

## EMBRACING UNCERTAINTY, COMPLEXITY AND CHANGE: AN ECO-PRAGMATIC REINVENTION OF A FIRST GENERATION ENVIRONMENTAL LAW

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I.	Introduction. . . . .	4
II.	Eco-Pragmatism. . . . .	7
	A. Historical Roots of Pragmatism. . . . .	7
	B. Farber’s “Eco-Pragmatism”. . . . .	8
	C. Strengthening the “Eco” in Eco-Pragmatism. . . . .	10
	1. Background Discussion. . . . .	10
	2. The Role of Economics in Eco-pragmatism. . . . .	15
	a. Rejection of Pure Risk-Based and Cost/Benefit Standards . . . . .	15
	b. The Eco-Pragmatic Response: Embracing Feasibility. . . . .	24
	3. Necessity of a Baseline/Ecological Integrity as a Baseline. . . . .	28
	4. Lack of information and changing information. . . . .	34
III.	History of Pesticide/Ecology Relationship. . . . .	40
	A. History of Pesticide Usage. . . . .	40
	B. Ecological Risks of Pesticides. . . . .	43
	C. History of Ecology in Pesticide Regulation. . . . .	51
IV.	FIFRA (A License to Kill) . . . . .	57
	A. Registration and Other Approval Mechanisms. . . . .	57
	B. Continuing Duties of Registrants. . . . .	62
	C. Cancellation and Suspension. . . . .	64
	D. Enter GMOs. . . . .	67
V.	Is FIFRA Eco-Pragmatic? . . . . .	70
VI.	Reinventing FIFRA though eco-pragmatism. . . . .	77
	A. Reinventing the Cost/Benefit Balancing. . . . .	78
	B. An Ecological Integrity Baseline. . . . .	87
	C. Addressing Uncertainty and Change. . . . .	91
VII.	Conclusion. . . . .	98

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## I. INTRODUCTION

*These sprays, dusts, and aerosols are now applied almost universally to farms, gardens, forests, and homes – nonselective chemicals that have the power to kill every insect, the “good” and the “bad,” to still the song of birds and the leaping of fish in streams, to coat the leaves with a deadly film, and to linger on in soil – all this though the intended target may be only a few weeds or insects. Can anyone believe it is possible to lay down such a barrage of poisons on the surface of the earth without making it unfit for all life?*<sup>2</sup>

*If Rachel Carson were alive today I believe she would give America a mixed grade.*<sup>3</sup>

If you heard a strange rumbling sound in late 2004, it may have been Rachel Carson rolling over in her grave in response to the National Audubon Society’s alarming “State of the Birds” Report.<sup>4</sup> The Report concludes that despite all of the environmental laws, regulations, polices, and programs established since Rachel Carson first sounded the environmental alarm, a large percentage of avian species found in the continental United States are in a significant state of decline.<sup>5</sup> While pesticides are only one of the many causes implicated in the bird declines,<sup>6</sup> that fact cannot be ignored that despite Carson’s dire warnings, and more than thirty years of intensive regulation, pesticides continue to pose significant risks to birds, other wildlife and ecosystems in general.

One of the great ironies of environmental law is that the ecological consequences of pesticide use, such as the devastating impacts DDT had on predatory bird populations, which fueled the environmental

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<sup>2</sup> RACHEL CARSON, *SILENT SPRING* 7-8 (40<sup>th</sup> Anniv. Ed., First Mariner Books 2002).

<sup>3</sup> E.O. WILSON, Afterword, *in* RACHEL CARSON, *SILENT SPRING* 362 (40<sup>th</sup> Anniv. Ed., First Mariner Books 2002).

<sup>4</sup> In the fall of 2004, the National Audubon Society (“AUDUBON”) published its State of the Birds USA 2004 report in Audubon magazine (hereinafter “Audubon Report”). A copy of the report may be viewed on the Internet at [www.audubon.org/bird/stateofthebirds/](http://www.audubon.org/bird/stateofthebirds/). In the Report, Audubon evaluated the status of 654 bird species native to the continental United States. The species evaluated inhabit the nation’s four major types of natural habitat – grass, shrubs, tree and water. The Report revealed a very disturbing trend, demonstrating that large percentages of bird species utilizing all of these habitats are in significant decline. The declines range from 13 percent to 70 percent, depending on the habitat type used by the species. *Id.* In addition to the Audubon Report, another significant report on the decline of bird species conducted by researchers at Stanford University was published in the Proceedings of the National Academy of Sciences in 2004. Cagan H. Sekercioglu, Gretchen C. Daily and Paul R. Ehrlich, *Ecosystem Consequences of Bird Declines*, PNAS 2004 101: 18042-18047. This report predicts that by the year 2100, ten percent of all bird species are likely to disappear and that another fifteen percent could be on the brink of extinction. *Id.* Moreover, The Center for Biological Diversity recently released a report that found that EPA has approved registrations for pesticides that put more than 375 Endangered Species Act (ESA) listed species at risk. Brian Litmans & Jeff Miller, *Silent Spring Revisited: Pesticide Use and Endangered Species* (A Center for Biological Diversity Report, 2004), available at <http://www.biologicaldiversity.org/swcbd/Programs/science/pesticides/> (Last visited, August 4, 2005).

<sup>5</sup> Audubon Report.

<sup>6</sup> The Report identifies habitat loss as the leading cause of bird declines, with other factors, such as pesticide poisoning contributing to the declines. *Id.*

movement of the late 1960's and early 1970's, largely have been ignored for the past 30 years. Only very recently has there been renewed interest in the ecological (as opposed to human health) risks posed by pesticides.<sup>7</sup> Moreover, the explosion of pesticidal genetically modified organisms (GMOs) in agriculture has raised concerns regarding the novel risks to biodiversity posed by these new pesticides. Surprisingly, however, the primary federal statute governing pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),<sup>8</sup> has not changed significantly with regard to ecological matters since 1972 and remains primarily a consumer protection statute not well suited for ecological protection. Moreover, the manner in which the Environmental Protection Agency (EPA) has implemented FIFRA has not kept pace with developments in our understanding of the uncertainty, complexity, and changing nature of ecological systems.

For years, environmental legal scholars have sought a middle ground between absolutist risk-based approaches to environmental regulation and cost/benefit analysis approaches. In the past several years, scholars have begun exploring the emerging field of eco-pragmatism – a framework for environmental decision-making developed by Professor Daniel Farber -- as a way to achieve a workable middle ground. At the same time, scholars have begun to look at environmental law through the lens of ecological science. Common themes of complexity, uncertainty and change permeate both eco-pragmatism and ecological science. Science has only scratched the surface of understanding complex ecological systems. What little is understood about ecological science, teaches us that ecological systems are extremely complex, and ever changing. Eco-pragmatism seeks to address concerns with complexity, uncertainty and the change. By incorporating an understanding of ecological science into eco-pragmatism, these challenging issues can be addressed more effectively. Accordingly, an integrated approach drawing on the discipline of ecology—the study of the interactions of living organisms and their environments--and eco-pragmatism can provide a comprehensive framework for environmental regulation to protect ecological resources. To date, no significant attempts have been made to analyze FIFRA,<sup>9</sup> and only a few attempts have been made to analyze any other traditional pollution control law, comprehensively under eco-pragmatism or using

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<sup>7</sup> See, e.g., Wash. Toxics Coalition, et al. v. EPA, et al., Case No. C01-013132C, Order issued January 22, 2004.

<sup>8</sup> 7 U.S.C. § 136 -136y (2004).

<sup>9</sup> In fact, very few scholarly efforts have been made to analyze FIFRA in any comprehensive way at all. For one of the more comprehensive scholarly works, see Donald T. Hornstein, *Lessons From Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 YALE J. L. REF. 369 (1993) (using an analysis of FIFRA to frame an argument for an alternative framework for environmental law reform, which more aggressively addresses the causes of environmental problems, rather than relying on risk-based priority setting.).

principles of ecological science.<sup>10</sup> Pesticide law, perhaps more than any other pollution control law, lends itself to such analyses.

Since 1972 when FIFRA was amended to take environmental concerns into account, considerable advances have been made in the ecological sciences. Because regulation under FIFRA is accomplished through a national registration of products, risks are assessed on a one-time nationwide basis. Accordingly, localized ecological concerns are not considered. Moreover, the regulation of pesticides is unique in that, unlike other areas of environmental protection where environmental laws can seek to eliminate or minimize hazardous releases that result in unintended consequences of manufacturing or other processes, pesticides are intentionally released into the environment for the express purpose of killing, injuring or disrupting the behavior of living organisms in the environment. In other words, with pesticides, simply keeping them out of the environment is not an option. Consequently, the complexity and uncertainty manifest in ecological systems, as well as the disequilibria inherent in such systems, must be addressed as part of any system designed to address ecological risks posed by pesticides. This Article attempts to advance eco-pragmatism by consciously integrating principles of ecological science into an eco-pragmatic framework. In addition, by employing the experiential approach inherent in eco-pragmatism, this Article utilizes experience gleaned from over thirty years of U.S. policy on pesticide regulation to propose improvements to pesticide regulation within an eco-pragmatic framework.

Part II of this Article provides an analysis of eco-pragmatic theory. This Part further demonstrates the need for eco-pragmatic theory to be expanded to better integrate ecological concerns and shows how ecological principles can be used to bolster and further develop eco-pragmatism. Part III lays out the history of ecological issues in pesticide regulation and highlights the areas where current pesticide law does not adequately address ecological concerns. The ecological risks posed by traditional synthetic chemical pesticides and pesticidal genetically modified organisms are set forth. This Part further demonstrates that for pesticide regulation, in particular, it is imperative to expand the role of ecological considerations. Part IV of this Article describes current U.S. pesticide law and its application. Part V evaluates FIFRA from an eco-pragmatic perspective and concludes that although some components of the statute are surprisingly eco-pragmatic, substantially more could be done to use eco-pragmatic theory as a means to improve FIFRA's ability to protect ecological integrity. Finally, in Part VI, a new Eco-

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<sup>10</sup> One recent attempt to analyze the Clean Water Act, 33 U.S.C. § 1251 - 1387, using ecological principles is Robert Adler, *Two Lost Books in the Water Quality Trilogy: The Elusive Objectives of Physical and Biological Integrity*, 33 *Envtl.*

pragmatic approach to pesticide regulation is proposed.

## II. ECO-PRAGMATISM

### A. *The Historical Roots of Pragmatism*

The roots of eco-pragmatism can be traced back to the philosophical pragmatism<sup>11</sup> movement of the early twentieth century. In its broadest sense, pragmatism can be described as a philosophy that relies on action, experimentation and workable solutions, rather than theoretical constructs.<sup>12</sup> An aspect of philosophical pragmatism that is particularly relevant to integrating ecological principles into environmental law is pragmatism's flexibility, which is rooted in the acceptance of indeterminacy and the limitations of human understanding.<sup>13</sup> Pragmatists embrace the idea that as more knowledge becomes available, and as society evolves, ethical concerns also evolve. This philosophical acceptance of indeterminacy and change complements the ecological principles of uncertainty and change, which are discussed in greater detail below.

Pragmatists also recognize that communities may hold many conflicting values. Pragmatic methodology is designed to resolve conflicts in the way that best serves the community.<sup>14</sup>

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L. 29 (2003).

<sup>11</sup> Philosophical pragmatism has been applied over the years to a variety of disciplines. For example, Oliver Wendell Holmes is credited with developing legal pragmatism, an attempt to apply pragmatism to legal theory. Legal pragmatism grew out of Holmes' belief that the law evolves out of experience rather than logic. Other proponents of legal pragmatism included Benjamin Cardozo and Richard Posner. See Joel A. Mintz, *Some Thoughts on the Merits of Pragmatism as a Guide to Environmental Protection*, 31 B.C. ENVTL. AFF. L.REV. 1, 9-13 (2004).

<sup>12</sup> For a good discussion of early philosophical pragmatism, see generally Mintz, *supra* note 11. Philosophical pragmatism rejects dogma and particular outcomes in favor of a method of using experience and experimentation to determine what "works." Mintz, *supra* note 11, at 1. In pragmatism, decisions are measured by their consequences and the extent to which they fulfill the needs of society. Pragmatism has been described as emphasizing "practice over theory." See Ruhl, *supra* note CC, at 531. Pragmatists believe that the value of an idea stems from its practical ability to benefit the community and to solve society's problems. SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH 14 (2003). One of the most influential philosophical pragmatists of the twentieth century, John Dewey stressed the idea that knowledge is better gleaned from experience than abstract reasoning. See generally, JOHN DEWEY, EXPERIENCE AND NATURE (Eugene Freeman, ed., 2d. Ed. 1971). Other traditional philosophical pragmatists include William James, Charles Pierce, Josiah Royce and George Herbert Mead. Mintz, *supra* note 11 at 1-2. Also, see generally, THE AMERICAN PRAGMATISTS (Milton Konvitz and Gail Kennedy, eds. 1960). In keeping with this practical measure of the value of ideas, pragmatists believe that ideas are valuable and true when they are accepted by what is referred to as a "critical community of inquiry." SHAPIRO & GLICKSMAN, *supra* at 16. In other words, only after a community has analyzed, deliberated and vetted an idea and found it to be beneficial in solving a problem is that idea valuable to the community. Further, the value of such ideas changes as the community changes.

<sup>13</sup> Early twentieth century philosophical pragmatists were fascinated by the scientific developments of the time. Darwin's theory of evolution led these early pragmatists to view human thought in evolutionary terms, constantly evolving as a "problem-solving capacity, oriented towards survival." *Id.* at 15 (quoting Thomas C. Grey, *Holmes and Legal Pragmatism*, 41 STAN. L. REV. 787, 796 (1989)). Decisions may change as new experience or experimentation point to better ways to meet such societal needs.

<sup>14</sup> SHAPIRO & GLICKSMAN, *supra* note 12 at 20.

Conflicts over environmental policy and law are borne of the conflicting values of those who seek to reduce environmental risks and those whose primary concern is economic efficiency.<sup>15</sup> Thus, pragmatism can serve as a useful tool to reconcile the inevitable conflicts, which environmental policy must address.<sup>16</sup>

### B. Farber's "Eco-pragmatism"

Professor Daniel Farber's 1999 book, *Ecopragmatism*,<sup>17</sup> paved the way for the recent flurry of scholarship attempting to use pragmatic theory as a guiding principle for environmental regulation.<sup>18</sup> Many environmental law scholars seemingly have been yearning for a theoretical

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<sup>15</sup> See J.B. Ruhl, *Working Both (Positivist) Ends Toward a New (Pragmatist) Middle in Environmental Law*, 68 GEO. WASH. L. REV. 522, 23 (2000) (book review). (stating that "[s]ince almost immediately after its statutory big bang in the early 1970s, [footnote omitted] two extreme and opposing philosophies – one devoted to protecting the economy and the other to protecting the environment – have waged a war of annihilation that has left in its wake a mish-mash of laws, regulations, judicial opinions, and countless administrative decisions and policies that we today call environmental law").

