with shifts in political power, precautionary approaches tend to have more stability and endurance when incorporated into statutory requirements. However, some precautionary principles first established by the exercise of an agency’s discretion have become institutionalized and play a significant role in achieving the agency’s mission.

A. *Precautionary Approaches Established by Agency Discretion*

The policy of achieving caution by including a margin of safety in agency standards was critical in *Dioxin/Organochlorine Center v. Clarke*.<sup>118</sup> In this case, EPA imposed a total maximum daily load of an ambient concentration of dioxin of 0.013 parts per quadrillion (“ppq”) for rivers in the Columbia River Basin.<sup>119</sup> The Dioxin/Organochlorine Center claimed that this standard was “arbitrary and capricious”<sup>120</sup> because it would not protect subpopulations adequately, given that they consumed more fish than the 6.5 grams per day used by EPA in its risk calculations.<sup>121</sup> The court rejected this argument because EPA had made the following conservative assumptions in its risk calculations:

First, the EPA notes that the “potency factor” it adopted for dioxin was the most stringent in the world. Potency factors for dioxin used by other agencies or foreign governments would have resulted in numerical values between five and sixteen hundred times less stringent.

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<sup>117</sup> *Id.* (stating that “EPA has used the TRI as the cornerstone of its pollution prevention strategy and as a means for improving the effectiveness of existing regulatory programs,” and giving several examples).

<sup>118</sup> 57 F.3d 1517 (9th Cir. 1995).

<sup>119</sup> *Id.* at 1519.

<sup>120</sup> *Id.* at 1520.

<sup>121</sup> *Id.* at 1524.

Second, the EPA argues that it reasonably concluded that higher consumption of fish among subpopulations did not imply that the total quantity of fish consumed would be maximally contaminated.<sup>122</sup>

The court balanced the non-cautionary failure of EPA to consider risk to Native Americans who consumed much more fish than the amount assumed in the risk calculations with the cautionary nature of using an extremely high "potency factor" for dioxin and concluded that the plaintiff had failed to prove EPA's decision was unreasonable.<sup>123</sup> Had EPA been less cautious in its assumptions, the court would have had more difficulty in finding a counterweight to balance against a clear flaw in the calculation of risk.<sup>124</sup> In this case, a precautionary approach not only had a positive effect on the environment and on public health, but it also protected the EPA from an administrative and regulatory perspective as well.

In performing risk assessments, agencies must often decide whether or not to assume the existence of a threshold below which no harm occurs.<sup>125</sup> An agency's assumption that there is no threshold is strong

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<sup>122</sup> *Id.* (The court held "that the EPA's decision to adopt a 0.013 ppq ambient dioxin concentration cannot be considered arbitrary and capricious with regard to the effect of dioxin on human subpopulations").

<sup>123</sup> *Id.*

<sup>124</sup> *See, e.g., Nat'l Res. Def. Council v. U.S. Env'tl. Prot. Agency*, 16 F.3d 1395, 1398-99 (4th Cir. 1993). In this case, "six factors [were] considered in determining the numeric dioxin criteria: (1) cancer potency; (2) risk level; (3) fish consumption; (4) bioconcentration; (5) water intake; and (6) body weight." *Id.* at 1398 n.3. The fourth circuit found for the defendant states even though the defendant states did not use the most conservative value for "cancer potency" because they did use a value that was somewhat conservative and their overall balancing of the six factors was reasonable. *Id.* at 1398-99, 1405-06.

<sup>125</sup> *See, e.g., City of Waukesha v. U.S. Env'tl. Prot. Agency*, 320 F.3d 228 (D.C. Cir. 2003) (upholding EPA no-threshold for radioactive substances); *Chlorine Chemistry Council v. U.S. Env'tl. Prot. Agency*, 206 F.3d 1286 (D.C. Cir. 2000); *Pub. Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1498 (D.C. Cir. 1986) (upholding an Occupational Safety and Health Administration rule that employed "a linear, no-threshold model similar to that used by EPA's Carcinogen Assessment Group" for determining exposure limits for ethylene oxide). In *Chlorine Chemistry Council*, the EPA refused to adopt a threshold for chloroform in drinking water even though a report from its scientific advisory board recommended one because it represented changing a longstanding policy, and EPA wanted more time to evaluate the scientific evidence and analytical approach used by the board. *Chlorine Chemistry Council*, 206 F.3d at 1290-91. The court rejected the EPA's position because the statute required it to use the best available scientific evidence as the basis for its drinking water standards, and the EPA's refusal to follow the recommendation of its scientific advisory board violated that statutory mandate. *Id.* at 1291. *See also Int'l*

evidence that it is applying a precautionary principle.<sup>126</sup> Two important examples of such assumptions are the EPA's positions that: (1) there is no safe threshold level for carcinogens in the absence of contrary evidence; and (2) there is no threshold level below which radioactive substances cause no harm.

EPA's position on carcinogens was upheld in *International Fabricare Institute v. Environmental Protection Agency*.<sup>127</sup> In an action challenging a rule established under authority granted in the Safe Drinking Water Act, EPA had set regulatory limits on certain contaminants based on its policy that "in the absence of other data, . . . there is no known threshold' at which these known or probable carcinogens can be safely tolerated."<sup>128</sup> Although the no threshold assumption was challenged by industrial groups who offered a letter written by two established scientists to an industry magazine ("the Ames letter")<sup>129</sup> and the statement of one additional doctor (Dr. Gori), EPA did not change its position.<sup>130</sup> The court upheld the EPA's decision to assume the absence of a threshold at which carcinogens begin to cause harm:

The Ames letter advanced the argument that "low doses of carcinogens appear to be . . . less hazardous than is generally thought[.]" Gori pointed out the difficulties inherent in drawing conclusions about humans from studies done on animals. Neither document, however, reflected the results of any new empirical studies or laboratory experiments. Neither offered a new statistical analysis of existing data.<sup>131</sup>

Therefore, in the court's opinion, the evidence offered by the industrial groups did no more than point out that there was a lack of scientific

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*Fabricare Inst. v. Env'tl Prot. Agency*, 972 F.2d 384 (D.C. Cir. 1992) (setting the threshold at zero for the dry cleaning chemical in question).

<sup>126</sup> See, e.g., Barton, *supra* note 70, at 514-15 (tracing a shift from assimilative capacity to the precautionary principle in international instruments).

<sup>127</sup> 972 F.2d 384 (D.C. Cir. 1992).

<sup>128</sup> *Int'l Fabricare Inst.*, 972 F.2d at 388 (quoting National Primary Drinking Water Regulations, National Secondary Drinking Water Regulations, 56 Fed. Reg. 3526, at 3533 (1991)).

<sup>129</sup> Bruce N. Ames & Lois Swirsky Gold, *Pesticides, Risk, and Applesauce*, 244 SCIENCE 755 (1989). Bruce Ames and Lois Gold were professors at the University of California at Berkeley. *Id.*

<sup>130</sup> *Int'l Fabricare Inst.*, 972 F.2d at 391.

<sup>131</sup> *Id.* (citations omitted).

certainty and a lack of scientific consensus on the question of a threshold for the carcinogens in question and carcinogens in general.<sup>132</sup> Instead of justifying a change of position, the letter and the doctor's statement underscored the wisdom in the precautionary approach taken by EPA.<sup>133</sup>

Agencies' no threshold rules for radioactive substances have also been upheld. In *City of Waukesha v. Environmental Protection Agency*, EPA based its standards for radium 226 and 228 in drinking water on a no threshold assumption.<sup>134</sup> Various municipal water utilities and consumer groups challenged these standards, arguing that data from studies of clock dial painters proved the existence of a threshold.<sup>135</sup> EPA rejected this argument, and the court upheld that decision:

Petitioners further contend that the dial painter data require the use of a quadratic dose-response curve for bone cancer . . . rather than the linear, non-threshold ("LNT") model used by EPA, which assumes that the risk is directly proportional to the dosage and that there is no threshold dosage below which there is no risk. Here, again, the agency sufficiently justified its choice of model to satisfy the "rational relationship" standard.<sup>136</sup>

Thus, it appears that courts will apply the reasonableness or rational relationship standard when an agency's precautionary approach to regulating risks from radioactive substances or carcinogens is challenged. The application of this deferential standard will almost always result in court approval of an agency's precautionary position.<sup>137</sup>

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<sup>132</sup> *Id.*

<sup>133</sup> For other cases in which agencies' no threshold rules for carcinogens have been challenged, see *supra* note 125.