<sup>16</sup> SHAPIRO & GLICKSMAN, *supra* note 12 at 21, 52.

<sup>17</sup> DANIEL A. FARBER, *ECO-PRAGMATISM: MAKING SENSIBLE ENVIRONMENTAL DECISIONS IN AN UNCERTAIN WORLD* 35 (1999). Eco-pragmatism draws on the wider movement in legal scholarship known as legal pragmatism FARBER, *supra* note AA, at 9. Legal pragmatism holds that decisions should be made by drawing on many sources. In the environmental setting, these sources include scientific understanding and normative judgments, as well as economic considerations. *Id.* at 10. Professor Farber's book starts from the premise that the legitimacy of environmental values is a given in the U.S. The harder question, he maintains, is what priority to assign to those environmental values, and how to weigh them against other values such as economic needs. A basic tenet of Farber's approach is that for environmental law to be socially sustainable, it must be pluralist, flexible and not overly draconian. In other words, to be socially sustainable, environmental protection must proceed as "a marathon, not a sprint." *Id.* at 13.

<sup>18</sup> Although Farber was the first to develop the field of eco-pragmatism, the field of Environmental Pragmatism had been in existence since the late 1980s. See, e.g., ANDREW LIGHT AND ERIC KATZ, *ENVIRONMENTAL PRAGMATISM* (1996). Environmental pragmatism was developed as a way to apply philosophical pragmatism to attempt to address environmental concerns. Mintz, *supra* note 11, at 6. Although eco-pragmatism certainly derives much from environmental pragmatism, Farber's eco-pragmatism is an attempt to apply pragmatism to environmental laws and policies in particular. *Id.* at 14. Farber's book has been reviewed by a number of prominent environmental law scholars, generating varied reactions. While some scholars have expressed reservations over Farber's ideas, others have generally reacted positively to the overall thrust of the book, if not to the specifics. See Lisa Heinzerling, *Pragmatists and Environmentalists*, 113 HARV. L. REV. 1421 (2000) (book review) (criticizing Farber's approach for being too modest and not sufficiently transformative); Christopher H. Schroeder, *Clear Consensus, Ambiguous Commitment*, 98 MICH. L. REV. 1876, 1880 (2000) (book review) (describing Farber's book as containing "valuable discussion of [environmental] problems [and] offering important insights into dealing with them."); Christopher H. Schroeder, *Prophets, Priests and Pragmatists*, 87 MINN. L. REV. 1065, 1097 (2003) (stating that "Pragmatism's essential appeal is thus that it is the best bet for putting environmental policy on a glide path to the goals that the [environmental] prophets wants, and indeed the steepest glide path feasible."); J. B. Ruhl, *supra* note 15 (generally providing a very favorable review of eco-pragmatism, but expressing disappointment for its lack of passion). See also Paul Boudreax, *Environmental Costs, Benefits, and Values: A review of Daniel A. Farber's Eco-Pragmatism*, 13 TUL. ENVTL. L.J. 125, 167 (1999) (book review) (stating that while Farber's Eco-Pragmatism provides a good starting point for broad-based thinking about problems in environmental law, it fails in its specific recommendations on how to apply Pragmatism to environmental policy). Despite any perceived shortcomings in the book, it cannot be denied that Farber's ideas have been provocative and have led the way for a flurry of scholarly analysis of how pragmatic ideas could be applied to environmental law. See e.g., *THE JURISDYNAMICS OF ENVIRONMENTAL PROTECTION: CHANGE AND THE PRAGMATIC VOICE IN ENVIRONMENTAL LAW*, JIM CHEN, ED. ENVIRONMENTAL LAW INSTITUTE (Environmental Law Institute 2003) (a compilation of writing on eco-Pragmatism and related concepts including works by Jim Chen, Daniel Farber, J.B. Ruhl, Dan Tarlock, Christine Klein, Jonathon Alder, Christopher Schroeder, Douglas Kysar, James Salzman, Richard Lazarus,

framework to guide the development of an environmental middle ground between the two extremes of absolute risk-based regulation, which does not adequately take costs into account and cost/benefit analysis,<sup>19</sup> which as described in section III.C.2.a below has many shortcomings in the area of environmental protection. Eco-pragmatism, for many, provides the rationale for moving beyond the goal of economic efficiency and focusing instead on attempting to reduce human and environmental risks to the extent feasible.<sup>20</sup> Nevertheless, despite the recent wealth of scholarship on eco-pragmatism, very few attempts have been made to apply the approach in any systematic way to an existing environmental regulatory scheme.<sup>21</sup>

In his book, Farber outlines the four most difficult questions that need to be answered in developing an environmental regulatory system: 1) How we determine how much an environmental rule is worth, which taps into the long-standing debate over risk-based approaches to environmental protection versus cost/benefit approaches; 2) The appropriate baseline for environmental decision-making, which raises the issue of whether there is some inherent value in environmental protection such that we should err on the side of protection; 3) How we determine how much it is worth to spend today to achieve a benefit that may not occur until decades into the future, which raises the issue of what is the appropriate discount rate to use in environmental valuation;<sup>22</sup> and 4) How we know when to proceed in the face of imperfect information, which

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Lisa Heinzerling, Holly Doremus, and Alyson Flournoy, among others); SHAPIRO & GLICKSMAN, *supra* note 12 at 46 (arguing that pragmatism provides the rationale for regulating based on risk, which has been missing from debates on environmental policy); Jamie A. Grodsky, *The Paradox of (Eco)Pragmatism*, 87 MINN. L. REV. 1037 (2003)(arguing that eco-pragmatism’s middle ground compromise and flexibility must be tempered to include clear rules that can be adjusted over time. Farber himself has continued to weigh-in on the subject. See Daniel A. Farber, *Building Bridges Over Troubled Waters: Eco-Pragmatism and the Environmental Prospect*, 87 MINN. L. REV. 854 (2003).

<sup>19</sup> FARBER, *supra* note 17, at 35.

<sup>20</sup> See generally SHAPIRO & GLICKSMAN, *supra* note 12 (providing much of the justification for a pragmatic approach to environmental law that Farber’s book was criticized for lacking.)

<sup>21</sup> One of the few attempts to apply an eco-pragmatic approach to environmental law is J.B. Ruhl’s 2003 article, *Is the Endangered Species Act Eco-Pragmatic?*, 87 MINN. L. REV. 885 (2003). In this article, Ruhl identifies what he refers to as the five pillars of eco-pragmatism: 1) drawing an environmental baseline; 2) institutionalizing the precautionary principle; 3) integrating impact assessment; 4) the importance of empiricism; and 5) adaptive management. *Id.* at 888-889. After testing the Endangered Species Act (ESA) against these five pillars, Ruhl concludes that “all the eco-pragmatism pieces are there.” *Id.* at 941. For example, Ruhl identifies the ESA’s jeopardy prohibition as providing an environmental baseline, the ESA’s take prohibition as an institutionalization of the precautionary principle, the ESA’s incidental take procedure as utilizing impact assessment, the ESA’s best available evidence standard as employing empiricism, and the recent implementation of habitat conservation planning under the ESA as incorporating adaptive management techniques. *Id.* at 941.

<sup>22</sup> There is much debate over the appropriate discount rates that should be used in environmental cost/benefit analyses or other forms of balancing, such as constrained balancing. The higher the discount rate used, the more likely that the analysis will conclude that the resource using or polluting activity is efficient. Whereas, a low discount rate affords greater value to

raises the related issues of whether precautionary approaches should be used in environmental decision-making and how to incorporate adaptive management ideas into environmental laws. Farber sets out to answer these questions within a pragmatic framework, finding that the pragmatic answers to the four questions are: 1) economics should be utilized in a hybrid approach which bridges the gap between pure risk-based and cost/benefit approaches; 2) environmental law should start with a presumption in favor of the environment (an environmental baseline); 3) a low discount rate should be employed in the valuation of long-term environmental benefits; and 4) flexible, adaptive approaches are necessary to allow regulation to adapt as new information becomes available. Despite the strengths of eco-pragmatism, as described more fully below, the theory could be strengthened considerably by more consciously incorporating into it principles of ecological science.

### *C. Strengthening the Eco in Eco-pragmatism*

#### 1. Background Discussion

In his review of Farber's work, Professor J.B. Ruhl has described eco-pragmatism as a marriage of two themes: the "eco" theme, a scientifically based theme, which focuses on the dynamic character of natural systems, and the "pragmatic" theme, which draws on the philosophy of pragmatism.<sup>23</sup> As Ruhl describes it, the fusion of the concept of ecological dynamism and environmental pragmatism form eco-pragmatism, a new approach to environmental decisions making in an uncertain world.<sup>24</sup> Despite his general affinity for eco-pragmatism, Ruhl expresses

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future benefits, and as a result, is more likely to conclude that the benefits of regulation outweigh the costs. Cost/benefit and other balancing analyses are influenced dramatically by the choice of discount rate. Eco-pragmatism argues in favor of the use of a low discount rate. FARBER, *supra* note 17 at 89-90,133. Although a detailed discussion of the appropriate discount rate to use in environmental decision-making is used is beyond the scope of this article, there are sound reasons for adopting a low discount rate. For instance, the consequences of environmental decisions extend deep into the future. The further out in time we attempt to predict environmental consequences, the more the accuracy of such projections diminishes. FARBER, *supra* note 17 at 133. Using a low discount rate is a way to take the long view. Ruhl, *supra* note 15 at 539. A low discount rate does not devalue long-term environmental benefits. Moreover, our limited understanding of environmental issues lends support to more cautious predictions of future benefits. As hard as it is to put a dollar value on environmental values, it is almost impossible to put a dollar value on what they will be worth in twenty or thirty years. Our limited understanding of natural systems suggests we may not even begin to understand the value that natural systems may be found to hold in the future. High discount rates can make significant future benefits look insignificant today. FARBER, *supra* note 17 at 151. Perhaps the most compelling rationale for employing low discount rates is what is known as "inter-generational equity." There is so much that is not known about the value of natural systems today, that it would be reckless to fritter away resources today which may later be found to have great value (utilitarian or otherwise) to future generations. *Id.* at 151-152. Thus, we should be prudent in how much we discount the environmental benefits that natural systems hold for future generations.

<sup>23</sup> J.B. Ruhl, *supra* note 15 at 523.

<sup>24</sup> *Id.* at 524.



disappointment that Farber's work fails to address, except in a very cursory fashion, the "eco" partner in the eco-pragmatism marriage.<sup>25</sup> As Ruhl points out, the past thirty years have evidenced dramatic changes in the study of natural systems.<sup>26</sup> During this period, the field of ecology has come into its own, and the new fields of conservation biology and ecosystem management have been born. Moreover, unprecedented developments in our understanding of natural systems have occurred. Our once-accepted view of the "balance of nature" has been challenged and we now are beginning to see nature as being considerably more complex and dynamic than we once believed.<sup>27</sup> Accordingly, environmental decision-makers must accept, and incorporate into their decision-making the continually changing nature of ecosystems.<sup>28</sup>

A close study of ecological principles reveals that these principles are consistent in many ways with eco-pragmatism, and in fact, may serve to bolster and further develop Farber's ideas. A good starting point for an attempt to understand the complexity of, uncertainty and changing nature of natural systems is an understanding of the numerous fields of inquiry and terminology used to describe these systems. Ecology is the science of the interactions of living organisms with each other and their physical environment.<sup>29</sup> The field of ecology has existed for many decades; however, it has only been in the last twenty years or so, that ecological study has advanced to the point where we are beginning to understand the importance of biodiversity to natural systems. "Biodiversity" has been defined as "the richness, abundance, and variability of plant and animal species and communities and the ecological processes that link them with one another and with soil, air and water."<sup>30</sup> The measure of biodiversity is not merely an accounting of the number of species present in an area; it also has a functional component.<sup>31</sup> Accordingly, a focus on preserving individual species from extinction is not sufficient to preserve biodiversity unless ecological processes are also maintained.<sup>32</sup> Thus, an overriding goal of biodiversity protection is to maintain all of the elements of biodiversity, including both structural diversity (i.e., forms and levels of

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<sup>25</sup> *Id.*

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

<sup>27</sup> *See generally*, DANIEL B. BOTKIN, *DISCORDANT HARMONIES: A NEW ECOLOGY FOR THE TWENTY-FIRST CENTURY* (1990) and Judy L. Meyer, *The Dance of Nature: New Concepts in Ecology*, 69 CHI-KENT L. REV. 875 (1994).

<sup>28</sup> Ruhl, *supra* note CC, at 528.

<sup>29</sup> RICHARD O. BROOKS ET AL., *LAW AND ECOLOGY: THE RISE OF THE ECOSYSTEM REGIME* at 7 (ASHGATE, 2002).

<sup>30</sup> MALCOM L. HUNTER, JR., *FUNDAMENTALS OF CONSERVATION BIOLOGY* 20-21 (1996) (providing the 1993 Wildlife Society definition of biodiversity).

<sup>31</sup> *Id.* at 21.

organization) and functional biodiversity (i.e., ecological and evolutionary functions).<sup>33</sup>

A relatively new applied scientific discipline, conservation biology, addresses the complex relationship between human activities and the protection of ecological systems. Professor Michael Soule, one of the founders of Conservation Biology has defined it as “a new stage in the application of science to conservation problems, [which] addresses the biology of species, communities, and ecosystems that are perturbed, either directly or indirectly, by human activities or other agents. Its goal is to provide principles and tools for preserving biological diversity.”<sup>34</sup>

Although conservation biology is still a relatively young, and not well-defined, science, certain postulates have been proposed. Professor Soule divides these postulates into two categories: 1) functional postulates; and 2) ethical or normative postulates.<sup>35</sup> He describes the functional postulates as a set of fundamental rules gleaned from basic sciences, including ecology, that are geared toward the maintenance of both the form and function of natural biological systems.<sup>36</sup> Perhaps most pertinent for legal analysis are Soule’s ethical or normative postulates, which can be utilized as a fundamental ecological baseline for an environmental management or regulatory system: 1) biological diversity is good; and 2) ecological complexity is good.<sup>37</sup>

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<sup>32</sup> See *id.* at 21.