<sup>134</sup> 320 F.3d 228 (D.C. Cir. 2003).

<sup>135</sup> *Id.* at 249.

<sup>136</sup> *Id.* (citations omitted).

<sup>137</sup> In an extensive opinion in *In re TMI Litigation*, 193 F.3d 613 (3rd Cir. 1999), the court devoted careful attention to the question of a threshold of harm for exposure to radioactive substances. It adopted the rule that for deterministic effects, which "result when an organism can no longer compensate for the extent of dead cells by proliferating viable cells," there was a threshold. *Id.* at 640-42. However, the court found that for stochastic effects there is no threshold:

Stochastic effects are those which result when an irradiated cell is modified rather than killed. Even at very low doses it is possible that ionizing radiation may deposit sufficient energy into a cell to modify it. Thus, there is a finite possibility for the occurrence of a stochastic event

Moreover, if an agency in the exercise of its discretion adopts a precautionary nuclear policy, but not a standard, courts will not interpret the policy as duty of care under tort law. For example, the Nuclear Regulatory Commission and the Department of Energy have a policy of requiring the nuclear industry to limit exposure to a level of radiation “as low as reasonably achievable (“ALARA”).”<sup>138</sup> When plaintiffs claiming harm from radiation from the Three Mile Island accident attempted to recover on the theory that defendants had violated ALARA, the court rejected the argument that these precautionary policies had created a duty or standard.<sup>139</sup> A contrary result might have discouraged agencies from adopting precautionary policies.

*B. Institutionalizing Caution by Statute*

1. The Endangered Species Act of 1973

The Endangered Species Act of 1973 (“ESA”) is an example of a statute in which Congress not only authorized but required a precautionary approach.<sup>140</sup> The Secretaries of the Department of Interior and Commerce are directed to list endangered species,<sup>141</sup> which are defined as those that are “in danger of extinction throughout all or a significant portion of its range,”<sup>142</sup> and threatened species, which are species that are likely to become endangered.<sup>143</sup> The fact that protection is to begin before a species is actually endangered demonstrates that the ESA is designed to prevent harm, and is thus inherently precautionary. Moreover,

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even at very small doses. Consequently, it is assumed that there is no threshold for the initiation of a stochastic event.

*Id.* at 642 (citations omitted).

<sup>138</sup> 10 C.F.R. § 20.1101(b) (2007) (noting the policy of the Nuclear Regulatory Commission); 10 C.F.R. § 835.101 (noting the policy of the Department of Energy).

<sup>139</sup> *In re TMI*, 67 F.3d 1103 (3rd Cir. 1995).

<sup>140</sup> Endangered Species Act of 1973, Pub. L. No. 93-205, 87 Stat. 884 (1973) (codified at 16 U.S.C. §§ 1531-44 (2007)).

<sup>141</sup> 16 U.S.C. § 1533(a) (2007). This obligation is judicially enforceable. *See, e.g.*, *Northern Spotted Owl v. Hodel*, 716 F. Supp. 479, 480 (W.D. Wash. 1988).

<sup>142</sup> 16 U.S.C. § 1532(6).

<sup>143</sup> *Id.* § 1532(20).

the obligation to designate critical habitat for each listed species<sup>144</sup> reflects this same preventative, and therefore precautionary, approach.<sup>145</sup>

In *Tennessee Valley Authority v. Hill*,<sup>146</sup> the Supreme Court held that by enacting the ESA Congress had adopted a policy which Congress itself described as “institutionalized caution.”<sup>147</sup> The members of Congress adopted the policy because of their “concern over the risk that might lie in the loss of *any* endangered species.”<sup>148</sup> The Court found that “Congress was concerned about the *unknown* uses that endangered species might have and about the *unforeseeable* place such creatures may have in the chain of life on this planet.”<sup>149</sup> This articulation of the risk management approach taken by Congress is quite similar to Principle 15 of the Rio Declaration,<sup>150</sup> although it omits the requirement that protecting endangered species must be cost-effective.<sup>151</sup>

The Supreme Court’s interpretation of Section 7 of the ESA in *Tennessee Valley Authority v. Hill* proved to be too cautious for development interests. Only five years after the Court’s decision, Congress passed the Endangered Species Act Amendments of 1987.<sup>152</sup> This Act amended Section 7, which requires federal agencies to ensure that their actions are not likely to jeopardize the continued existence of any endangered species and which prohibits federal actions that adversely modify the critical habitat of a listed species,<sup>153</sup> to establish a committee which, in response to a petition, can grant exemptions to the limitations placed on federal agencies in this section.<sup>154</sup> An exemption can be granted only if the committee finds that:

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<sup>144</sup> *Id.* § 1533(a)(3)(A)(I). This obligation is also judicially enforceable. *See, e.g.*, Northern Spotted Owl v. Lujan, 758 F. Supp. 621, 627-628 (W.D. Wash. 1991).

<sup>145</sup> *See* John Harte, *Land Use, Biodiversity, and Ecosystem Integrity: The Challenge of Preserving Earth’s Life Support System*, 27 *ECOLOGY L.Q.* 929, 943-46 (2001).

<sup>146</sup> 437 U.S. 153 (1978).

<sup>147</sup> *Id.* at 194.

<sup>148</sup> *Id.* at 177.

<sup>149</sup> *Id.* at 178-79.

<sup>150</sup> *See* Rio Declaration, *supra* note 58, princ. 15.

<sup>151</sup> *See Tenn. Valley Auth.*, 437 U.S. at 184 (stating that “[t]he plain intent of Congress in enacting this statute was to halt and reverse the trend toward species extinction, *whatever the cost*”) (emphasis added).

<sup>152</sup> Endangered Species Act Amendments of 1978, Pub. L. No. 95-632, 92 Stat. 3751 (1978).

<sup>153</sup> Endangered Species Act of 1973 § 7, 87 Stat. at 892 (codified as amended at 16 U.S.C. § 1536(a)(2) (2007)).

<sup>154</sup> Endangered Species Act Amendments of 1978 § 3, 92 Stat. at 3752-60 (codified at 16 U.S.C. § 1536(e)-(p)).

- (i) there are no reasonable and prudent alternatives to the agency action;
- (ii) the benefits of such action clearly outweigh the benefits of alternative courses of action consistent with conserving the species or its critical habitat, and such action is in the public interest; [and]
- (iii) the action is of regional or national significance . . . .<sup>155</sup>

The prohibition on the taking of endangered or threatened species contained in Section 9 of the ESA<sup>156</sup> was also weakened.<sup>157</sup> In 1982, Section 10 was modified to give the agencies administering the ESA the discretion to issue permits that allow for the incidental taking of endangered and threatened species if the applicant submits a habitat conservation plan that complies with statutory and regulatory requirements.<sup>158</sup> The amendments to Sections 7, 9, and 10 show that Congress weakened the prohibitions in the original ESA to give the agencies authority to balance the cost and impact on the economy of protecting a species with the risk of extinction of the species. With these amendments, the current code provisions stemming from the ESA are much closer to Principle 15 of the Rio Declaration than the original Act.<sup>159</sup> The law does, however, continue to embody a strong precautionary principle.

Although the ESA itself is precautionary, its implementation is frequently not.<sup>160</sup> Protection of a species is triggered only when it is listed.<sup>161</sup> Therefore, the failure to list a species or a delay in its listing can defeat the law's objective. Even though obligations regarding listing are mandatory,<sup>162</sup>

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<sup>155</sup> 16 U.S.C. § 1536(h)(1)(A).

<sup>156</sup> Endangered Species Act of 1973 § 9, 87 Stat. at 893-95.

<sup>157</sup> See Endangered Species Act Amendments of 1978 § 4, 92 Stat. at 3760 (codified at 16 U.S.C. § 1538(b)(2)).

<sup>158</sup> Endangered Species Act Amendments of 1982, Pub. L. No. 97-304, § 6, 96 Stat. 1411, 1422-24 (1982) (codified at 16 U.S.C. § 1539(a)).

<sup>159</sup> See Rio Declaration, *supra* note 58, princ. 15.

<sup>160</sup> This is a common phenomenon with statutes that protect the environment. See *infra* Part IV.B.4 (discussing the implementation of the Clean Air Act); see also *infra* Part IV.B.5 (discussing the implementation of the Clean Water Act).

<sup>161</sup> 16 U.S.C. § 1533(d).

<sup>162</sup> See, e.g., *Env'tl Def. Ctr. v. Babbitt*, 73 F.3d 867, 871 (9th Cir. 1995) (compelling the Secretary of the Interior to act on a proposed rule listing the red-legged frog as an endangered species in a timely manner); *Am. Lands Alliance v. Norton*, 242 F. Supp. 2d 1 (D.D.C. 2003) (finding that the FWS violated the ESA when it failed to investigate whether the Gunnison sage grouse should be listed as an endangered species after a public petition was filed); *Northern Spotted Owl v. Lujan*, 758 F. Supp. 621 (W.D. Wash.

agency discretion provides ample room for delay. One commentator has characterized the practice of administrative agencies as “exploiting their discretion to the fullest to avoid political controversy.”<sup>163</sup> The struggle to have the Canada Lynx listed provides an example of this exploitation of discretion.<sup>164</sup> The initial petitioning process resulted in a decision by the Fish and Wildlife Service (“FWS”) not to list this species.<sup>165</sup> Conservation groups challenged this decision in court and the district court found against the agency.<sup>166</sup> Next, the FWS announced that a listing was warranted, but would have to wait while the Service worked on “higher priority” species.<sup>167</sup> This resulted in a second suit which was eventually settled by the agency’s agreement to list the species.<sup>168</sup> Yet another lawsuit was necessary to force the agency to designate critical habitat for the Canada Lynx.<sup>169</sup> Additional, and perhaps more well-known, examples of agencies failing to implement the ESA in accordance with its precautionary approach include the listing of the snail darter<sup>170</sup> and the northern spotted owl.<sup>171</sup>

## 2. The Delaney Clauses

The Delaney Clauses present another example of the implementation of the precautionary principle through substantive statutory standards. These clauses prohibit the use of color and food additives that have been found to cause cancer in humans or animals.<sup>172</sup> As enacted, these statutes are precautionary regarding cancer risk, but not regarding risk qua risk. This was observed by the Court of Appeals for the D.C. Circuit in *Public*

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1991) (confirming that the FWS had a duty to designate critical habitat for the northern spotted owl after it was listed as a threatened species).

<sup>163</sup> Holly Doremus, *Adaptive Management, the Endangered Species Act, and the Institutional Challenges of “New Age” Environmental Protection*, 41 WASHBURN L.J. 50, 58 (2001).

<sup>164</sup> *Defenders of Wildlife v. Norton*, 239 F. Supp. 2d 9 (D.D.C. 2002). See Robert L. Glicksman, *The Value of Agency-Forcing Citizen Suits to Enforce Nondiscretionary Duties*, 10 WIDENER L. REV. 353, 370-371 (2004) (discussing the history and details of this protracted dispute).

<sup>165</sup> *Defenders of Wildlife*, 239 F. Supp. 2d at 14-15.

<sup>166</sup> *Id.* at 15.

<sup>167</sup> *Id.* at 15-16.

<sup>168</sup> *Id.* at 16.

<sup>169</sup> *Id.* at 17.

<sup>170</sup> See *Tenn. Valley Auth. v. Hill*, 437 U.S. 153 (1978).

<sup>171</sup> For a summary of the protracted struggle regarding the northern spotted owl and its outcome, see PERCIVAL, *supra* note 116, at 924-28.

<sup>172</sup> 21 U.S.C. § 379e(5)(B) (2007) (discussing the use of color additives); 21 U.S.C. § 348(c)(3)(A) (discussing the use of food additives).

*Citizen v. Young*.<sup>173</sup> In this case, a public interest group challenged the inherent authority of the Food and Drug Administration to approve two color additives, where the risks of inducing cancer by the two additives were one in nineteen billion and one in nine million, because they presented only a de minimis risk.<sup>174</sup> The court rejected the agency's claim of inherent authority, pointing out the possibility that this policy may increase overall risk:

The primary goal of the Act is human safety, but literal application of the Delaney Clause may in some instances increase risk. No one contends that the Color Additive Amendments impose a zero-risk standard for non-carcinogenic substances . . . . As a result, makers of drugs and cosmetics who are barred from using a carcinogenic dye carrying a one-in-20-million lifetime risk may use instead a noncarcinogenic, but toxic, dye carrying, say, a one-in-10-million lifetime risk. The substitution appears to be a clear loss for safety.<sup>175</sup>

This example underscores the fact that the precautionary principle, like all general approaches, can be implemented in a way that might have the unintended consequence of increasing rather than decreasing caution.<sup>176</sup> Such examples demonstrate that the implementation of a precautionary approach might require refinement to eliminate the unintended consequences. This is exactly what the President and Congress did in 1992 after a court held that the EPA had no authority under the Delaney Clause to adopt a de minimis exception regarding food additives.<sup>177</sup> The President, EPA, and Congress worked together to follow the path that the court suggested was the only way to achieve their objectives.<sup>178</sup> In the end, Congress enacted the Food Quality Protection Act to

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<sup>173</sup> 831 F.2d 1108, 1111-13 (D.C. Cir. 1987).

<sup>174</sup> *Id.*

<sup>175</sup> *Id.* at 1113.

<sup>176</sup> See, e.g., Rena I. Steinzor, *The Legislation Of Unintended Consequences*, 9 DUKE ENVTL. L. & POL'Y F. 95 (1998) (discussing the application of Superfund liability to ordinary garbage as a negative example of legislation's unintended consequences).

<sup>177</sup> *Les v. Reilly*, 968 F.2d 985, 989 (9th Cir. 1992).

<sup>178</sup> *Id.* at 990 ("If there is to be a change, it is for Congress to direct."). See Stephen L. Johnson, *Implementation of the Food Quality Protection Act*, 52 FOOD & DRUG L.J. 525, 525, 525 n.4 (1997) (stating that "Congress passed the FQPA unanimously . . . [and President Clinton] sign[ed] the bill into law a little over a week later. . . . [T]he legislation

provide that pesticide chemical residues in raw or processed food are not included in the definition of "food additive."<sup>179</sup> Such residues are permitted if EPA finds that there is reasonable certainty that they present no harm.<sup>180</sup> The amendment, like those to the ESA discussed above,<sup>181</sup> brought the Delaney Clause more in line with the precautionary principle given in Principle 15 of the Rio Declaration.<sup>182</sup> Today, if cost-effective methods can be found by industry to limit but not eliminate the presence of pesticide chemical residues in foods, the foods can still be sold.<sup>183</sup>

### 3. The Occupational Safety and Health Act

As the discussion of the implementation of the ESA above demonstrates,<sup>184</sup> the precautionary nature of a policy is greatly dependent on how agencies exercise their discretion. This was recognized by the Supreme Court in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*,<sup>185</sup> a case involving the Occupational Safety and Health Act.<sup>186</sup> The Court was asked to consider the legality of a standard issued by the Occupational Safety and Health Administration ("OSHA") for benzene.<sup>187</sup> As is often the case, there was insufficient data to set the standard with scientific certainty, and OSHA had exercised its judgment in a cautionary way in attempting to manage the risk this chemical posed in the workplace.<sup>188</sup> The plurality approved of this approach to risk management: "so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in

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was backed by a wide variety of public interest, industry, and academic groups," and noting that this support included "Dr. Lynn Goldman, Ass't Admin., Environmental Protection Agency providing the recommendations of the National Academy of Sciences"). Mr. Johnson was Acting Director of the Office of Pesticide Programs, Environmental Protection Agency. *Id.* at 525 n.\*.

<sup>179</sup> Food Quality Protection Act of 1996 § 402, Pub. L. No. 104-170, 110 Stat. 1489, 1513 (1996) (codified at 21 U.S.C. § 321(s) (2007)).

<sup>180</sup> 21 U.S.C. § 346a.

<sup>181</sup> See *supra* notes 152-59 and accompanying text.

<sup>182</sup> Rio Declaration, *supra* note 58, princ. 15.

<sup>183</sup> See 21 U.S.C. § 346a.

<sup>184</sup> See *supra* notes 160-71 and accompanying text.

<sup>185</sup> 448 U.S. 607, 656 (1980).

<sup>186</sup> Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (1970) (codified as amended at 29 U.S.C. §§ 651-78 (2007)).