<sup>33</sup> *Id.* at 21, 28.

<sup>34</sup> Michael E. Soule, *What is Conservation Biology? In ENVIRONMENTAL POLICY AND BIODIVERSITY* (R. Edward Grumbine, ed., Island Press, 1994). Conservation biology has also been described as a “regulatory science that seeks to develop scientific standards that can be applied to regulatory criteria and then to develop the management strategies to meet these standards.” A. Dan Tarlock, *The Nonequilibrium Paradigm in Ecology and the Partial Unraveling of Environmental Law*, 27 LOY. L.A. L. REV. 1121, 1130 (1994). Conservation biology arose in the late 1970s and early 1980s as a reaction to the unprecedented worldwide extinction crisis that many biologists believe is occurring due to the activities of humans. HUNTER, *supra* note 30, at 14. Accordingly, conservation biology is an applied “crisis” discipline that is to biology what surgery is to physiology Soule, *supra* at 35. The driving force behind conservation biology is the belief that without serious efforts to reverse the trend of mass extinctions, millions of species may be at risk of extinction *Id.* at 48. The loss of species may have devastating consequences for humans, as well as for the planet as a whole. Due to the permanence of extinction, rare species are often the focus of conservation biology. EDWARD O. WILSON, *THE DIVERSITY OF LIFE* 228 (Harvard University Press 1992). The seminal works on conservation biology include: *CONSERVATION BIOLOGY: AN EVOLUTIONARY-ECOLOGICAL PERSPECTIVE* (Michael E. Soule & Bruce A. Wilcox, eds., Sinauer 1980) and *CONSERVATION BIOLOGY: RESEARCH PRIORITIES FOR THE NEXT DECADE* (Michael E. Soule & Cordon H. Orians, eds., Island Press 2001).

<sup>35</sup> Soule, *supra* note 34, at 38-45.

<sup>36</sup> Soule’s functional postulates include the following: 1) Many species are products of co-evolutionary processes – i.e., in most communities, species make up a significant part of other species’ environment; 2) Species are interdependent – i.e., mutualistic relationships exist between many species and thus, there are always uncertainties about the impact that the extinction of one species will have on another Species; 3) Many species are highly specialized. –i.e., the majority of animal species depend on a particular host. Thus, if such a host becomes extinct, many other species may be adversely affected; 4) Extinction of “keystone species” can have long-term consequences; 5) Introduction of generalist species may reduce diversity; and 6) Many ecological processes have thresholds below and which they become discontinuous, chaotic or suspended. *Id.* at 38-42.

<sup>37</sup> *Id.* at 42-44.

Most of the law and policy initiatives focused on conservation biology and biodiversity protection have focused on deciding which lands to preserve based on their diversity, uniqueness, connectivity to other lands, or other factors. While the importance of preserving significant lands cannot be overstated, such preservation would be in vain if steps are not taken to address contamination of air, water and land, both inside and outside of preserved areas. Environmental pollution is the most subtle form of ecological degradation and despite the banning of numerous pesticides over the past thirty years, pesticide pollution remains one the most serious forms of ecological degradation.<sup>38</sup> No matter how strictly protected an area is from human activity, it will never be truly protected if contaminants, such as pesticides, enter the area through the water or air, or if species that use the area are exposed to harmful contaminants whenever they leave the confines of the protected area.<sup>39</sup>

Although some legal scholars have analyzed environmental law in a general sense from a conservation biology perspective,<sup>40</sup> to date the attempts that have been made to evaluate specific management or regulatory schemes using such an approach have focused primarily on natural resources management or the Endangered Species Act,<sup>41</sup> rather than pesticide law or pollution control law, more generally.

Another important ecological concept is that of ecosystem management. It has been said that conservation biology leads to ecosystem management. In other words, ecosystem management is a tool to carry out the principles of conservation biology. Although environmental literature is rife with varying descriptions and definitions of ecosystem management, there appears to be general consensus that overriding goal of ecosystem management is to protect ecological

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<sup>38</sup> RICHARD B. PRIMACK, *ESSENTIALS OF CONSERVATION BIOLOGY* 145-46 (Sinauer 1993).

<sup>39</sup> Although the primary threat to species and ecosystem diversity is habitat destruction, even when habitats are preserved, many populations have been reduced in size to such an extent that they are extremely vulnerable to other environmental stresses, such as hazardous pollutants. Moreover, the vast majority of land in the United States is privately owned, and it would be naive to believe that enough property could be put into perpetual preservation to achieve true ecological integrity on a large scale. Thus, it is necessary to complement land preservation programs with effective regulatory programs that protect of widespread ecological integrity while allowing human activities to proceed.

<sup>40</sup> See, e.g., Walter Kuhlmann, *Making the Law More Ecocentric: Responding to Leopold and Conservation Biology*, 7 *DUKE ENVTL. L. & POL'Y* 133 (1996); Robert B. Keiter, *Conservation Biology and the Law: Assessing the Challenges Ahead*, 69 *CHI-KENT L. REV.* 911 (1994), Fred P. Bosselman & A. Dan Tarlock, *The Influence of Ecological Science on American Law: An Introduction*, 69 *CHI-KENT L. REV.* 847 (1994); and William H. Rodgers, *Adaptation of Environmental Law to the Ecologists' Discovery of Disequilibria*, 69 *CHI-KENT L. REV.* 887 (1994).

<sup>41</sup> See, e.g., Holly Doremus, *Adaptive Management, the Endangered Species Act, and the Institutional Challenges of "New Age" Environmental Protection*, 41 *WASHBURN L.J.* 50 (2001).

integrity over the long term.<sup>42</sup> Ecological integrity has been defined as the total native diversity of species, populations, and ecosystems, and the ecological patterns and processes that maintain such diversity.<sup>43</sup>

Interestingly, at the same time that ecological science, conservation biology and ecosystem management were developing in the scientific world, parallel ideas including many of those that form the basis of eco-pragmatism, were developing in the legal arena. While not couched in terms of “conservation biology,” eco-pragmatism, boiled down to its essentials, starts to look startlingly like conservation biology. Parallels between the cross-disciplinary applied science of conservation biology and the legal theoretical construct of eco-pragmatism exist in a number of respects. For instance, both approaches articulate the need to start from an ecological baseline. Moreover, both disciplines recognize the importance of adaptive management approaches to address the changing nature of both biological systems and our ability to comprehend them. Finally, although both systems argue in favor of taking costs into account in environmental-decision-making, neither approach would elevate costs to the level of being the deciding factor.<sup>44</sup>

Perhaps most significantly, both disciplines acknowledge that although we can never completely prevent all human disturbances, we do not necessarily need to. Human disturbances that are similar in characteristic, magnitude and duration to natural disturbances are not as likely to pose significant risks to species or ecosystems as are human disturbances that are substantially different in characteristic, magnitude or duration from natural disturbances.<sup>45</sup>

## 2. The Role of Economics In Eco-Pragmatism

Professor Daniel Farber’s *Eco-pragmatism*, analyzes what role economic considerations should play in environmental decision-making from a pragmatic standpoint.

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<sup>42</sup> See R. EDWARD GRUMBINE, *Introduction*, in ENVIRONMENTAL POLICY AND BIODIVERSITY (R. Edward Grumbine, ed., Island Press, 1994)

<sup>43</sup> See *Id.* at 8 (citing B. Norton, *A New Paradigm for Environmental Management* 23-41 in R. COSTANZA ET AL., ECOSYSTEM HEALTH (Island Press 1992).

<sup>44</sup> Leading conservation biologist, Professor Reed Noss, has described an approach to applying principles of conservation biology to environmental law. See Reed F. Noss, *Some Principles of Conservation Biology, As They Apply to Environmental Law*, 69 CHI.-KENT L. REV. 887, 898-900 (1994). Some of the guiding principles of conservation biology can be summarized as follows: 1) ecosystems are more complex than science can understand; 2) the less data or more uncertainty involved, the more conservative environmental decision-making should be; 3) ecosystems are not static, but instead are constantly in a state of disequilibria; 4) conservation biology is by its very nature value-laden and goal-driven; 5) environmental management decisions must be concerned with ecological processes at multiple levels of biological organization See *id.* at 898-900.

<sup>45</sup> Tarlock, *supra* note 33, at 1130.

Farber offers a sound rationale for reaching the conclusion that a hybrid, or feasibility, approach is the most pragmatic. Significantly, when ecological principles are incorporated into the eco-pragmatic analysis, they lend further support to Farber's conclusions.

a. A Rejection of Pure Risk-Based and Cost/Benefit Standards

The past twenty years of environmental law scholarship is characterized by a struggle between two opposite extremes – those who believe environmental values are paramount and those who believe economic interests are paramount.<sup>46</sup> Environmental regulation in the U.S. frequently is criticized for being unrealistic because it is based on protecting the public or environment from risks without considering the costs associated with such protection.<sup>47</sup> Of course it would be absurd to attempt to eliminate all environmental risks at all costs.<sup>48</sup> Opponents of pure risk-based approaches contend that environmental regulations seek to attain zero risk regardless of the costs of attaining such a goal. For the most part these criticisms are unfounded.<sup>49</sup> Despite the outcry of the opponents of risk-based regulation, the vast majority of federal environmental laws are not purely risk-based and few if any are zero-risk statutes.<sup>50</sup> Instead, most environmental laws allow

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<sup>46</sup> FARBER, *supra* note 17 at 35.

<sup>47</sup> As Supreme Court Justice Breyer and Professor Cass Sunstein have described, some environmental risk reduction requires expenditures of money that go well beyond the bounds of common sense. See STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 14 (1993) and Cass Sunstein, *Health-Health Tradeoffs*, 63 *CHI. L. REV.* 1533 (1996).

<sup>48</sup> FARBER, *supra* note 17 at 3.

<sup>49</sup> Although examples of environmental excesses certainly can be found, many if not most of such criticisms have been demonstrated to be without merit. FARBER, *supra* note 17 at 22. In one of the most comprehensive analyses of the costs of environmental regulation to date, Lisa Heinzerling, demonstrated that many of the oft-cited examples of the excesses costs of environmental regulations are not accurate. Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 *YALE L. J.* 1981 (1998). Heinzerling has shown that many of the examples used by cost/benefit proponents are either exaggerations or are examples of regulations that were considered but never adopted for a variety of reasons *Id.* In this article, Heinzerling scrutinizes the "Morrall table," developed in 1986 by John Morrall, an economist at the Office of Management and Budget. *Id.* at 1983, 1987-89. The table includes information on the costs of various risk-reducing regulations per life saved. *Id.* at 1987-88. The numbers from this table have been relied on extensively by scholars, environmental policy-makers and politicians to support arguments that environmental regulations are not cost-effective and that taxpayer money could be better spent elsewhere. *Id.* at 1983. Heinzerling demonstrates that the estimates of the costs of environmental regulations developed by Morrall, and widely relied upon by proponents of cost/benefit analysis, are seriously flawed. First, Heinzerling shows how Morrall included a large number of regulations that were never adopted by the regulatory agency. *Id.* at 1999-2014. Heinzerling demonstrates that the alleged highest cost environmental regulations on Morrall's table have never taken effect. *Id.* at 1983, 1999-2014. In fact, some of these proposed rules were withdrawn by the agency specifically because of the high costs associated with them. *Id.* at 2000-10. Moreover, Heinzerling shows how Morrall's use of cost estimates skew the results by being up to 1000 times higher than the agency estimates. *Id.* at 1983, 1991-1993. Further, Heinzerling shows how Morrall's estimates are misleading in that he used a high (10%) discount rate. *Id.* at 2018-24. Heinzerling's analysis shows that by using the agencies cost estimates and a lower discount rate, the cost per life saved for most of these regulations falls well within the accepted range. *Id.*

<sup>50</sup> This is for good reason. It is impossible to eliminate all risk. First, as risks are reduced to lower levels, the costs of eliminating remaining risks may be excessively high. Second, in many cases it is impossible to attain zero risk because

or require the consideration of other factors such as the costs of regulation or the economic feasibility of regulation. Even where zero-risk or absolutist risk-based environmental laws have been tried, frequently the recognition of the illogical outcomes that these approaches can result in have led to either the interpretation of the laws to take other factors into account, or the amendment of the laws imposing these strict risk-based requirements.<sup>51</sup>

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technology does not exist to measure very small amounts of pollutants or very small environmental disruptions that may cause risk. Third, it is not uncommon for risk reduction measures that are employed to address one risk to cause some other unintended risk. Finally, risk is inherent in nature. *Id.* at 72-74.

<sup>51</sup> Perhaps the most notable absolutist zero-risk-based law was the Delaney Clause of the Federal Food Drug and Cosmetic Act (FFDCA). 21 U.S.C. § 348 (1994). As one of the few environmental statutes to attempt to impose a zero-risk standard, the Delaney Clause was highly controversial. In fact, EPA attempted to interpret into the statute, a de minimis exception, despite the absolutist language contained in the law. EPA's de minimis interpretation of the Delaney Clause was struck down by the Ninth Circuit in *Les v. Reilly*, 968 F.2d. 985 (9<sup>th</sup> Cir. 1992). After many years of controversy, Congress, in 1996, eliminated the zero-risk language in favor of the more flexible "safety" standard in the Food Quality Amendment Act. Pub. L. No. 104-170, 110 Stat. 1489 (codified at 7 U.S.C.A. §§ 136-136y and 21 U.S.C.A. §§ U301-381 (West Supp. 1996). Prior the 1996, food additives in or on processed foods were regulated under section 409 of the FFDCA, whereas, pesticide residues in or on raw agricultural commodities were regulated under section 408 of the FFDCA. Section 408 deemed any poisons or deleterious pesticide chemical that is not generally recognized as safe added to a raw agricultural commodity unsafe unless a tolerance is established and the pesticide residue is within the tolerance limit. Section 408 authorized EPA to establish tolerances "to the extent necessary to protect public health," and mandated that in making such determination EPA give appropriate consideration to certain factors including the necessity for the production of an adequate a, wholesome and economical food supply. Thus, the standard for setting a tolerance under section 408 included economic considerations. The term "pesticide chemical" is defined as any substance which, alone, in chemical combination or in formulation with one or more other substance, is a pesticide within the meaning of FIFRA and which is used in the production, storage or transportation of raw agricultural commodities. 21 U.S.C. § 321(q). Generally recognized as Safe, or GRAS, is defined as generally recognized among experts qualified by scientific training and expertise to evaluate its safety as having been adequately shown through scientific principles (or for a substance in food prior to January 1958, based on common use in food) to be safe under conditions of its intended use. 21 U.S.C. § 3221(s). For processed foods, however, a completely different standard applied. Pursuant to the pre-1996 section 402 of the FFDCA, a food was deemed to be adulterated if it contained any food additive not authorized by a food additive regulation under section 409. The standard for setting a food additive regulation, however, was far different from the standard for a tolerance under section 408. Under section 409, to issue a food additive regulation, EPA would have to find that the use of the food additive under the conditions of use specified in the regulation would be "safe." Further, section 409 contained the Delaney Clause which provided that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animals or if tests show it induces cancer in man or animals. Accordingly, section 409 contained a strict "safety" standard and a complete prohibition of any carcinogenic food additive in any amount. After many years of controversy over the disparity and unsuccessful attempts by EPA to interpret the Delaney Clause as imposing a de minimis risk standard rather than a zero risk standard, the 1996 FQPA amendments to FFDCA eliminated the absolutist Delaney Clause. Further, the 1996 Act eliminated the prior standards in both section 408 and section 409 and substituted a standard of "safety" in both sections. Accordingly, under the current law, tolerances must be established for pesticide residues in food, whether in raw agricultural commodities or processed foods, at a level that is considered "safe." Safe is defined to mean there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. This "reasonable certainty standard" while still a risk-based standard, replaces the zero-risk Delaney Clause with a negligible risk standard.