<sup>187</sup> *Indus. Union Dep't*, 448 U.S. at 611.

<sup>188</sup> *Id.* at 613.

interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection.”<sup>189</sup>

#### 4. The Clean Air Act

Under the 1970 Clean Air Act Amendments (“CAA”), hazardous air pollutants (“HAP”) from stationary sources are regulated in Section 112.<sup>190</sup> Before additional amendments were passed in 1990, Section 112 required a three part process: (1) EPA was to publish a list of HAPs and hold hearings regarding the risk of each; (2) EPA was to issue standards for each unless it concluded on the basis of the information generated at the hearings that a pollutant clearly was not a hazardous air pollutant; and (3) the standard was to be set at a level which provided “an ample margin of safety to protect the public health.”<sup>191</sup> The pre-1990 version of Section 112 appears to be precautionary because of the allocation of the burden of proof on those opposing regulation, and the direction to establish a standard of proof with a margin of safety for public health.<sup>192</sup> However, this precautionary nature was rendered illusory by a Second Circuit decision regarding the discretion of EPA in deciding whether or not to classify a substance as a hazardous air pollutant:

The contention of the Administrator and industry intervenors that § 112(b)(1)(A) only requires that the Administrator list those pollutants which may result in a “significant” increase in mortality or serious illness is not so unreasonable that it justifies this court’s interference with the Administrator’s discretionary power to identify hazardous air pollutants. . . . I hold only that the Administrator’s interpretation of that section is not so unreasonable that this district court, constrained by Congress’ grant of limited jurisdiction, should depart from the well settled rule that courts should show “great deference to the interpretation given the statute by the officers or agency charged with its administration.”<sup>193</sup>

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<sup>189</sup> *Id.* at 656.

<sup>190</sup> Clean Air Act Amendments of 1970 § 4(a), Pub. L. No. 91-604, 84 Stat. 1676, 1685-86 (1970) (codified as amended at 42 U.S.C. § 7412 (2007)).

<sup>191</sup> *Id.*

<sup>192</sup> *See id.*

<sup>193</sup> *Natural Res. Def. Council v. Thomas*, 689 F. Supp. 246, 256 (S.D.N.Y. 1988), *aff’d*, 885 F.2d 1067 (2d Cir. 1989) (citations omitted).

Over time the slow progress made by EPA in identifying and controlling hazardous air pollutants made it clear that the Section needed to be amended in order to be effective.<sup>194</sup> This history is documented in *Natural Resources Defense Council v. Thomas*,<sup>195</sup> where the court noted that:

The EPA first set emission standards for air pollutants under § 112 shortly after the Act's enactment in 1970. To date, the EPA has listed or issued final regulations for approximately eight or nine pollutants and has made final decisions not to regulate approximately one dozen others. Overall, it can be safely said that the EPA has not rushed to regulate air pollutants under § 112.<sup>196</sup>

In the current version of Section 112 Congress has listed 189 chemicals which are defined as HAPs.<sup>197</sup> This congressional determination of which chemicals should be regulated has been criticized by some scholars:

Prior to the amendment, a substance could be regulated as a HAP only after EPA made a science-based determination following a rigorous risk analysis that determined the substance posed a substantial risk to human health at ambient air levels. Thus, the amendment substituted legislative fiat for risk assessment . . . .<sup>198</sup>

Under the current version of Section 112, modifications to this list may be made as follows:

(B) The Administrator shall add a substance to the list upon a showing by the petitioner or on the Administrator's own determination that the substance is an air pollutant and that emissions, ambient concentrations, bioaccumulation or deposition of the substance are known to cause or *may reasonably be anticipated to cause* adverse effects to human health or adverse environmental effects.

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<sup>194</sup> For a detailed history of the events leading up to the changes in Section 112, see PERCIVAL, ET AL., *supra* note 116, at 455-64.

<sup>195</sup> 689 F. Supp. 246.

<sup>196</sup> *Id.* at 249 (citations omitted).

<sup>197</sup> 42 U.S.C. § 7412(b) (2007).

<sup>198</sup> Goldstein & Carruth, *supra* note 49, at 253 (citation omitted). In 2003, Dr. Goldstein was president of the Society for Risk Analysis. *Id.* at 247 n.\*.

(C) The Administrator shall delete a substance from the list upon a showing by the petitioner or on the Administrator's own determination that there is adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.<sup>199</sup>

In addition to this fundamental change in the listing process, Congress replaced the "ample margin of safety to protect the public health" standard<sup>200</sup> with a technology-based standard aimed at achieving the maximum degree of reduction in emissions.<sup>201</sup> Thus, Section 112 now contains the three precautionary elements: (1) the preventative standard that allows a substance to be added to the list of HAPs if it "may reasonably be anticipated to cause adverse effects;"<sup>202</sup> (2) the allocation of the burden of proof on the party advocating the deletion of a substance from the list of HAPs;<sup>203</sup> and (3) the imposition of a strict technology-based standard on those that release a HAP into the air.<sup>204</sup> The current version of Section 112 based on these three precautionary elements has been sharply criticized by the President of the Society of Risk Analysis as an example of what he refers to as "pre-emptive precautionary approaches,"

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<sup>199</sup> 42 U.S.C. § 7412(b)(3) (emphasis added).

<sup>200</sup> Clean Air Act Amendments of 1970 § 4(a), 84 Stat. at 1685.

<sup>201</sup> 42 U.S.C. § 7412(d)(2). The pre-1990 standard of an "ample margin of safety" is still present in the amended statute, but plays a reduced role. *See id.* § 7412(f)(2).

<sup>202</sup> *Id.* § 7412(b)(3)(B).

<sup>203</sup> *Id.* § 7412(b)(3)(C).

<sup>204</sup> *Id.* § 7412(d)(2). A technology-based law requires pollution limits to be set to implement technology that is economically feasible no matter how small the risk. *See* Oliver Houck, *Tales from a Troubled Marriage: Science and Law in Environmental Policy*, 302 SCIENCE 1926, 1928 (2003).

The theory of [technology-based standards] was very simple: If emissions could be reduced, just do it. It did not matter what the impacts were. It did not matter whether a plant was discharging into Rock Creek, the Potomac River, or the Atlantic Ocean. It didn't matter what scientists said the harm was or where it came from. Just do it.

*Id.* This is clearly precautionary. However, under a technology-based law, if such technology does not exist, risks might not be mitigated adequately even if they are significant. Regulators interested in a precautionary approach must look to other laws to address the risk gaps created by technology-based laws. *See, e.g., Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 497 (1987) (holding that "nothing in the [CWA] bars aggrieved individuals from bringing a nuisance claim pursuant to the law of the source State").

or rules that supplant standard risk-based approaches.<sup>205</sup> This characterization gives too little weight to EPA's initial obligation to demonstrate that a pollutant may reasonably be anticipated to be a HAP and too little recognition to Congress' delegation of authority to EPA.

In an en banc opinion that has been cited with approval by the Supreme Court, the Court of Appeals for the D.C. Circuit reviewed EPA's interpretation of the phrase "will endanger" in the CAA as allowing for the regulation of emissions that "present a significant risk of harm."<sup>206</sup> The court rejected the argument that the EPA can act only after it has concluded a "rigorous step-by-step proof of cause and effect."<sup>207</sup> The court then explained the process EPA must apply in blending science and policy:

Of course, we are not suggesting that the Administrator has the power to act on hunches or wild guesses . . . [H]is conclusions must be rationally justified. . . . However, we do hold that in such cases<sup>208</sup> the Administrator may assess risks. He must take account of available facts, of course, but his inquiry does not end there. The Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as "fact," and the like.<sup>209</sup>

Section 112 is a risk management model designed to be precautionary. It reflects an integration of science and policy rather than a purely scientific approach by authorizing EPA to give science a weight that does not control the outcome and to act long before there is scientific consensus as long as the ultimate balance is reasonable.

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<sup>205</sup> Goldstein & Carruth, *supra* note 49, at 249-50, 253 (stating that "[t]he central elements of the amended HAPs program mandate precautionary action that is not based on, and in fact supplants, risk analysis").

<sup>206</sup> *Ethyl Corp. v. U.S. Env'tl. Prot. Agency*, 541 F.2d 1 (D.C. Cir. 1976) (en banc). The Supreme Court approved of this opinion's analysis in *Immigration & Naturalization Serv. v. Chadha*, 462 U.S. 919, 953 n.16 (1983).