It should be noted that prior to 1970, the Food and Drug Administration regulated food additives as well as pesticide residues in food under the FFDCA. Under the Reorganization Act of 1970, authority for the regulation of pesticides under both FIFRA and FFDCA was transferred to the newly formed Environmental Protection Agency. Reorganization Plan No. 3 of 1970, 84 § 2086. Since 1970, EPA has regulated pesticide residues in or on raw agricultural commodities under section 408 of the FFDCA and pesticide residues in or on processed foods as food additives under section 409 of the

At the opposite end of the spectrum from the pure risk-based approaches to environmental regulation are those approaches that elevate economic efficiency above all other considerations. Cost/benefit analyses involve balancing the “social benefit” of a regulation against the cost to society to comply with the regulation.<sup>52</sup> Cost/benefit standards are based on the premise that maximum economic efficiency is the goal of any regulatory system.<sup>53</sup> Proponents of cost/benefit analysis often build their arguments in favor of economic efficiency by using examples of environmental regulations that achieved minimum risk reduction for enormous costs.<sup>54</sup>

The cost/benefit analysis measure of value is the consumer’s willingness to pay for goods

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FFDCA.

<sup>52</sup> For a general overview of cost/benefit analyses, see CASS R. SUNSTEIN, *THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION* (2002).

<sup>53</sup> The argument in favor of economic efficiency is that limited resources should be spent where they will do the most good. This makes sense in the context of choosing between two technologies to achieve the same level of risk reduction. For example, if, all else being equal, it would cost ten million dollars to install an end-of-pipe technology that would reduce water pollutants, thereby saving five lives, but it would cost only one million dollars to use alternative raw materials in the manufacturing process that would achieve the same risk reduction goal, no reasonable person would question the decision to utilize the more economically efficient risk reduction method. However, the real world is rarely so clear-cut, and typically environmental decisions are not a choice between two equally effective risk reduction methods. More often they involve complex trade-offs in risk reduction, costs and normative choices that are not easily monetized. Consequently, cost/benefit analyses reach far beyond the obvious and simple goal of achieving an environmental benefit for the lowest cost possible. See FARBER, *supra* note 17 at 7.

<sup>54</sup> *Id.* at 22. For example, the fact that an individual drives a sport utility vehicle (SUV) that gets poor gas mileage does not necessarily imply that such person does not value clean air or energy efficiency. The individual may have purchased the SUV with the primary consideration of safety and space for the family and its gear. Nevertheless, the individual may value clean air and energy efficiency and may fully support the imposition of tougher fuel economy standards on SUVs. The phenomenon of individual economic preferences frequently conflicting with societal desires is well illustrated by the following exercise that Professor Scott Barrett of the Paul H. Nitze School of Advanced International Studies at Johns Hopkins University, uses in his classroom. Professor Bartlett’s exercise can be seen as a variant of the prisoner’s dilemma to show individuals may make different choices when acting in a mode of consumer/wealth acquirer versus in a mode of democratic citizen. Professor Barrett first hands out two playing cards, one black and one red, to each student in his class. He then instructs the students that each player will receive five dollars for keeping a red card plus one dollar for every red card handed in by any other player. Thus, if there are twenty students playing, and each player hands in her red card, each of the twenty students will receive twenty dollars. If none of the twenty player hands in her red card, each student will receive only five dollars. If six players hand in their red cards, the other fourteen students receive eleven dollars each, but the six who handed in their cards, only receive six dollars each. The incentive for each individual player to keep her red card is obvious. Accordingly, when Barrett’s class has played this game, typically less than two-thirds of the players turn in their red cards. Barrett explains that this is what the economists call a public good. All players benefit, and no player can be excluded from receiving that benefit.

When Barrett asks these same students to vote anonymously on whether to allow a government regulation that would confiscate all of the red cards, thereby resulting the best possible outcome for all students (i.e., each student receives twenty dollars), invariably, a majority votes in favor of the government regulation. In her article, *What Makes Environmental Treaties Work?*, in which she describes Professor Barrett’s game, Frances Cairncross reaches the following interpretation of this game: “[I]n other words, left to themselves, individual players are selfish, but they yearn for some outside force to make everybody behave better and improve the outcome of the game for all the players.” Frances Cairncross, *What Makes Environmental Treaties Work?* CONSERVATION IN PRACTICE, vol. 5, num. 2, 12-19 (2004) (discussing Professor Scott Barrett’s book, *ENVIRONMENT AND STATECRAFT: THE STRATEGY OF ENVIRONMENTAL TREATY-*

or services.<sup>55</sup> The concept of willingness to pay does not necessarily translate well to ecological values.<sup>56</sup> Moreover, relying on willingness to pay may skew cost/benefit analyses away from protecting environmental values because embedded within the willingness to pay concept is an assumption that industry has the right to utilize resources, and that if environmentalists want to protect those resources, they have to be willing to pay for such protection.<sup>57</sup>

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MAKING (1990)).

<sup>55</sup> *Id.* at 36. The willingness to pay standard is a key component of welfare economics. For a good general discussion of the Pareto Criteria, as well as other theories of economic efficiency, including Kaldor-Hicks efficiency, *see generally* Jules Coleman, *Efficiency, Utility, and Wealth Maximization in FOUNDATION OF THE ECONOMIC APPROACH TO LAW* (Avery Wiener Katz, ed., Foundation Press 1998). As Farber explains, welfare economics is based on the simple concept of the Pareto improvement. Under this standard, a decision that results in at least one person benefiting and no one being harmed is a sound decision. Of course, in real world decision-making, it is rare to find such a simple outcome. Thus, welfare economics has developed the concept of economic efficiency whereby, an outcome is considered to be more economically efficient than other outcomes if in an overall sense, the gains of the winners outweigh the losses of the losers. This is accomplished if a hypothetical transfer of some of the gains from the winners to offset the losses of the losers would result in a Pareto improvement (i.e., once the losers losses have been offset by some of the winners gains, the winners maintain at least some gain and the losers now have suffered no losses). FARBER, *supra* note 17, at 44.

<sup>56</sup> It can be difficult to determine how much people would be willing to pay for a given ecological service or benefit. Although it may be a relatively easy task to determine how much people are willing to pay to for certain types of values, such as how much more people are willing to pay for a safe product versus an unsafe product, in the environmental arena, many values that are sought to be protected by environmental laws are what is known as “non-use” values. These non-use values include “option value,” which is how much people are willing to pay to leave open the option of receiving a benefit in the future. An example of option value is the value people are willing to pay to preserve tropical rainforests to preserve the option of obtaining plants with medicinal value in the future. *Id.* at 48. Another type of non-use value is “existence value,” which is how much people are willing to pay to protect something that they will never directly benefit from. An example of existence value is how much people are willing to pay to protect an endangered species even if they will never receive any direct benefit from that species, and in fact may never even see that species. *Id.* These non-use values are much more difficult to monetize in a cost/benefit analyses than are other types of values that provide a more direct impact to the person who is willing to pay for them. *Id.* at 49. One way that economists attempt to monetize these values is through a survey technique called contingent valuation. Cass Sunstein has criticized this technique as unreliable because surveys asking people hypothetically how much they would pay to preserve a particular non-use value may be skewed by people answering in a way that makes them feel morally satisfied rather than stating their real valuation. *Id.* at 49 (citing CASS SUNSTEIN, *FREE MARKETS AND SOCIAL JUSTICE* 142-43 (1997)). On the other side of the debate critics argue that contingent valuation is not an appropriate way to value natural resources. John Heyde, *Is Contingent Valuation Worth the Trouble?*, 62 *CHI. L. REV.* 331 (1995).

<sup>57</sup> The question then becomes one of how much are the environmentalists willing to pay to protect the resources. If instead, one assumes that environmentalists have the right to protect resources, and that industry must pay environmentalists, or the public, if it wishes to utilize those resources, the question becomes one of how much are environmentalists or the public willing to accept to allow the resources to be used. The amount of money environmentalists are willing to accept to allow a resources to be used is typically twice as high as the amount of money the same environmentalists is willing to pay to protect the resource. *Id.* at 100. Nevertheless, most cost/benefit analyses use willingness to pay. SHAPRIO & GLICKSMAN, *supra* note 12 at 57. This is but one example of how cost/benefit analyses are not value-neutral. The value-based assumptions that underlie the analyses can dramatically alter outcomes. *See also Id.* at 56, explaining that willingness to pay and willingness to accept are typically different due to the distribution of wealth in society. A person’s wealth does not tend to limit willingness to accept in the same way it limits willingness to pay. As a result, willingness to pay tends to result in less regulation. *Id.* at 66.

An example of the difference between willingness to pay and willingness to accept provided in Farber’s book is the example of whalers desiring to kill a pod of whales. If one assumes that the whalers have a right to kill the whales for their own economic benefit, the question becomes how much are the environmentalists willing to pay the whalers not to kill the



Proponents of cost/benefit analysis believe that sound decision-making is based on market indicators, whereas, environmentalists believe that such decision should be based on political indicators (Farber refers to this as “willingness to pay” versus “willingness to vote”).<sup>58</sup> This distinction has been described as follows: “social regulation expresses what we believe, what we are, what we stand for as a nation, not simply what we wish to buy as individuals.”<sup>59</sup> Moreover, relying solely on consumer choices leaves out the possibility of decision-making based on community analysis, deliberation and vetting of ideas.<sup>60</sup> Critics of cost/benefit analysis focus their arguments on the distinction between private consumer choices and public choices based on public values.<sup>61</sup> In the pesticides arena, an economic argument could be made that the fact that most consumers purchase food that is treated with chemical pesticides means that consumers are making a conscious choice to do so, based on economic and other factors. While it is true that consumers may purchase such foods because they are generally significantly less expensive than foods that are grown without chemical inputs, to assume that this consumer choice means that consumers have consciously determined that the health and environmental risks of pesticides in food are outweighed by the increased cost of organically produced food is overly simplistic.

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whales. This willingness to pay then becomes the economic value of the whales. If instead, one assumes that the environmentalists have the legal right to protect the whales, the question becomes how much are the whalers willing to pay the environmentalists the right to hunt the whales. Under this scenario, it is likely that the environmentalists will demand a much higher price from the whalers than they would be willing to pay in the first scenario. One explanation for this phenomena is that by assuming the environmentalists have the right to protect the whales, and the consequent right to sell the hunting rights to the whalers, the environmentalists have been made wealthier and more powerful. Thus, the demand curve is shifted in favor of a higher price to hunt the whales. Consequently, under the second scenario, the whaling that may have been economically efficient under the first scenario, may no longer be efficient. *Id.* at 99. Another explanation for the difference between willingness to pay and willingness to accept, may be that people tend to be attached to the status quo and that change can only be purchased at a high price. *Id.* at 100.

<sup>58</sup> FARBER, *supra* note 17 at 42.

<sup>59</sup> *Id.*, quoting MARK SAGOFF, *THE ECONOMY OF THE EARTH: PHILOSOPHY, LAW AND THE ENVIRONMENT* at 17 (1988). Professor Cass Sunstein made this point eloquently, when he explained human character as being more than simply the acts an individual chooses to do at any given point in time. *See Id.* at 54-55.

<sup>60</sup> *See* SHAPIRO & GLICKSMAN, note 12 at 60.

<sup>61</sup> Nevertheless, economists do recognize that there is a difference between private consumer choices and environmental benefits. Economists consider environmental benefits to be a public good. Public goods cannot be provided solely through the marketplace because all members of the public benefit from the good and there is no way to charge all members of the public for the benefit they receive. The classic example of a public good in the environmental context is clean air. All members of the public breathe air, and thus, there is no way for a private enterprise to charge the public for the air it breathes. Accordingly, there is no way for the private enterprise to benefit financially by ensuring its operations result in clean air. In recent years, Professor Cass Sunstein has introduced a modified form of cost/benefit analysis, in which public values rather than private preferences govern environmental decision-making. *See* FARBER, *supra* note 17 at 95 (describing the proposal in CASS SUNSTEIN, *FREE MARKETS AND SOCIAL JUSTICE* 139 (1996) involving a two-stage decision-making process. A traditional quantitative cost/benefit analysis would constitute the first stage. The second stage would take into consideration other non-quantifiable values.). FARBER, *supra* note 17 at 95.

First, consumers may not be fully informed of the environmental and health risks associated with pesticide use. The time and thought that go into sorting out technical risk assessment information may be more than the average consumer can, or desires to, commit. Moreover, as described at length in this article, many of the risks of pesticides use are not well understood, even by the experts. Thus, it would be unreasonable for consumers to be able to make decisions on preliminary or confusing data that experts are having difficulty grappling with. Moreover, the price of food treated with pesticides do not reflect the true cost of growing the food because of a failure to internalize what economists refer to as negative externalities. For example, the price of purchasing food treated with pesticides does not reflect the price that society may have to pay later to clean-up pesticide contaminated sites, the long-term costs of society of the loss of insect pollinators, or the long term costs to society of the development of pest resistance due to overuse of pesticides. Moreover, the price of the food is artificially low due to numerous government programs that encourage the use of chemical inputs in agriculture.<sup>62</sup> While these numerous and complex programs are far beyond the scope of this article, the fact that crop subsidies, crop protection insurance and other government programs provide economic incentives for using pesticides and economic disincentives for growing crops without chemical pesticides, results in artificially low food prices, which in turn, results in consumers perhaps purchasing more food grown with pesticides than they would in a pure market.<sup>63</sup> Accordingly, in the agricultural pesticide arena, as well as many other arenas, a cost/benefit analysis that relies on market costs and benefits does not reflect consumers' true preferences. Moreover, this example makes clear that the assumptions upon which costs/benefit analyses are based, including perfect information, no externalities, and a truly free market, deviate so far from reality that cost/benefit analysis, standing alone, are an unreliable guide.

One controversial issue in the cost/benefit debate is whether environmental values are

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<sup>62</sup> For a detailed discussion of government policies that encourage pesticide use, see Kenneth A. Dahlbert, *Government Policies that Encourage Pesticide Use in the United States*, in THE PESTICIDE QUESTIONS: ENVIRONMENT, ECONOMICS AND ETHICS 281 (David Pimentel & Hugh Lehman, eds., 1993) (discussing a wide range of local, state, and federal programs including price supports, incomes supports, farm credit programs, crop insurance programs, export policies, and tax policies) See also David Pearce & Robert Tinch, *The True Price of Pesticides in BUGS IN THE SYSTEM: REDESIGNING THE PESTICIDE INDUSTRY FOR SUSTAINABLE AGRICULTURE* 50 (William Vorley & Dennis Kenney, eds. 1998).

<sup>63</sup> *Id.* For a good summary of agricultural price supports, see Robert L. Thompson, *Agricultural Price Supports* in the Concise Encyclopedia of Economics, available at <http://www.econlib.org/library/enc./Agricultural Price Supports.html> (last visited July 18, 2003).

significant only to the extent that they can be translated into economic terms.<sup>64</sup> Opponents of cost/benefit analysis maintain that economists “price everything and value nothing.”<sup>65</sup> Cost/benefit analysts tend to limit their view of the benefits of environmental regulation to human lives saved or cancers averted.<sup>66</sup> The true benefits of environmental protection extend far beyond counting the numbers of lives saved. For example, non-lethal human health effects, including subchronic neurological, behavioral or reproductive effects are not well understood, not easily quantified, and rarely included in any meaningful way in cost/benefit analyses.<sup>67</sup> Moreover, as described in detail below, ecological systems are not well understood by science and the value of such systems is not readily quantified. Consequently, human disruptions to ecological systems are rarely part of cost/benefit analyses. Further, ethical, religious, aesthetic and other normative values of environmental protection are not typically included in cost/benefit analyses. Finally, even those components of the cost/benefit analysis that are more easily monetized, such as the cost of compliance with environmental regulations, are difficult to estimate. Frequently, regulatory agencies are asked to take industry at its word,<sup>68</sup> and often in retrospect, the true costs of compliance are not as high as the pessimistic estimates of industry would suggest.<sup>69</sup>

Another concern often raised by opponents of strict cost/benefit analyses is that even when costs and benefits are balanced in an overall sense, what is left out of the equation is who pays the costs and who gets the benefits. In other words, if a disproportionate share of the costs are borne by segments of the population who do not share proportionally in the benefits, is there truly a balance of the costs and the benefits? Environmental risks tend to be disproportionately borne by vulnerable populations – frequently people of color, low income and/or weak political power–

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<sup>64</sup> FARBER, *supra* note 17, at 35.

<sup>65</sup> *See generally*, FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (The New Press 2004). *See also*, DAVID PEIRCE & DOMINIC MORAN, THE ECONOMICS OF BIOLOGICAL DIVERSITY CONSERVATION *IN* CONSERVATION BIOLOGY FOR THE COMING DECADE (Chapman & Hall 1998).

<sup>66</sup> FARBER, *supra* note 17 at 88. Cost/benefit analyses typically rely on the concept of “statistical lives” saved, because under most risk assessments, it is virtually impossible to identify the actual person that would have died but for the environmental regulation. Typically people value a statistical life less than an actual life. This is illustrated by the lengths that people will go, and the money they are willing to spend to save a child who falls into a well, as compared to how much society is willing to spend to save an anonymous statistical person. *See e.g.*, SHAPRIO & GLICKSMAN, *supra* note 12 at 64. In the ecological context, there are many examples of people going to great lengths to save a beached whale, while only being willing to spend a significantly lesser amount to save the statistical dolphin from the shrimper’s net. It is even harder to predict how much people will be willing to spend to protect a statistical ecological service.

<sup>67</sup> FARBER, *supra* note 17 at 88.

<sup>68</sup> *Id.* at 90.

<sup>69</sup> FARBER, *supra* note 17 at 167-68.

who do not share in the benefits gained by industrial pursuits.<sup>70</sup> The benefits of development and industry typically go to the advantaged segments of society who typically do not bear a great portion of the risks resulting from such activities. Environmental Justice<sup>71</sup> proponents point out that cost/benefit analyses and other market-based systems can lead to the creation of risk “hot spots,” where overall the cost/benefit analysis may weigh in favor of an activity going forward, but within a given segment of society, typically economically and politically disadvantaged populations, the cost/benefit analysis weighs in the opposite direction – i.e., hot spots of risk with very little benefit. Accordingly, proponents of Environmental Justice reject strict cost/benefit analyses.<sup>72</sup>

A similar argument can be made with regard to ecological resources. Risk hot spots may emerge in situations where, overall the cost/benefit analysis weighs in favor of allowing a pesticide to be used, but in a particular geographic area, or with a particular species or ecosystem, risk may be disproportionately high. This may occur with regard to sensitive species, including threatened or endangered species, or with ecosystems with low resistance and or low resilience. One example of such a risk hot spot is the global amphibian crisis, in which pesticides are implicated.<sup>73</sup> Although the cost/benefit analysis for a particular pesticide may reflect that the benefits outweigh the costs overall, this does nothing to protect the highly sensitive and highly vulnerable amphibian populations.<sup>74</sup>

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<sup>70</sup> See generally CLIFFORD RECHTSCHAFFEN & EILEEN GAUNA, ENVIRONMENTAL JUSTICE: LAW, POLICY AND REGULATION (Carolina Academic Press 2003).

<sup>71</sup> Although a detailed consideration of Environmental Justice is beyond the scope of this article, it is a compelling issue in environmental policy, and it provides one example of how cost/benefit analysis does not adequately address ethical, moral or fairness issues that cannot be monetized. For an excellent discussion of how market-based approaches disproportionately impact vulnerable populations see *Id.* at 33-37.

<sup>72</sup> Proponents of cost/benefit analysis counter this argument by pointing out that segments of society that are disadvantaged will not necessarily be better off under an inefficient system. However, Environmental Justice advocates do not argue in favor of inefficiency for inefficiency’s sake, but rather they are willing to tolerate some level of economic inefficiency to accomplish other important societal goals such as fairness.

<sup>73</sup> See Carlos Davidson, *et al.*, *Spatial Tests of the Pesticide Drift, Habitat Destruction, UV-B, and Climate-Change Hypotheses for California Amphibian Declines*, 16 CONS. BIOL. 1588 (2002).

<sup>74</sup> Moreover, the amendment of FIFRA by the 1996 Food Quality Protection Act to include a “safety” standard for human food consumption may have resulted in a shift of risk away from food consumers to occupational workers and ecological resources. For example, organophosphate pesticides degrade quickly into benign breakdown products in the environment and on agricultural food products. Thus, the FQPA standard of “safety” for human food consumers may favor the use of organophosphate pesticides over other pesticides that do not break down as quickly, and thus leave residue on foods. However, as described above, organophosphates are highly acutely toxic to humans, other mammals, and birds and have been implicated in thousands of bird deaths. Accordingly, relying more heavily on organophosphates to meet the FQPA standard, while reducing risks to food consumers, may result in significantly increased risk to vulnerable farm worker populations and to ecological resources. The risk to farmworkers for pesticide exposure is extremely high. Ivette Perfecto & Baldemar Velasquez, *Farmworkers: Among the Least Protected*, in Rechtschaffen & Gauna, *supra* note 70, at 67-68.

Finally, the values inherent in ecological integrity or biodiversity are particularly ill suited to be reduced to a dollar value.<sup>75</sup> Of course many ecological products and services have instrumental value. Although, many species in nature can be eaten, made into medications, made into clothing or shelter, burned for fuel or otherwise used in a market-based economy,<sup>76</sup> what is considerably more difficult to value are the aesthetic, inspirational, religious or spiritual reasons that many people value ecosystems.<sup>77</sup> And perhaps even more challenging is attempting to reduce to dollars and cents the value that species have as members of ecosystems. For example, species in an ecosystem may serve important roles as producers, consumers, decomposers, competitors, dispersers, or pollinators.<sup>78</sup> Each of these roles provides value to other members of the ecosystem, including humans.<sup>79</sup> Another concern with the strict cost/benefit approach is that the lack of knowledge and uncertainty regarding biological systems, argues in favor of a cautious approach to the cost/benefits analysis. Our current limited understanding of ecological systems and inadequate methodologies for monetizing values, limit the ability of cost/benefit analyses to be sufficiently precise to control environmental decision-making.<sup>80</sup>

In sum, the shortcomings of cost/benefit analysis are numerous. First, current data and methodologies are not adequate for accurate and precise analyses. Second, cost/benefit analyses do not adequately address ecological values, community values and other normative considerations. It is impossible to reduce such values to monetary terms. Finally, far from being value-neutral, cost/benefit analyses are laden with biases in favor of those who seek to use resources and away from those who seek to protect resources. Accordingly, Eco-pragmatism rejects the notion that cost/benefit analyses should control environmental decision-making. Nevertheless, economic analyses are considered to be useful factors to inform environmental

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Because the vast majority of farmworkers are minorities – primarily Latinos – these risks raise significant environmental Justice concerns. *Id.*

<sup>75</sup> See, e.g., J.B. Ruhl, *supra* note 15 at 543.

<sup>76</sup> HUNTER, *supra* note 30, at 43.

<sup>77</sup> *Id.* Noted zoologist E.O. Wilson has coined the term “biophilia” to describe the deep emotional and spiritual relationship that many people share with other living organisms and the related sense of awe that frequently accompanies experience with the natural world. See generally, E.O. WILSON, BIOPHILIA: THE HUMAN BOND WITH OTHER SPECIES (1984).

<sup>78</sup> HUNTER, *supra* note 30, at 52.

<sup>79</sup> *Id.* at 52.

<sup>80</sup> FARBER, *supra* note 17 at 42. Farber estimated the costs and benefits of a number of environmental regulations from 1988 and determined that the costs ranged from 55 to 77 billion and the benefits ranged from 16 to 135 billion dollars. *Id.* At 167-68. Thus, he concludes, the return on every dollar spent ranged between 21 cents and \$2.27. *Id.* As Farber puts it “we were either losing 80 percent of our investment or a more than doubling our money and we don’t know which!” *Id.* at

decision- makers.<sup>81</sup> In other words, cost/benefit analysis should assist rather than control environmental decision-making.<sup>82</sup>

#### b. The Eco-Pragmatic Response: Embracing Feasibility

In contrast to strict cost/benefit approaches, eco-pragmatism attempts to grapple with the complexities and lack of understanding of species and ecosystem values. Eco-pragmatism also recognizes that, in the real world, public policy decision-making must occur within certain unavoidable constraints. Accordingly, one of the foundations of pragmatism is a rejection of comprehensive rationality in favor of bounded rationality.<sup>83</sup> In a perfect world with perfect scientific data on ecological risks and perfect cost/benefit methodologies that adequately value all costs and benefits, a cost/benefit approach may be compelling. However, with the complexity pervasive in ecological systems, the dearth of good data and the confused state of cost/benefit methodology, all coupled with the need to act now, the pragmatist must find another way. The pragmatist will look to what has worked best in the experience of environmental law to date, and what has worked best is at least arguably, technology-based approaches.

All but the most staunch proponents of cost/benefit analysis seem to recognize that cost/benefit analysis involves so many assumptions, judgment calls, values and unquantifiable factors, that it is overly simplistic to view cost/benefit analysis as a clear-cut quantifiable test, where all one has to do is plug the numbers in and the “right” answer comes out.<sup>84</sup> Eco-pragmatic theory recognizes that there are many ethical considerations that go beyond mere economic efficiency that must be taken into account in making environmental decisions.<sup>85</sup>

For all of the reasons discussed above, eco-pragmatism rejects pure risk-based approaches

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168.

<sup>81</sup> FARBER, *supra* note 17 at 9; *see also*, SHAPIRO & GLICKSMAN, *supra* note 12 at 63.

<sup>82</sup> Ruhl, *supra* note 15 at 538.

<sup>83</sup> Bounded rationality recognizes that institutions that make policy decisions do not have complete information or unlimited time so as to enable them to make some theoretically optimal choice in every case. SHAPIRO & GLICKSMAN, *supra* note 12 at 23. The reality is that all institutional decision-making is “bounded” by limited time, limited costs and limited information. *Id.* If these bounds did not exist, arguably cost/benefit analysis would be able to provide optimal choices. Pragmatism does not ignore the existence of such bounds, but instead accepts these constraints and recognizes that decision-making must take them into account, and adapt as new information becomes available.

<sup>84</sup> FARBER, *supra* note 17 at 94. Although economists are quite adept at providing simplified examples of how market efficiencies work in theory, for every clever example described by an economist, one can find an equally clever examples highlighting the shortcomings of pure market efficiencies in the environmental arena describe by proponents of risk-based approaches.