<sup>207</sup> *Ethyl Corp.*, 541 F.2d at 28.

<sup>208</sup> By "such cases," the court was referring to cases "[w]here a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator." *Id.*

<sup>209</sup> *Id.*

Sections 108<sup>210</sup> and 109<sup>211</sup> of the CAA also allow for the incorporation of the precautionary principle into regulatory policies. These sections regulate criteria pollutants, which are air pollutants for which EPA has been able to construct a criteria document including a dose-response table based on the latest scientific knowledge.<sup>212</sup> To date EPA has been able to develop criteria documents for only six pollutants.<sup>213</sup> Once a pollutant is listed as a criteria pollutant, EPA must establish a national ambient air quality standard for it at a level “the attainment and maintenance of which in the judgment of the administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.”<sup>214</sup> This standard is clearly precautionary.

Before EPA can regulate an air pollutant under these sections, however, it must develop a criteria document that is so complex and demanding of time and resources that the precautionary nature of Sections 108 and 109 can be diminished through agency implementation.<sup>215</sup> The scientific complexity of developing a criteria document can be a mask for a political or economic hostility to listing a pollutant. In the extremely rare instances when adequate scientific data to develop a criteria document for a pollutant exist, the pollutant must be listed<sup>216</sup> and the precautionary principle of Section 109 becomes applicable. Moreover, the Administrator of EPA has discretion to apply a precautionary approach to conclude that adequate scientific data exist to justify listing a pollutant even if the data are far short of scientific certainty.<sup>217</sup> Former EPA Administrator Carol Browner concluded that fine particulate matter of less than 2.5 micrometers in diameter (“PM2.5”) fell within the precautionary approach of Sections 108 and 109 and warranted regulation.<sup>218</sup> As the editor of a leading environmental science journal published by the

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<sup>210</sup> 42 U.S.C. § 7408.

<sup>211</sup> *Id.* § 7409.

<sup>212</sup> *Id.* § 7408(a)(2).

<sup>213</sup> 40 C.F.R. §§ 50.4-50.12 (2007).

<sup>214</sup> 42 U.S.C. § 7409(b).

<sup>215</sup> *See, e.g.,* *Whitman v. Am. Trucking Ass’n*, 531 U.S. 457, 476 (2001) (describing EPA’s efforts to tighten the standards for two criteria pollutants); *PERCIVAL ET AL.*, *supra* note 116, at 507-08 (describing the administrative process beginning in 1988 with EPA announcing its concern for asthmatics who might need protection from short-term sulfur dioxide peaks and extending to a proposed rule seven years later).

<sup>216</sup> *Natural Res. Def. Council, Inc. v. Train*, 545 F.2d 320 (2d Cir. 1976).

<sup>217</sup> 42 U.S.C. § 7408(a)(2).

<sup>218</sup> Jerald L. Schnoor, *Carol Browner’s Legacy: PM2.5*, 40 ENVTL. SCI. & TECH. 4531 (2006), available at <http://pubs.acs.org/subscribe/journals/esthag/40/i15/pdf/080106comment.pdf>.

American Chemical Society describes it, Ms. Browner “had little knowledge of ambient-air quality for PM2.5, exposure information, or dose-response relationships. There was no ‘smoking gun’—no explanation of how the inhalation of fine particles could possibly cause disease, let alone death.”<sup>219</sup> In praising Browner’s “philosophy and courage” in applying the precautionary principle in the face of this scientific uncertainty, the editor stated:

Sometimes EPA has to take a stand and make a decision in the face of huge scientific uncertainty, especially when human lives are at stake. You may get it right and look like a hero. Occasionally, you may be wrong and may relax the standard later. Some would choose to invoke the precautionary principle in such cases. That may explain Carol Browner’s philosophy and courage back in 1997. PM2.5 levels have already declined by 10% nationwide since then. Presumably, many lives have been saved. Browner has a lasting legacy.<sup>220</sup>

As is almost always the case, an agency has the discretion to act in many ways that fall between what is required and what is allowed by statute. The agency’s choice to emphasize economic, political, or public health concerns within these bounds will be upheld so long as it is rational.

## 5. The Clean Water Act

Parallel to Section 112 of the CAA, which is intended to regulate hazardous air pollutants, is Section 307 of the Clean Water Act (“CWA”), which targets toxic water pollutants.<sup>221</sup> Like Section 112, Section 307 changed over time from a health-based standard to a technology-based regulation.<sup>222</sup> The change was the result of a lawsuit brought against the EPA by the Natural Resources Defense Council, along with other environmental

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<sup>219</sup> *Id.*

<sup>220</sup> *Id.*

<sup>221</sup> Federal Water Pollution Control Act Amendments of 1972 § 307, Pub. L. No. 92-500, 86 Stat. 816, 856-58 (1972) (codified as amended at 33 U.S.C. § 1317 (2007)).

<sup>222</sup> For a discussion of the history and details of this transition, see Glicksman, *supra* note 164, at 362-65.

organizations, that was ultimately settled.<sup>223</sup> The settlement, referred to as the Flannery Decree in honor of the judge hearing the case, included a list of sixty-five toxic pollutants that EPA was obligated to regulate.<sup>224</sup> This list,<sup>225</sup> along with technology-based standards, was later adopted by Congress in an amendment to the CWA.<sup>226</sup> A decision by EPA to modify the list by either addition or deletion will be upheld unless a court finds it was arbitrary and capricious.<sup>227</sup> These characteristics of Section 307 are certainly precautionary. However, the legal standard a reviewing court must apply to the effluent limitations imposed by EPA does not reflect as precautionary an approach. These limitations are to be upheld only if they are based on substantial evidence.<sup>228</sup>

Section 307 does not mention the burden of proof.<sup>229</sup> Would EPA have to prove its effluent limitation was based on substantial evidence or would the challenger be required to prove it was not? In *Industrial Union Department v. American Petroleum Institute*,<sup>230</sup> the plurality stated that “[o]rdinarily it is the proponent of a rule or order who has the burden of proof in administrative proceedings.”<sup>231</sup> The language used by Congress in Section 307 supports this allocation: “[s]uch standard . . . shall be final except that if, on judicial review, such standard was not

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<sup>223</sup> *Natural Res. Def. Council, Inc. v. Train*, 519 F.2d 287 (D.D.C. 1975), *aff'd and remanded sub nom. Env'tl Def. Fund, Inc. v. Costle*, 636 F.2d 1229 (D.C. Cir. 1980).

<sup>224</sup> For a discussion of the Flannery decision and the subsequent history of the consent order, see Rosemary O'Leary, *The Courts and the EPA: The Amazing "Flannery Decision,"* 5 NAT. RES. & ENV'T 18, 20 (1990) (stating that in amending the CWA shortly after the decision, Congress “endorsed the consent decree’s approach to the control of toxic pollutants and wrote several parts of the decree into the Act”).

<sup>225</sup> This list can be found at 40 C.F.R. § 401.15 (2007).

<sup>226</sup> Clean Water Act of 1977 § 53, Pub. L. No. 95-217, § 53, 91 Stat. 1566, 1589-90 (1977) (codified as amended at 33 U.S.C. §§ 1317(a)(1)-(2) (2007)).

<sup>227</sup> 33 U.S.C. § 1317(a)(1) (2007).

<sup>228</sup> *Id.* § 1317(a)(2). The substantial evidence test is more demanding than the rational basis test. *See, e.g., Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 619-20 (1966) (defining substantial evidence as “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. It must be enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. This is something less than the weight of the evidence.”) (citations omitted) (internal quotation marks omitted); *Food Mktg. Inst. v. Interstate Commerce Comm'n*, 587 F.2d 1285, 1289 (D.C. Cir. 1978) (stating that “the Commission’s determination was to be reviewed under a rational basis test . . . [not] the more demanding ‘substantial evidence’ test”).

<sup>229</sup> *See* 33 U.S.C. § 1317.

<sup>230</sup> 448 U.S. 607 (1980).

<sup>231</sup> *Id.* at 653.

based on substantial evidence, the Administrator shall promulgate a revised standard."<sup>232</sup>

Although the standard of proof and the allocation of the burden of proof both detract from the precautionary nature of Section 307, some cautionary characteristics remain. EPA must meet only a rational basis standard, and not a preponderance of the evidence standard, to prove that the listed substances are toxic and cause harm.<sup>233</sup> EPA's effluent limitations also escape the preponderance of the evidence standard, and are instead subject to the substantial evidence standard.<sup>234</sup> In addition, EPA must base its effluent limitations on the "best available technology economically achievable" and the best control measures and practices achievable.<sup>235</sup>

If, for a particular navigable water, the requirements of Section 307 do not result in compliance with the state's water quality standard for a toxic pollutant, Section 304 will be implicated.<sup>236</sup> This clearly precautionary approach has been described "as a 'safety net' to back up the technology-based controls on which the Act primarily relies."<sup>237</sup> Under Section 304, the state will be required to develop an individual control strategy to augment the controls under Section 307 so as to come into compliance with the state water quality standard.<sup>238</sup>

Regulation of non-toxic water pollutants is mandated by Section 301 of the CWA, which prohibits the discharge of any pollutant from a point source into a navigable water without a permit.<sup>239</sup> Each of the precautionary characteristics regarding toxic water pollutants has an analogue for non-toxic pollutants. Moreover, many of the impediments to a precautionary approach for toxic pollutants discussed above are absent for non-toxic pollutants.

"Pollutant" is defined broadly and thus, in contrast to the list of toxic pollutants, provides little limitation on the jurisdiction of EPA.<sup>240</sup>

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<sup>232</sup> 33 U.S.C. § 1317(a)(2).

<sup>233</sup> *Id.* § 1317(a)(1).

<sup>234</sup> *Id.* § 1317(a)(2).

<sup>235</sup> *Id.*

<sup>236</sup> Water Quality Act of 1987 § 308, Pub. L. No. 100-4, 101 Stat. 7, 38-41 (1987) (codified as amended at 33 U.S.C. § 1314(l) (2007)).

<sup>237</sup> PERCIVAL ET AL., *supra* note 116, at 637.

<sup>238</sup> 33 U.S.C. § 1314(l).

<sup>239</sup> Federal Water Pollution Control Act Amendments of 1972 § 301, 86 Stat. at 844-46 (codified as amended at 33 U.S.C. § 1311 (2007)).

<sup>240</sup> "The term 'pollutant' means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water." 33 U.S.C. § 1362(6).

The standard for effluent limitations for these non-toxic pollutants is the best available technology,<sup>241</sup> as opposed to the more rigorous standard for toxic pollutants of “best available technology economically achievable.”<sup>242</sup> The more lenient standard for non-toxic pollutants is admittedly less precautionary. However, it reflects the reality that non-toxic pollutants generally present lower risks than toxic pollutants.<sup>243</sup> The effluent limitations for non-toxic pollutants must satisfy only the rational basis standard, rather than the higher substantial evidence standard for toxic pollutants.<sup>244</sup> For non-toxic pollutants, the states are required to develop regulatory programs for such pollutants in navigable waters that do not meet any applicable water quality standards.<sup>245</sup> This involves imposing limitations on discharges of non-toxic pollutants based on the total maximum daily load the navigable water can receive and be in compliance with the water quality standard.<sup>246</sup>

The Secretary of the Army acting through the Corps of Engineers has the authority to regulate the discharge of dredged or fill material into a navigable water under Section 404 of the CWA.<sup>247</sup> Such a discharge requires either a general permit<sup>248</sup> or an individual permit, the issuance of which is to be controlled by guidelines published by the Corps and

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<sup>241</sup> *Id.* § 1311(b)(1)(A). A special category called nonconventional pollutants is also established in Section 301. *Id.* § 1311(g). These are listed as “ammonia, chlorine, color, iron, and total phenols.” *Id.* Specific procedures are given for listing and delisting them. *Id.* § 1311(g)(4)-(5).

<sup>242</sup> 33 U.S.C. § 1317(a)(2).

<sup>243</sup> “Toxic pollutant” is defined in the CWA as:

those pollutants, or combinations of pollutants, including disease-causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.

*Id.* § 1362(13). The definition of “pollutant,” by comparison, has no requirement that the substance cause death or disease. *Id.* § 1362(6).

<sup>244</sup> *Chem. Mfr. Ass’n v. U.S. Env’tl. Prot. Agency*, 870 F.2d 177 (5th Cir. 1989) (applying the rational basis standard to EPA’s effluent limitations and imposing the burden of proof on EPA to demonstrate the reasonableness of its limitations).

<sup>245</sup> 33 U.S.C. § 1313(d)(1)(C).

<sup>246</sup> *Id.*

<sup>247</sup> Federal Water Pollution Control Act Amendments of 1972 § 404, 86 Stat. at 884 (codified as amended at 33 U.S.C. § 1344 (2007)).

<sup>248</sup> 33 U.S.C. § 1344(e).

EPA.<sup>249</sup> The joint guidelines and the Corps' regulations incorporate several precautionary principles.<sup>250</sup>

The prohibition on issuing a permit for a discharge of dredged or fill material in special aquatic sites<sup>251</sup> if there is a "practicable alternative" that would have less impact on an aquatic ecosystem is one example of a precautionary approach contained in the guidelines.<sup>252</sup> The existence of a practicable alternative is a bar to the lawful issuance of a permit, not just a factor to be considered.<sup>253</sup> The guidelines create a presumption that there are practicable alternatives if the proposed activity is not water-dependent.<sup>254</sup> The guidelines also state that "all practicable alternatives to the proposed discharge which do not involve a discharge into a special aquatic site are presumed to have less adverse impact on the aquatic ecosystem."<sup>255</sup> These presumptions are not a shifting of the burden of proof; they merely shift the burden of going forward with evidence.<sup>256</sup> Thus, these presumptions are not as strong a precautionary strategy as they could be.<sup>257</sup>

One other weak precautionary principle is associated with Section 404. This can be found in a regulation that is intended to control earth-moving activities in waters of the U.S., particularly in wetlands.<sup>258</sup> As part of a settlement agreement,<sup>259</sup> EPA and the Corps of Engineers

<sup>249</sup> *Id.* § 1344(b).

<sup>250</sup> Guidelines for Specification of Disposal Sites for Dredged or Fill Material, 40 C.F.R. §§ 320.1-.80 (2007).

<sup>251</sup> *Id.* § 230.3(q-1).

<sup>252</sup> *Id.* § 230.10(a).

<sup>253</sup> See *Bersani v. Robichaud*, 850 F.2d 36, 39 (2d Cir. 1988). For an extensive discussion of practicable alternatives, see Mark T. Pifher, *The Section 404(b)(1) Guidelines and Practicable Alternatives Analysis*, in *WETLANDS LAW AND POLICY: UNDERSTANDING SECTION 404*, 221, 234-39 (Kim Diana Connolly, Stephen M. Johnson, & Douglas R. Williams eds., 2005).

<sup>254</sup> 40 C.F.R. § 230.10(a)(3).

<sup>255</sup> *Id.*

<sup>256</sup> See *id.*; *Utahans for Better Transp. v. U.S. Dep't of Transp.*, 305 F.3d 1152, 1163, 1187 (10th Cir. 2002). This is consistent with the approach taken by the Federal Rules of Evidence:

In all civil actions and proceedings . . . a presumption imposes on the party against whom it is directed the burden of going forward with evidence to rebut or meet the presumption, but does not shift to such party the burden of proof in the sense of the risk of nonpersuasion . . . .

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<sup>257</sup> For an analysis of the cases related to the application of these presumptions, see Pifher, *supra* note 253, 231-41.

<sup>258</sup> 33 C.F.R. § 320.1(b) (2007).

<sup>259</sup> *N.C. Wildlife Fed'n v. Tulloch*, Civil No. C90-713-CIV-5-BO (E.D.N.C. 1992).

issued a strict rule that is referred to as the Tulloch Rule.<sup>260</sup> This rule defined discharge of dredged material to include all incidental redeposit,<sup>261</sup> unless the person conducting the activity could prove that the activity would not destroy or degrade the wetlands.<sup>262</sup> This strict regulation was held to exceed the authority of the Corps of Engineers in *National Mining Association v. U.S. Army Corps of Engineers*.<sup>263</sup> In response to that decision, EPA and the Corps issued another regulation:<sup>264</sup>

The Corps and EPA regard the use of mechanized earth-moving equipment to conduct landclearing, ditching, channelization, in-stream mining or other earth-moving activity in waters of the United States as resulting in a discharge of dredged material unless project-specific evidence shows that the activity results in only incidental fallback. This paragraph . . . does not and is not intended to shift any burden in any administrative or judicial proceeding under the CWA.<sup>265</sup>

This regulation, which was modified after the comment period to remove a rebuttable presumption provision, expressly does not affect the burden of proof.<sup>266</sup>

## 6. The Federal Insecticide, Fungicide, and Rodenticide Act

The Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”)<sup>267</sup> prohibits the distribution of any pesticide not registered by

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<sup>260</sup> Clean Water Act Regulatory Programs, 58 Fed. Reg. 45,008 (Aug. 25, 1993) (stating that the Army Corps of Engineers and the EPA changed their regulations in response to the Tulloch decision “to clarify that . . . excavation activities involve discharges of dredged material when performed in waters of the United States, and that these activities [are] regulated . . . when they . . . destroy or degrad[e] . . . waters”).