<sup>85</sup> *Id.* at 9. As Shapiro and Glicksman have put it, we should be trying to do better than simply attempting to “achieve the ‘optimal’ level of injury, death or environmental destruction.” SHAPIRO & GLICKSMAN, *supra* note 12 at 21, 50.

and cost/benefit analysis in favor of a hybrid approach based on the concept of feasibility.<sup>86</sup> Under the hybrid approach, environmental risks are reduced to the amount feasible and cost/benefit analysis is used to assist, rather than control decision-making.<sup>87</sup> This type of approach has been described as “doing the best that we can.”<sup>88</sup> In other words, while the goal is environmental risk reduction, there is recognition that at some point the costs of further risk reduction become too high to justify. Pragmatic risk regulation attempts to reconcile conflicting values by “striving to achieve the maximum level of protection consistent with reasonable costs.”<sup>89</sup>

Although there has been extensive debate in the academic world over the appropriateness of utilizing a cost/benefit analysis or pure risk based approaches in environmental regulation, the truth is that for the most part, Congress has rejected both pure risk-based and cost/benefit standards and most of the substantial environmental regulatory programs involve “hybrid” standards – i.e., risk based standard that take economic considerations into account but do not require strict cost/benefit balancing. Professors Shapiro and Glicksman have surveyed existing environmental regulatory statutes to determine which contain cost/benefit standards, which contain feasibility standards, and which are pure risk-based. Their work demonstrates that the majority of existing statutes contain standards that require risk to be avoided to the extent feasible or to the extent that the best available technology can achieve. Accordingly, these statutes are referred to as technology-based statutes. The most common examples of environmental statutes that utilize technology-based standards include the Clean Water Act<sup>90</sup> and the Clean Air Act.<sup>91</sup> While these standards take costs into account, they are not cost/benefit balancing standards.

Shapiro and Glicksman describe constrained balancing as regulation whereby the legislature establishes a level of environmental protection to be achieved by identifying regulatory objectives based on some model technology.<sup>92</sup> In this way, costs are considered in choosing an

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<sup>86</sup> Farber has defined feasibility as where costs are “not grossly disproportionate to the benefits to be achieved.” FARBER, *supra* note 17 at 94.

<sup>87</sup> *Id.* at 122-123.

<sup>88</sup> SHAPIRO & GLICKSMAN, *supra* note 12 at 22, 50.

<sup>89</sup> *Id.* at 147.

<sup>90</sup> *See, e.g.*, 33 U.S.C. § 1311(b) (setting forth technology-based standards for point sources of water pollution).

<sup>91</sup> *See, e.g.*, 42 U.S.C. § 7502(c) (1) (specifying that existing stationary sources of air pollution in nonattainment areas implement all “reasonable available control technology”).

<sup>92</sup> *Id.* at 37.

appropriate technology as the model, but costs are not directly weighed against benefits.<sup>93</sup> This approach is what is commonly referred to as “technology based”<sup>94</sup> standard setting and is also what Farber refers to as feasibility based decision-making. Under constrained balancing or

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<sup>93</sup> *Id.* at 37. Examples of this type of approach include: the Clean Air Act’s requirement for non-attainment areas that existing stationary sources implement all “reasonably available control technology” as expeditiously as practicable, 42 U.S.C. § 7502(c)(1), the requirement of the Safe Drinking Water Act that EPA establish maximum contaminant levels as close as feasible to achieving the level at which no known or anticipated health effects will occur. 42 U.S.C. § 300g-1(b)(4).

<sup>94</sup> Technology-based standards are credited with much of the pollution reduction that has occurred since the environmental movement of the 1960s and 1970s. *See* Wendy E. Wagner, *The Triumph of Technology-Based Standards*, 2000 U. Ill. L. Rev 83, 85 (2000). Technology-based standards are the dominant mode of controlling the amount of pollution released in to the environment in the US. *Id.* at 88. These standards typically are developed by EPA in response to a Congressional mandate for EPA to establish pollution limitations based on some prescribed standard such as the “best available technology.” *Id.* at 89. Once Congress has mandated the use of a particular technology-based standard, EPA will conduct a review of currently available technologies for specific industrial sectors and chooses the technology that best fulfills the Congressionally-prescribed standard. *Id.* Typically, the specific technology chosen is not required to be employed. Instead, EPA determines the level of pollution control that can be achieved using the chosen standard. *Id.* Industry is then free to utilize any technology it chooses that complies with the numerical standard. *Id.* Accordingly, industry has an incentive to develop the most efficient technology to meet the numerical standard. One drawback to using feasibility as a standard is that feasibility will vary with the economic strength of the industry. FARBER, *supra* note 17 at 83. For example, it may be feasible for a strong manufacturing sector may be able to install costly pollution control technology, while it may be completely infeasible for a weak sector of the economy to install the same technology. As a result, more economically successful industries are penalized for their success with the imposition of stricter rules that do not apply to less successful industries. *Id.* Many justifications have been expressed for using technology based approaches to environmental protection. These approaches tend to better address non-economic values, while still taking economic concerns into account. *See* SHAPIRO & GLICKSMAN, *supra* note 43 at 65. In addition, feasibility-based approaches recognize and account for bounded rationality *See id.* at 65. *See also*, note 83 and accompanying text. A feasibility standard is pragmatic in the sense that it is consistent with widely-shared beliefs that environmental protection is important to society. SHAPIRO & GLICKSMAN, *supra* note 12 at 21. Feasibility approaches tend to prod industry toward environmental risk reduction, until the point is reached where additional protection would be technologically or economically infeasible. *See, e.g.*, J.B. Ruhl, *supra* note 15 at 537. Moreover, some commentators maintain that technology based standards are the best standards available because we do not have enough data to conduct true cost/benefit analyses for most environmental decisions Adam Babich, *Too Much Science in Environmental Law*, 28 COLUM. J. ENVTL. L. 119 (2003). Finally, from a pragmatic perspective, technology based approaches have worked well in our thirty year history of environmental law implementation. *See generally*, Wagner, *supra*. After conducting an extensive analysis of the role of technology-based standards in environmental law over the past thirty years, Professor Wendy Wagner concludes that technology-based approaches are one of the most important innovations in environmental law. *Id.* at 86. Wagner also lauds technology-based standards for being relatively easy to promulgate, readily enforceable, even-handed, adaptable and efficient. *Id.* at 94-105 (finding that the rate of promulgation for technology-based standards outpaces other standards from three to ten times and describing how technology-based standards apply equally to all members of the regulated industry within a given category). Wagner explains that technology-based standards are easily enforceable because the numerical level of pollution allowed is clearly prescribed by rule. *Id.* Once emissions or discharges are sampled for pollutants, regulated entities either meet the numerical standard or they do not. *Id.* How they choose to meet the standard is irrelevant. For the same reason, technology-based standards are very predictable. *Id.* Regulated entities can readily determine what numerical standards they are expected to comply with by looking at the EPA rule for that industry category. *Id.* at 100. *See also*, THOMAS O. MCGARITY, MEDIA, QUALITY, TECHNOLOGY, AND COST/BENEFIT BALANCING STRATEGIES FOR HEALTH AND ENVIRONMENTAL REGULATION, LAW & CONTEMP. PROBS. 159-199, N. 194 (1983). Wagner demonstrates that technology-based standards generally are very efficient. *See generally* Wagner, *supra*. She also asserts that technology-based standards create incentives for regulated interests to develop more efficient technologies. *Id.* Wagner describes technology-based approaches as fulfilling a moral imperative for industry to “do the best it can” to reduce environmental harm. *Id.* at 92.



feasibility approaches, risk reduction is sought to the point that additional reduction would result in extraordinary or disproportionate costs.<sup>95</sup>

Shapiro and Glicksman refer to the second category of balancing approaches as “open-ended balancing,” which they describe as a type of balancing whereby the legislature prescribes the factors that the agency must consider in making a decision, but does not dictate the weight the agency must give to any particular factor.<sup>96</sup> Interestingly, Shapiro and Glicksman describe FIFRA as an open-ended balancing statute. And while it is true that a facial reading of the statutory standard of “unreasonable affects effects” would lead one to believe that it is indeed an open-ended balancing statute, whereby the agency has been directed to consider a variety of risk and benefit factors, but has not been directed as to how to weigh such factors, in practice, FIFRA has been interpreted and applied by EPA as being a cost/benefit balancing statute whereby for a pesticide to be registered its benefits must outweigh its costs. This interpretation has been articulated in agency orders<sup>97</sup> and upheld in many judicial decisions.<sup>98</sup> Thus, despite the significance of pesticides in the development of environmental law, FIFRA virtually stands alone in its cost/benefit approach to environmental protection.<sup>99</sup>

### 3. The Necessity of a Baseline

One of the most significant concepts in Farber’s work on eco-pragmatism is the idea of starting with an environmental baseline. Farber argues that there must be some overarching principle to help guide decision-making and to serve as a “tie-breaker” in the close cases.<sup>100</sup> Farber posits that environmental risks should be reduced to the extent feasible and that the environmental baseline should be protected except in the case where the costs of protecting the baseline” are grossly disproportionate to the benefits.”<sup>101</sup> Eco-pragmatism’s baseline starts with a

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<sup>95</sup> SHAPIRO & GLICKSMAN, *supra* note 12 at 52.

<sup>96</sup> *Id.* at 39. .

<sup>97</sup> In the Matter of Stevens Industries, Inc, et al., I.F.& R. Docket Nos. 63, et al. (Consolidated DDT hearings, June 2, 1972).

<sup>98</sup> Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 584, 594 (1971).

<sup>99</sup> The only other major environmental statute that employs a strict cost/benefit balancing approach is TSCA Section 6, 15 U.S.C. § 2605, which has been rendered impotent by the Fifth Circuit Court of Appeal decisions in Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5<sup>th</sup> Cir 1991) (holding that EPA did not have a reasonable basis to conclude that asbestos presents an unreasonable risk and that EPA failed to choose the least burdensome alternative to protect against such risk).

<sup>100</sup> FARBER, *supra* note 17 at 93, 104.

<sup>101</sup> *Id.* at 12.

presumption in favor of the environment.<sup>102</sup> However, Farber does not provide a comprehensive explanation of what the baseline should be. Ecological principles can be used to assist in developing an appropriate baseline.

Farber's primary justification for starting with an environmental baseline is the long-term commitment to environmental protection in the US.<sup>103</sup> Farber posits that there is a general recognition that nature has inherent value that goes far beyond the purely utilitarian uses of nature for human purposes.<sup>104</sup> Another justification for the environmental baseline is the limited scientific understanding, enormous data gaps, complexity and uncertainty of environmental issues.<sup>105</sup> Without a full understanding of the complex issues involved, prudence suggests a presumption in favor of environmental protection. Consequently, environmental law should take a stance in favor of environmental protection instead of attempting to be neutral. Under eco-pragmatism, there is a presumption in favor of environmental protection, but the presumption can be rebutted where the costs of protecting the baseline are disproportionately large.<sup>106</sup>

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<sup>102</sup> Ruhl, *supra* note 15 at 537. As Farber explains, for any environmental regulatory scheme, there are at least three possible baselines that could be employed. FARBER, *supra* note 17 at 103. The first such baseline would be a neutral baseline in which there is neither a presumption in favor of the environmental nor one in favor of industrial/economic pursuits. *Id.* at 103. The second such baseline is one that holds a presumption in favor of industrial/economic pursuits. Under this baseline, regulated interests begin with a presumptive entitlement. *Id.* The third such baseline is one in which the presumptive entitlement is assigned to those who stand to benefit from the regulatory program. *Id.* In other words, under the third baseline, there is a presumption in favor of environmental protection. Farber asserts that the environmental baseline is the appropriate baseline to use.

<sup>103</sup> *Id.* at 94. Farber has been criticized for overstating the public commitment to environmental protection. See Paul Boudreaux, *Costs, Benefits and Values: A Review of Daniel A. Farber's Eco-Pragmatism*, 13 TUL. ENVTL. L.J. 125, 148 (1999) (asserting that Farber has "overstretched" and that although Americans like to label themselves as environmentalists, the depth of their commitment is unclear). Nevertheless, there are numerous surveys and studies that consistency demonstrate the existence of such a commitment. For a general discussion of American environmental values and public opinion surveys regarding such values, see ROBERT V. PERCIVAL, CHRISTOPHER H. SCHROEDER, ALAN S. MILLER AND JAMES P. LEAPE, ENVIRONMENTAL REGULATION: LAW, SCIENCE AND POLICY (4<sup>th</sup> ed. Aspen 2003). One recent study conducted by the Yale Center for Environmental Law and Policy, indicates that most Americans are seriously concerned about the country's environmental health and want more attention paid to environmental problems. This survey also suggests that most Americans, whether they be Democrat, Republican or Independent, are as concerned with problems of air pollution and toxic contamination of soil and water as they are with issues of jobs and the cost of gas. See *The Environmental Deficit: Survey on American Attitudes on the Environment*, Yale Center for Environmental Law & Policy, Yale University School of Forestry & Environmental Studies (May 2004).

<sup>104</sup> Moreover, to the extent to which nature provides utility, it is a public good that should not be frivolously plundered to benefit a few. FARBER, *supra* note 17 at 108-109.

<sup>105</sup> *Id.* at 12.

<sup>106</sup> *Id.* Although beyond the scope of this article, Farber also asserts that the ecological baseline should be adopted by the judicial system as canon of statutory interpretation, which he refers to as a "green canon." *Id.* at 124. Farber looks to legislative intent, as well as to the more formalistic view of the statutory mandate of the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.* (2004), for the government to use all practicable means, consistent with other essential considerations of national policy to achieve certain prescribed environmental goals, as bases for his green cannon. *Id.* at

Deciding to establish an “environmental baseline,” raises the issue of what is an environmental baseline, particularly in the area of ecological protection. Is the environmental baseline a zero-risk baseline, or is some other measure of environmental protection more appropriate? Farber does not attempt to answer this question. In the area of ecological protection, establishing an environmental baseline takes on additional complexity beyond that of human health protection.<sup>107</sup> This article proposes the use of the maintenance of ecological integrity as an environmental baseline. One significant component of ecological integrity is biodiversity – a measure of species abundance and richness used by ecologists to assess the health of ecosystems.<sup>108</sup> In addition to having considerable scientific justification for protecting biological diversity, it is important to keep in mind that the protection of biodiversity is mandated under international law. The 1992 United Nations Environment Programme Convention on Biological Diversity<sup>109</sup> first created the international obligation to protect biodiversity. However, although the United States is a signatory to the Convention, the convention has not been ratified, and therefore, the United States is not formally bound by it. Nevertheless, Article 18 of the Vienna Convention on the Law of Treaties provides that a State that has signed a Treaty must refrain from “acts that would defeat the object and purpose of the Treaty.”<sup>110</sup> Accordingly, the United States arguably is prohibited from taking any action that would defeat the purpose of the 1992 Convention to Protect Biological Diversity.<sup>111</sup> Accordingly, there is at least some basis in international law for arguing that the United States is obligated to have in effect programs that conserve biological diversity.

Support for an ecological integrity baseline also exists in U.S. domestic law. A number of

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124-127.