<sup>261</sup> 33 C.F.R. § 323.2(d)(1)(iii).

<sup>262</sup> *Id.* § 323.2(d)(4)(I).

<sup>263</sup> 145 F.3d 1399 (D.C. Cir. 1998).

<sup>264</sup> Further Revisions to the Clean Water Act Regulatory Definition of “Discharge of Dredged Material,” 66 Fed. Reg. 4550 (Jan. 17, 2001).

<sup>265</sup> 33 C.F.R. § 323.2(d)(2)(I).

<sup>266</sup> Further Revisions to the Clean Water Act Regulatory Definition of “Discharge of Dredged Material,” 66 Fed. Reg. at 4552.

<sup>267</sup> Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-104, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y (2007)).

EPA under the Act.<sup>268</sup> The purpose of registration is “to prevent unreasonable adverse effects on the environment.”<sup>269</sup> An application for registration must include, “if requested by the Administrator [of EPA], a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator . . . .”<sup>270</sup> Although this statutory provision addresses the issue of providing information, it does not answer the question of who has the burden of proof to show or disprove “unreasonable adverse effects on the environment.”<sup>271</sup> The burden of proof issue is relevant in both the initial registration<sup>272</sup> and in cancellation proceedings.<sup>273</sup> The EPA regulations allocate the burden as follows: “At the hearing, the proponent of suspension shall have the burden of going forward to present an affirmative case for the suspension. However, the ultimate burden of persuasion shall rest with the proponent of the registration.”<sup>274</sup> The Seventh Circuit<sup>275</sup> and the District of Columbia Circuit<sup>276</sup> have both upheld this allocation for initial registration and suspension-cancellation proceedings. The requirement that EPA first present evidence that the pesticide will cause “unreasonable adverse effects on the environment”<sup>277</sup> protects the manufacturer from risk management based on mere suspicion of harm, while placing the burden of persuasion on the manufacturer protects the environment from the risk of a false negative caused by scientific uncertainty. This is a clear application of the precautionary principle.

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<sup>268</sup> 7 U.S.C. § 136a(a) (2007).

<sup>269</sup> *Id.*

<sup>270</sup> *Id.* § 136a(c)(1)(F).

<sup>271</sup> *Id.* § 136a(a).

<sup>272</sup> *Stearns Elec. Paste Co. v. U.S. Eenvtl. Prot. Agency*, 461 F.2d 293, 304 n.37 (7th Cir. 1972) (quoting H. Rep. 1125(88th Cong. 2d Sess.)). “This bill places the burden of proof on industry to establish that a pesticide can safely be marketed before a certificate of registration can be issued.” *Id.* (quoting 110 Cong. Rec. H2948-49 (1964) (statement of Rep. Sullivan)).

<sup>273</sup> *Id.* at 304 n.38 (stating that since the statute provides for cancellation unless a registrant requests renewal it implies that the burden of proof is on the registrant).

<sup>274</sup> 40 C.F.R. § 164.121(g) (2007).

<sup>275</sup> *Stearns Elec. Paste Co.*, 461 F.2d at 304 (holding that the 1964 amendments to FIFRA had shifted the burden of proof to registrants in both initial registration and in cancellation proceedings).

<sup>276</sup> *Envtl. Def. Fund, Inc. v. U.S. Eenvtl. Prot. Agency*, 548 F.2d 998, 1016 (D.C. Cir. 1977) (stating that “Congress intended any substantial question of safety to trigger the issuance of cancellation notices, shifting to the manufacturer the burden of proving the safety of his product”) (citation omitted) (internal quotation marks omitted).

<sup>277</sup> 7 U.S.C. § 136a(a).

## 7. The Toxic Substances Control Act

The Toxic Substances Control Act (“TSCA”)<sup>278</sup> is aimed at regulating toxic products, as opposed to toxic waste, to protect against unreasonable risks of injury to human health or the environment.<sup>279</sup> The core of TSCA is found in Section 6, which states in part:

If the Administrator [of EPA] finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements.<sup>280</sup>

The precautionary nature of TSCA is evident in the standard of “a reasonable basis,” which means that EPA is not required to prove causation of harm to scientific certainty or even to satisfy the preponderance of the evidence rule.<sup>281</sup> Moreover, under Section 4 of TSCA, if EPA finds there is insufficient data to make a judgment regarding the risk of injury to health or the environment for a chemical, it can require that the manufacturer conduct testing.<sup>282</sup> This is analogous to placing the burden of going forward with the evidence on the manufacturer, but leaving EPA with the burden of proof to show there is a reasonable basis for concluding the chemical creates an unreasonable risk. This is clearly a precautionary approach. However, the requirement that the EPA regulate harmful chemicals in the “least burdensome” manner possible<sup>283</sup> detracts from the cautionary nature of TSCA. This can be seen from EPA’s attempts to regulate asbestos under TSCA, in which EPA developed a comprehensive approach to reduce the risk of asbestos regardless of the

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<sup>278</sup> Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601-92 (2007)).

<sup>279</sup> 15 U.S.C. § 2601(a) (2007); *Rollins Env'tl. Servs. Inc. v. Parish of St. James*, 775 F.2d 627, 632 (5th Cir. 1985).

<sup>280</sup> 15 U.S.C. § 2605(a).

<sup>281</sup> *Id.*

<sup>282</sup> *Id.* § 2603(a).

<sup>283</sup> *Id.* § 2605(a).

circumstances of exposure.<sup>284</sup> Because EPA only considered two alternatives, namely, a virtual ban and no change, the Fifth Circuit held that EPA had failed to meet the “least burdensome” requirement and thus found the regulation inconsistent with TSCA in *Corrosion Proof Fitting v. EPA*.<sup>285</sup>

## 8. Certification Requirements

Several federal statutes whose purposes include environmental protection require that actions by federal agencies must be in compliance or conformity with state laws in addition to federal laws. These types of requirements are precautionary because they reduce the risk of federal agencies facilitating the violation of laws intended to protect the environment. They ensure that the environmental harms that the federal or state laws were enacted to protect do not become unintended consequences of federal actions.

### a. Section 401 of the Clean Water Act

Section 401 of the CWA requires any applicant for a federal license or permit that will result in a discharge into navigable waters to submit a certification from the involved state that the discharge will comply with the state’s specific effluent limits and water quality standards.<sup>286</sup> This requirement extends to applications for licenses from any federal agency, not just EPA or the Corps of Engineers.<sup>287</sup>

### b. Section 176 of the Clean Air Act

Section 176 of the CAA prohibits federal agencies from funding or approving any activity regarding transportation that does not comply

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<sup>284</sup> Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions, 54 Fed. Reg. 29,460 (July 12, 1989).

<sup>285</sup> 947 F.2d 1201 (5th Cir. 1991).

<sup>286</sup> Federal Water Pollution Control Act Amendments of 1972, Pub. L. No. 92-500, § 401, 86 Stat. 816, 877-80 (1972) (codified as amended at 33 U.S.C. § 1341(a)(1) (2007)).

<sup>287</sup> PUD No. 1 of Jefferson County v. Wash. Dep’t of Ecology, 511 U.S. 700, 722 (1994) (requiring a certification from the Federal Energy Regulatory Commission in connection with a license to construct a hydroelectric project).

with the relevant state implementation plan.<sup>288</sup> The head of the agency is given the responsibility for “assurance of conformity” with the plan.<sup>289</sup>

c. The Coastal Zone Management Act

The Coastal Zone Management Act<sup>290</sup> provides that once a state coastal zone management program has been approved by the Secretary of Commerce for federal administrative grants:

any applicant for a required Federal license or permit to conduct an activity . . . affecting any land or water use or natural resource of the coastal zone of that state shall provide in the application . . . a certification that the proposed activity complies with the enforceable policies of the state’s approved program and that such activity will be conducted in a manner consistent with the [state] program.<sup>291</sup>

d. The Wild and Scenic Rivers Act

A weak version of the conformity assurance model of a precautionary approach is contained in the Wild and Scenic Rivers Act.<sup>292</sup> That provision, which can be described as a give notice and wait requirement, states that:

No department or agency of the United States shall recommend authorization of any water resources project that would have a direct and adverse effect on the values for which such river was established . . . or request appropriations to begin construction of any such project, . . . without advising the Secretary . . . in writing of its intention so to

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<sup>288</sup> Clean Air Act Amendments of 1977 § 129, Pub. L. No. 95-95, 91 Stat. 685, 749-50 (1977) (codified as amended at 42 U.S.C. § 7506(c) (2007)). For an interpretation of this requirement, see *Envtl. Def. Fund v. Env’tl. Prot. Agency*, 167 F.3d 641 (D.C. Cir 1999). This case is discussed in Michael R. Yarne, *Conformity as Catalyst: Environmental Defense Fund v. Environmental Protection Agency*, 27 *ECOLOGY L.Q.* 841 (2000).

<sup>289</sup> 42 U.S.C. § 7506(c) (2007).

<sup>290</sup> Coastal Zone Management Act of 1972, Pub. L. No. 92-582, 86 Stat. 1280 (1972) (codified as amended at 16 U.S.C. §§ 1452-66 (2007)).

<sup>291</sup> 16 U.S.C. § 1456(c)(1)(C)(3)(A) (2007).

<sup>292</sup> Wild and Scenic Rivers Act, Pub. L. No. 90-542, 82 Stat. 906 (1968) (codified as amended at 16 U.S.C. §§ 1271-87).

do at least sixty days in advance, and without specifically reporting to the Congress in writing at the time it makes its recommendation or request in what respect construction of such project would be in conflict with the purposes of this [Act] and would affect the component and the values to be protected by it under this [Act].<sup>293</sup>

This provision does not actually require conformity; it only permits Congress to impose it.<sup>294</sup> Moreover, because it attaches to interactions between agencies and Congress, that is, recommending authorization and requesting appropriations, it is unlikely that violations will be detected.

#### CONCLUSION

As the examples in this Article illustrate, the precautionary principle has found its way into United States environmental laws, regulations, and policies. It is premature, and probably unrealistic, to characterize this scattering of examples as a trend.

The best evidence to demonstrate that there is no trend toward the incorporation of precautionary principles in U.S. law is provided by legislation regarding pollution and waste prevention. A trend in the direction of caution would include substantive laws requiring that waste be prevented at least when it is cost effective to do so. There is no such U.S. environmental law. Instead there are the Pollution Prevention Act of 1990<sup>295</sup> and the waste minimization provisions of the Resource Conservation and Recovery Act ("RCRA"),<sup>296</sup> located in Section 3002(b)<sup>297</sup> and Section 3005(h).<sup>298</sup>

The Pollution Prevention Act acknowledges that "[s]ource reduction is fundamentally different and more desirable than waste management and pollution control."<sup>299</sup> However, instead of requiring the better course the Act merely declares that strategy to be the policy of the

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<sup>293</sup> 16 U.S.C. § 1278.

<sup>294</sup> *See id.*

<sup>295</sup> Pollution Prevention Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (1990) (codified at 42 U.S.C. § 13101-09 (2007)).

<sup>296</sup> Resource Conservation and Recovery Act of 1976, Pub. L. No. 94-580, 90 Stat. 2795 (1976) (codified at 42 U.S.C. §§ 6910-6992k (2007)).

<sup>297</sup> 42 U.S.C. § 6922(b).

<sup>298</sup> *Id.* § 6925(h).

<sup>299</sup> *Id.* § 13101(a)(4).

United States.<sup>300</sup> Thus, the “significant opportunities for industry to reduce or prevent pollution at the source through cost-effective changes in production, operation, and raw materials use”<sup>301</sup> are left as goals to be voluntarily accepted or rejected by industry.

The two waste prevention provisions in the RCRA both require certifications. Section 3002(b) requires the generator of hazardous waste to certify that it has a waste minimization program in place *that the generator determines* to be economically practicable and that “the proposed method of treatment, storage, or disposal is that practicable method currently available to the generator which minimizes the present and future threat to human health and the environment.”<sup>302</sup> Because the standard in the statute is determined by the generator, the provision does no more than establish an illusory requirement. The same language is used in section 3005(h)<sup>303</sup> with the same result.

The modification of these three laws might well mark the beginning of a trend. Requiring industry to reduce waste and pollution at the source through cost-effective means would certainly qualify as a precautionary approach. Some optimism is appropriate here. The success of the voluntary 33/50 Program demonstrates that waste minimization can be defined so as to be both measurable and economically achievable.<sup>304</sup> Even greater success in pollution prevention through changes in manufacturing processes has been achieved under the Emergency Planning and Community Right to Know Act merely by requiring the public disclosure of offsite releases of hundreds of toxic chemicals.<sup>305</sup> However, laws *mandating* waste minimization in the production process are not likely to be enacted in the near future. Such laws would constitute a major change in Congressional policy from the longstanding attempt of keeping EPA out of the manufacturing process.<sup>306</sup>

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<sup>300</sup> *Id.* § 13101(b).

<sup>301</sup> *Id.* § 13101(a)(2).

<sup>302</sup> *Id.* § 6922(b).

<sup>303</sup> *Id.* § 6925(h).

<sup>304</sup> “The 33/50 Program targeted 17 priority chemicals and set as its goal a 33% reduction in releases and transfers of these chemicals by 1992 and a 50% reduction by 1995, measured against a 1988 baseline.” U.S. ENVTL. PROT. AGENCY, EPA-745-R-99-004, 33/50 PROGRAM: THE FINAL RECORD 1 (1999), *available at* <http://www.epa.gov/opptintr/3350/3350-fnl.pdf>. The program was able to achieve its goals. *Id.*

<sup>305</sup> See U.S. ENVTL. PROT. AGENCY, EPA-260-S-02-001, 2000 TOXICS RELEASE INVENTORY (TRI) PUBLIC DATA RELEASE REPORT: EXECUTIVE SUMMARY (2002), *available at* [http://www.epa.gov/tri/tridata/tri00/press/execsummary\\_final.pdf](http://www.epa.gov/tri/tridata/tri00/press/execsummary_final.pdf).

<sup>306</sup> See, e.g., *Am. Mining Cong. v. U.S. Env'tl. Prot. Agency*, 824 F.2d 1177 (D.C. Cir. 1987) (determining that EPA had exceeded its regulatory authority when it redefined “solid

Likewise, requiring federal agencies that have completed an environmental impact statement to select the cost-effective alternative that is predicted to cause the least environmental harm would be cautionary. This modification to NEPA would amount to a universal limitation on agencies' discretion and is, therefore, very unlikely.

Changes such as those mentioned above would take a step towards the incorporation of Principle 15 of the Rio Declaration into United States law.<sup>307</sup> These changes would reflect a disciplined, risk-based approach to achieving precaution in environmental decision-making. This is precisely the approach taken by former EPA Administrator Browner regarding PM2.5, and the environment as well as the American people are much better off for it.<sup>308</sup>

Has the precautionary principle made more than a cameo appearance in U.S. environmental law? EPA's decision to implement a PM2.5 standard alone justifies an affirmative answer.<sup>309</sup> When combined with the other examples discussed in this Article, support for this conclusion is quite strong. The more controversial question is whether or not the precautionary principle should be given a more prominent role in environmental regulation. Again, the examples discussed in this Article show that the answer is affirmative. Though it is clear that some laws are unlikely to incorporate the precautionary principle in the near future, it is time to adopt the precautionary philosophy and summon the courage necessary to work for its further implementation in the United States.

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waste" to include secondary materials reused within an industry's ongoing production process).

<sup>307</sup> See Rio Declaration, *supra* note 58, princ. 15.

<sup>308</sup> See *supra* notes 218-20 and accompanying text.

<sup>309</sup> See *supra* notes 218-20 and accompanying text.