<sup>107</sup> For example, in human health protection, a “no carcinogenicity” baseline could be established. Alternatively, a de minimis risk baseline could be established (e.g., a baseline of one cancer death per million). Other approaches could include establishing a baseline that is no greater than the risk from ambient pollutant levels. In the ecological arena, however, the issues are more complex.

<sup>108</sup> Professor Fred Bosselman has published a comprehensive analysis of scientific issues that biologists recognize as inherent in the concept of “biodiversity.” He maintains that the term “biodiversity” lacks the precision needed for a workable legal standard and sets out to provide a series of example to illustrate the various approaches that the law could take to address these scientific issues. Fred Bosselman, *A Dozen Biodiversity Puzzles*, 12 N.Y.U. ENVTL. L.J. 354 (2004).

<sup>109</sup> United Nations Convention on Biological Diversity, June 5, 1992, S. TREATY DOC. 20 (1993), reprinted in 31 I.L.M. 818 (entered into force Dec. 29, 1993).

<sup>110</sup> May 23, 1969, 1155 U.N.T.S. 331.

<sup>111</sup> Moreover, as Professor Daniel Tarlock has pointed out, Chapter 15 of Agenda 21, which was approved by the United Nations Conference on Environment and Development, obligates States to develop strategies to conserve biodiversity and for the sustainable use of biological resources A. Dan Tarlock, *Biodiversity Conservation in the United States: A Case*

statutes express goals and policies directed toward maintenance of ecological integrity. For example, the Clean Water Act provides the broad environmental objective “to restore and maintain the chemical, physical, and biological integrity of the nation’s waters.”<sup>112</sup> Perhaps the strongest support for such a baseline, however, can be found in the National Environmental Policy Act (NEPA).<sup>113</sup> In particular, section 101 of NEPA provides, among other things that it is the continuing policy of the U.S. to “create and maintain conditions under which man and nature can exist in productive harmony. . . .”<sup>114</sup>

While biodiversity certainly is an important indicator of ecosystem health, ecosystem health also relies on the integrity of the physical and chemical components of such systems, as well as the relationship between species and the physical world. Of course, one measure of ecological integrity is the presence of a diversity of species. Nevertheless, not all species within an ecosystem provide the same level of value to the other members of the ecosystem. Conservation biologists have identified certain types of species that provide greater value to ecosystems, and accordingly should be afforded greater protection. One such type of species, known as the “controller species,” plays a major role in controlling the movement of energy and

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*Study in Incompleteness and Indirection*, 23 *Envtl. L. Rep.* 10529 (2002).

<sup>112</sup> 33 U.S.C. § 1251(a) (2004). *See also*, 42 U.S.C. § 7401 (2004) (expressing one of the objectives of the Clean Air Act as being to protect the public health and welfare from adverse effects of air pollution). For further discussion of U.S. authorities that support an ecological integrity baseline, *see also* BROOKS, *supra* note 29; Robert L. Fischman, *Biological Diversity and Environmental Protection: Authorities to Reduce Risk*, 22 *Envtl. L.* 435 (1992). In addition to the specific provisions related to ecological integrity that can be found in domestic environmental pollution control laws, several commentators have argued that other areas of the law support the protection of ecological or biological integrity. *See, e.g.*, Robert L. Fischman, *The Meanings of Biological Integrity, Diversity, and Environmental Health*, 44 *NAT. RESOURCES J.* 989 (2004) (analyzing the National Wildlife Refuge mandate “to ensure that the biological integrity, diversity, and environmental health of the (Refuge) System are maintained.”); and Terry W. Frazier, *Protecting Ecological Integrity Within the Balancing Function of Property Law*, 28 *ENVTL. L.* 53 (1998) (arguing that ecological integrity should be a guiding principle by which legislatures, courts and administrative agencies, interpret, and apply property rules).

<sup>113</sup> 42 U.S.C. § 4321 to 4370f (2004).

<sup>114</sup> 42 U.S.C. § 4331(2004). This section declares the policy of the United States to use all practicable means to achieve a list of broad environmental goals. These goals include the following: 1. Fulfill the responsibilities of each generation as trustee of the environment for succeeding generations; 2. Assure for all Americans safe, healthful, productive, and aesthetically and culturally pleasing surroundings; 3. Attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences; 4. Preserve important historic cultural and natural aspects of our national heritage, and maintain, wherever possible, an environment which supports diversity and variety of individual choice; 5. Achieve a balance between population and resource use which will permit high standards of living and a wide sharing of life’s amenities; and 6. Enhance the quality of renewable resources and approach the maximum obtainable recycling of depletable resources. *Id.* For a detailed discussion of the possible use of NEPA as an environmental baseline which can inform statutory interpretation, *see generally*, Mary Jane Angelo, *Crouching Textualist, Hidden Intentionalist: Reclaiming Our Stolen “Green Destiny” out of the Judicial Sparring Over the Interpretation of Environmental Statutes*, in *ALTERNATIVE GROUNDS: DEFENDING THE ENVIRONMENT IN AND UNWELCOME JUDICIAL CLIMATE* (Michael Wolf, ed., 2005).

nutrients within an ecosystem.<sup>115</sup> Another type of species of special importance is known as the “keystone species.” These species provide more value to the ecosystem than would be predicted by their abundance in the ecosystem.<sup>116</sup> Some conservation biologists believe that the extinction of a keystone species has the potential to result in a domino effect, whereby numerous species go extinct and the entire ecosystem is drastically altered.<sup>117</sup> “Umbrella species” are species that typically have very large home territories, such that protecting a keystone species habitat will have the effect of protecting many other species as well.<sup>118</sup> Finally, species that are very sensitive to pollutants and other environmental stresses, such that the health of these populations serves as a good indicator of overall ecological health, are known as “indicator species.”<sup>119</sup> Of course, while certain types of species such as controller species and keystone species may warrant greater protection, due to our extremely limited understanding of the workings of ecological systems, it would be imprudent not to assume that every component of an ecosystem has some value unless proven otherwise.<sup>120</sup>

Both individual species and ecosystems exhibit a wide range of resilience to man-induced changes.<sup>121</sup> Because of the dramatic differences between species and between ecosystems and because so little is understood about the ability of a particular species or particular ecosystem to tolerate or bounce-back after damage from human activities, it is very difficult to determine whether a particular change will result in significant habitat destruction.<sup>122</sup> While it may be a gross overstatement to say that all ecosystems are so delicate and intricate that removing one part will necessarily cause the demise of the entire system, it is not an overstatement that removing one species from an ecosystem can negatively impact other species and, in the words of Princeton conservation biologist, David Wilcove, “there is no way of knowing ahead of time where the chain reaction will end.”<sup>123</sup>

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<sup>115</sup> Controller species typically include decomposer species. HUNTER, *supra* note 30, at 52.

<sup>116</sup> One commonly cited example of a keystone species is the red-cockaded woodpecker, which excavates cavities in living trees, providing habitat for a variety of species who live in tree cavities, but are not capable of excavating their own cavities. *Id.*

<sup>117</sup> *Id.* at 74.

<sup>118</sup> *Id.* at 54.

<sup>119</sup> *Id.* at 55. The pelican’s sensitivity to DDT made it a good indicator species for organochlorine pesticide contamination.

<sup>120</sup> DAVID S. WILCOVE, *THE CONDOR’S SHADOW: THE LOSS AND RECOVERY OF WILDLIFE IN AMERICA* AT 12 (1999).

<sup>121</sup> *Id.* at 6.

<sup>122</sup> *Id.* at 9.

<sup>123</sup> *Id.* at 11-12.

Moving beyond protection of individual species, even those of particular ecological import, the protection of ecosystem<sup>124</sup> diversity is crucial to the maintenance of overall ecological integrity. Ecosystems themselves provide numerous services,<sup>125</sup> some of which are easily quantifiable, and others of which are not. As Professor Laura Westra has stated “[h]uman survival depends on many of nature’s ‘goods and services’ that are invisible to markets and the economy; some are no doubt invisible to scientists.”<sup>126</sup> Natural resource economists have identified numerous ecosystem services that, if humans had to replace them, would be extremely expensive, if not technically infeasible. In fact, the value of global ecosystem services has been estimated at 33 trillion dollars.<sup>127</sup> Of course, as with individual species, our lack of understanding of the workings of these complex systems leaves open the very likely possibility that ecosystems perform many other valuable services that we do not yet fully understand or that we are not yet able to quantify.

Because ecology encompasses the relationships between the physical, the chemical and the biological, ecological integrity necessarily includes physical integrity, chemical integrity and biological integrity. To fully address ecological integrity, a variety of indicators of ecosystem health must be considered including not only the number of organisms or species, or the status of threatened or endangered species, but also the state of physical, chemical, and biological processes which, together with biological considerations, comprise ecological integrity. Ecological integrity can be measured by starting with a baseline condition found “at a site with a biota that is the product of evolutionary and biogeographic processes in the relative absence of the effects of modern human activity.”<sup>128</sup> Then existing or predicted conditions can be compared to this baseline to measure the extent of deviation. Numerous attempts have been made by scholars of conservation biology to define qualitatively, if not quantitatively, biological or ecological

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<sup>124</sup> An ecosystem is defined as a group of interacting organisms, or a community, and the physical environment they inhabit a particular point in time. HUNTER, *supra* note 30, at 62.

<sup>125</sup> One example of an ecosystem service is a wetland (a type of ecosystem) serving as a filter to treat water supplies. HUNTER, *supra* note 30, at 69. Other examples include beach dunes buffering upland properties from the effects of storms, and saltmarshes supporting fisheries, air purification, soil renewal, climate stabilization, and crop pollination. *Id.* at 69; *see also*, J.B. Ruhl, *supra* note 15 at 544 (citing NATURE’S SERVICES: SOCIETAL DEPENDENCE ON NATURAL ECOSYSTEMS (Gretchen C. Daily ed., 1997)).

<sup>126</sup> Laura Westra et. al., *Ecological Integrity and the Aims of the Global Integrity Project*, in *ECOLOGICAL INTEGRITY: INTEGRATING ENVIRONMENT, CONSERVATION AND HEALTH* 25 (David Pimentel et. al. eds., 2000).

<sup>127</sup> FARBER, *supra* note 17 at 67 (describing a 1997 report in the scientific journal *Nature*); *see also*, Robert Costanza et al., *The Value of the World’s Ecosystem Services and Natural Capital*, 387 *NATURE* 252 (1997).

integrity. For example, James R. Karr has developed an index of biological integrity (IBI) to address the objective articulated in the Clean Water Act, 33 U.S.C. § 1251(a) (2004), “to restore and maintain the chemical, physical, and biological integrity of the Nations Waters.”<sup>129</sup>

Whatever metrics are employed to evaluate whether an environmental regulatory program preserves ecological integrity, some system of measurement is needed to take into account diversity, health of significant species, and integrity of the physical and chemical world. By clarifying that ecological integrity will serve as the environmental baseline in eco-Pragmatism, a clear reference point can be established to which ecological changes of proposed man-induced activities can be measured against. Accordingly, whenever an environmental regulation or other risk reduction measure is proposed, an evaluation of the regulation will start with the presumption that the regulation must be sufficient not to completely preserve the status quo, but to maintain ecological integrity. Then the proposal can be evaluated to determine whether it will accomplish the goal of maintaining ecological integrity.

#### 4. Lack of Information and Changing Information

The fourth question sought to be answered by eco-pragmatism is, because our understanding of environmental issues continues to evolve as new information becomes available, how do we know when to proceed in the face of imperfect information and when to wait for better information before taking action. This question raises the related issues of whether precautionary approaches should be used in environmental decision-making and how to incorporate adaptive management ideas into environmental laws.

The lack of scientific understanding of natural systems overshadows the entire environmental decision-making process.<sup>130</sup> The limited ability for science to provide clear

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<sup>128</sup> Westra, *supra* note 126, at 23.

<sup>129</sup> James R. Karr, *Health, Integrity, and Biological Assessment: The Importance of Measuring Whole Things*, in Westra, *supra* note 126, at 209, 219-223. The IBI has been compared to the index of leading economic indicators, which considers a number of financial measures to assess the overall state of the economy. Similarly, the IBI takes into consideration a number of metrics to assess the overall condition of an ecological system. Examples of metrics used in determining the IBI include species richness, stress intolerant and tolerant indicator species, relative abundance of trophic guilds, presence of alien species, and the incidence of disease, lesions tumors or other anomalies in the biota. The IBI does not call for the measurement of physical or chemical parameters, but instead assumes that their impacts will be manifest in biological indicators. Because of the regional differences between ecological systems, the IBI must be calibrated on a regional basis. *Id.*

<sup>130</sup> FARBER, *supra* note 17 at 1, 5.

answers to environmental questions, has been an ongoing problem in environmental law.<sup>131</sup> As Justice Breyer has described, there is scientific uncertainty involved in every stage of any risk assessment. Thus, if there are ten independent steps in a risk analysis and each step involves an uncertainty factor of two, the estimate of the total risk has an uncertainty factor of one thousand.<sup>132</sup>

Even beyond the complex field of risk assessment, uncertainty pervades virtually all environmental decision-making.<sup>133</sup> The regulated community has taken full advantage of this scientific uncertainty. Decisions to regulate, they assert, should wait until science can conclusively demonstrate the need for such regulation.<sup>134</sup> Of course, using a lack of certainty as an excuse not to act can result in serious, and sometimes irreparable, environmental consequences.

Our very limited understanding of environmental issues, coupled with the complexity of ecological systems, suggests a basis for proceeding cautiously when deciding whether to allow potentially risky activities to occur. The precautionary principle, which has been adopted by a variety of international environmental agreements,<sup>135</sup> is one approach to proceeding cautiously. The precautionary principle resolves doubts in favor of the environment.<sup>136</sup>

The precautionary principle recognizes that as predictions are made further out in time, uncertainty tends to increase. Moreover, the precautionary principle takes into account the fact that inherent in any scientific evaluation is the opportunity for scientific error to occur.<sup>137</sup> Opponents of the precautionary principle contend that it is based on vague and baseless fears regarding environmental risks. But, the same could be said to argue for a precautionary approach.

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<sup>131</sup> See Tarlock, *supra* note 34 at 1135 (discussing the tension between scientific uncertainty and the law's desire for clear standards.).

<sup>132</sup> FARBER, *supra* note 17 at 163 (citing Breyer, *supra* note 47, at 45).

<sup>133</sup> See e.g., Tarlock, *supra* note 34 at 1135-39.

<sup>134</sup> See e.g., *id.* at 1135-36.

<sup>135</sup> See e.g., The Treaty on European Union and Final Act, Feb. 7 1992, 31 I.L.M. 247 (hereinafter Maastricht Treaty) (adopting the precautionary principle as a governing principle of European Union Law). See also 1992 United Nations Environment Programme Convention on Biodiversity. The preamble to the Cartagena Protocol on Biosafety provides that it is "reaffirming the precautionary approach . . . contained in . . . the Rio Declaration on Environment and Development . . . . Article 10(6) of the Protocol provides that "[I]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party or import . . . shall not prevent that Party from taking a decision, as appropriate, . . . in order to avoid or minimize such potential adverse effects.

<sup>136</sup> Ruhl, *supra* note 15 at 537.

<sup>137</sup> Type I scientific errors are those that mistakenly conclude an effect is real when it isn't, whereas type II errors are those that mistakenly conclude that an effect is not real when it really is. In the field of environmental protection, type II errors are of the greatest concern. If, for example, decision is made that allowing a particular activity to proceed will not cause harm to an endangered species, and that decision is based on a type II error, the activity may unintentionally result in jeopardy to the endangered species. FARBER, *supra* note 17 at 173.



Often the costs of regulation are based on vague and baseless fears about the potential economic consequences of regulation, dire predictions of which rarely come true.<sup>138</sup>

Farber emphasizes the need to proceed cautiously. He maintains that when environmental risks are still uncertain, we should take reasonable precautions. There are times when it is necessary to make difficult regulatory decisions with very incomplete or inconclusive data.<sup>139</sup> It may not be prudent to wait until complete or conclusive data are available. For many environmental decisions, a decision to wait is a decision to irreversibly impact a resource. Such is the case with a decision to withhold regulatory action on the protection of an endangered species due to incomplete information. By the time complete information becomes available, the species may be extinct or beyond recovery.

As described above, scientific uncertainty perhaps is even more profound in assessing risks to ecological systems than in assessing human health risks.<sup>140</sup> Once again, the incorporation of ecological principles into eco-pragmatism lends further support to the theory. Moreover, with regard to ecological issues, flexible and adaptive approaches are even more critical than with human health concerns. The science of understanding how species and ecosystems work and how human disruptions may impact them is still in its infancy.<sup>141</sup> During the early years of ecology we believed that natural systems were stable and that ecosystems evolved in a predetermined set of stages (known as succession) toward a stable “climax community.”<sup>142</sup> In the past twenty five years, the paradigm that ecosystems exist in a state of equilibrium has been replaced with the more complex nonequilibrium paradigm.<sup>143</sup> In recent years, ecological science has discovered that natural systems have multiple persistent states and multiple “successional pathways.”<sup>144</sup> Thus, the

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<sup>138</sup> Another way to view the precautionary principle is as a burden-shifting device, which shifts the burden of proof to the resource users or polluter to demonstrate its activities should be allowed. *Id.* at 171. By placing the burden of proof on the regulated entity, ties are resolved in favor of the environment.

<sup>139</sup> *Id.* at 164.

<sup>140</sup> See generally, Daniel A. Farber, *Probability Behaving Badly: Complexity Theory and Environmental Uncertainty*, 37 U.C. DAVIS L. REV. 145 (2003) (describing the high level of scientific uncertainty surrounding environmental problems).

<sup>141</sup> *Id.* at 167. In their article, *The Influence of Ecological Science on American Law: An Introduction*, 69 CHI.-KENT L. REV. 847 (1994), Professors Bosselman and Tarlock review four periods of ecological thought during the twentieth century and analyze how each period influenced environmental law and policy.

<sup>142</sup> See generally Meyer, *supra* note 27.

<sup>143</sup> See generally BOTKIN, *supra* note 27. The nonequilibrium paradigm was not widely accepted until the 1980s. See Tarlock, *supra* note 34 at 1129.

<sup>144</sup> Meyer, *supra* note 27 at 876.

current paradigm rejects the “balance of nature” paradigm.<sup>145</sup> To capture this concept, Professor Judy Meyer has coined the phrase “dance of nature” to replace the outdated “balance of nature.”<sup>146</sup>

Ecologists also began to realize that natural systems are periodically and continually disturbed by natural phenomena such as fire, flood, drought, and disease and pest outbreak, as well as by similar types of disturbances resulting from human activity.<sup>147</sup> Consequently, human disturbances are not necessarily “bad” for natural systems.<sup>148</sup> The goal for environmental protection, thus, should not be to suppress all human-caused disturbances, but rather to prevent human-caused disturbances that are not in line with the natural disturbance regime of the ecosystem.<sup>149</sup> To be able to proceed consistently with natural disturbance regimes, therefore, requires knowledge of the historical record of an ecosystem.<sup>150</sup> Unfortunately, this type of long term historical monitoring data rarely is available.

The non-equilibrium paradigm, however, should not lull us into believing that, because ecosystems naturally experience change, all anthropogenic change is acceptable.<sup>151</sup> Anthropogenic changes frequently differ from natural changes in character, magnitude and frequency.<sup>152</sup> Moreover, natural systems frequently react to anthropogenic disturbances in completely unpredictable ways.<sup>153</sup> Even very small disturbances can “flip” ecosystems into vastly different behavioral states, sometimes well after the event that started the reaction.”<sup>154</sup> Thus, as Meyer concludes, “[a]nthropogenic change is acceptable only if that change is within limits.”<sup>155</sup> The limits depend on the specifics of the ecosystems and its ability to keep pace with the changes that occur.<sup>156</sup>

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<sup>145</sup> *Id.* at 877.

<sup>146</sup> *Id.* at 877.

<sup>147</sup> *Id.* at 876.

<sup>148</sup> Ruhl, *supra* note 21, at 906-907.

<sup>149</sup> Meyer, *supra* note 27, at 879.

<sup>150</sup> *Id.* at 879.

<sup>151</sup> *Id.* at 882. *See also*, Tarlock, *supra* note 34 at 1130 (explaining that the nonequilibrium paradigm does not undermine the case for protection of ecosystems).

<sup>152</sup> Meyer, *supra* note 27 at 882.

<sup>153</sup> *See* Ruhl, *supra* note 21, at 906.

<sup>154</sup> *Id.* This phenomenon is frequently analogized with the “tipping” point of a canoe. A canoe can be progressively tipped more and more with only minor effect, until it reaches its tipping point, at which point the canoe completely capsizes. Once a tipping point is reached, the entire system can collapse or undergo dramatic change.

<sup>155</sup> Meyer, *supra* note 27 at 882.

<sup>156</sup> *Id.* at 882. Despite the complex and delicate nature of interactions between species in an ecosystem, both history and disequilibria theory teach us that change, including human disturbance, is not necessarily detrimental to overall ecosystem health. Ecosystems do possess the ability to resist certain disturbances and to recover from those that do have a detrimental

In addition to precautionary approaches, eco-pragmatism argues in favor of developing flexible regulatory systems that allow decisions to be modified as additional information becomes available.<sup>157</sup> One of the most significant aspects of pragmatism in general is the recognition that the combination of limited information and an ever changing society cannot tolerate static decision-making. Instead, mechanisms must be in place to ensure that as new information becomes available or as society's values evolve, the law must be able to adapt incrementally and accordingly.<sup>158</sup> Thus, eco-pragmatism suggests that environmental laws must have mechanisms built into them to allow regulatory agencies to make incremental adjustment to regulation to take into account new information, as well as to correct old mistakes.<sup>159</sup> Under the existing regulatory system, agencies such as EPA tend to be so concerned with making the "right" decision up front, that any lack of information or controversy tends to paralyze them. Instead, a pragmatic approach would favor agencies to make the best decision they have available based on the best information currently available with a corresponding recognition that such decisions will need to be adjusted over time.<sup>160</sup> Of course, one of the reasons that agency's are so concerned with making the perfect decision on the front end is that under the existing regulatory system, it is generally extremely

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effect. In ecological terms, "resistance" is the degree to which an ecosystem changes in response to a disturbance whereas "resilience" is the degree to which an ecosystem recovers after it has been disturbed. HUNTER, *supra* note 30, at 74. Thus, while not all human disturbance is detrimental to ecosystems, it is the frequency of the disturbance, the magnitude of the disturbance and the nature of the disturbance that determine whether there will be long term negative effects on the ecosystem. Meyer, *supra* note 27, at 882. Ecosystems tend to respond better to human disturbances that mimic those that occur in nature. In addition, the overall health of an ecosystem will determine how well the ecosystem will respond to disturbances. For example, species-rich areas may be both more resistant and more resilient to human disturbances than ecosystems that do not possess a great abundance and diversity of species. HUNTER, *supra* note 30, at 86-91. It is well established that genetic variability within a species improves the likelihood that the species will survive and evolve in response to a changing environment. *Id.* at 86-87. Likewise, variability between species within an ecosystem can improve the chances for an ecosystem to survive and evolve in response to human disturbances. *Id.* In fact, a lack of genetic diversity may cause problems even in ecosystems that are not experiencing change. For example, genetically uniform species may experience low fertility and high mortality rates among offspring, as is evidenced by the problems associated with the lack of genetic diversity in many zoos. HUNTER, *supra* note 30, at 88. Likewise, ecosystems that have not been compromised by chemical contamination may respond better than those that have been so compromised

<sup>157</sup> FARBER, *supra* note 17 at 12.

<sup>158</sup> See, e.g., SHAPIRO & GLICKSMAN, *supra* note 12 at 24-27. Shapiro and Glicksman have referred to such incremental adjustment as "muddling through" and argue that it is often the most rational way to make policy. *Id.* at 24. In fact, pragmatism shies away from dramatic reforms in favor of such incremental adjustments. *Id.* at 26.

<sup>159</sup> *Id.*

<sup>160</sup> See *id.* at 25. This willingness to change as new information becomes available must work both ways – i.e., one the one hand if a regulation is found not to be protective enough there should be a mechanism to adapt quickly to provide the requisite protection, and on the other hand, if a regulation is found to be too stringent, there should be a mechanism to provide quick regulatory relief. FARBER, *supra* note 17 at 12.

difficult and time-consuming to change course in mid-stream.<sup>161</sup>

The inherent complexity and unpredictability of natural systems,<sup>162</sup> coupled with our limited scientific understanding of such systems has led to the ground-breaking development in the field of conservation biology of adaptive management.<sup>163</sup> Adaptive management was developed in the context of natural resource management.<sup>164</sup> Nevertheless, to date, it has not been used widely in environmental regulation.<sup>165</sup> Adaptive management requires both a willingness to make environmental policy decisions even with limited scientific information, and the recognition that such decision must be continually monitored and evaluated and adjusted as new information or changed circumstances warrant.<sup>166</sup>

More flexible regulatory systems are needed to adapt to change or as new information becomes available. In addition, more emphasis must be put on acquiring necessary data through monitoring outcomes of environmental decisions. Based on information of the effects of a particular regulatory action acquired through monitoring programs, adjustments to can be made to produce better, more science-based, regulations.<sup>167</sup> Eco-pragmatism calls for a more experimental approach to regulation – i.e., in which regulatory actions are implemented, monitored and adjusted

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<sup>161</sup> The stasis inherent in the regulatory system stems in part from the time-consuming and cumbersome requirements of the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, the agencies' fear that any "opening up" of the rulemaking process will invite legal challenges, and the expectation on the part of the regulated community that once a decision is made, they will be able to rely on it indefinitely.

<sup>162</sup> The developing theory of dynamic systems is also referred to as complexity theory or chaos theory. *See* FARBER, *supra* note II at 146. Farber's article explores the uncertainty about environmental problems in the context of complexity theory. Farber posits that complexity theory provides strong support for adaptive management. *Id.* at 147.

<sup>163</sup> For a detailed discussion of adaptive management and how it is used in a number of environmental programs, including Habitat Conservation Planning under the ESA, U.S. Forest Service management planning, and everglades restoration, *see* Bradley C. Karkkainen, *Adaptive Ecosystem Management and Regulatory Penalty Defaults: Toward a Bounded Pragmatism*, 87 MINN. L. REV. 943 (2002).

<sup>164</sup> SHAPIRO & GLICKSMAN, *supra* note 12 at 167.

<sup>165</sup> *Id.*

<sup>166</sup> *Id.* Previous experience is used to inform adjustments to policy. Perhaps Bosselman and Tarlock said it best: "ecosystems are patches or collections of conditions that exist for finite periods of time [footnote omitted]. The accelerating interaction between humans and the natural environment makes it impossible to return to an ideal state of nature. At best, ecosystems can be managed rather than restored or preserved, and management will consist of a series of calculated risky experiments" that must be judged against a moving target. Bosselman & Tarlock, *supra* note 40, at 869-870. Although environmental experimentation is rife with risk, it may be the only effective way to proceed. For any system or organization to adjust to changing information or circumstances, feedback loops are necessary. *See* Tarlock, *supra* note 34 at 1139. To date, such feedback loops have not been widely used in environmental law, which tends to favor the consistency and predictability of clear fixed rules. *Id.* In fact, environmental law has tended to adhere so strongly to scientific findings, that it fails to reconsider such findings even as new data prove them to be incorrect. *Id.*

<sup>167</sup> FARBER, *supra* note 17 at 179.

based on the results of the monitoring.<sup>168</sup>

The difficulties with these types of flexible or adaptive schemes is that neither the law, nor the regulatory agencies that implement it, are quick reactors to change. Eco-pragmatism attempts to address this problem by proposing more decentralized approaches, whereby decisions can be modified on a local level and smaller scale more quickly to adapt to new information than could be accomplished in a large centralized system.<sup>169</sup> A decentralized system tends to be more flexible and to respond more quickly to new information.<sup>170</sup> One mechanism for accomplishing decentralization is through a devolution of regulatory responsibility to state and local governments. However, although there are certain advantages to localized decision-making, delegation of too much authority to states or local governments could result in a “race to the bottom.”<sup>171</sup> Thus, safeguards are necessary to prevent a disintegration of environmental protection. Such safeguards could include national minimum standards and national oversight of state regulation.<sup>172</sup>

In sum, eco-pragmatism provides a useful framework for environmental decision-making. Many of the shortcomings of eco-pragmatism can be overcome by consciously integrating it with principles of ecological science. An eco-pragmatic evaluation of pesticide law must start with an understanding of the history of pesticide use and the ecological risks posed by pesticides.

### III. THE HISTORY OF THE PESTICIDE/ECOLOGY RELATIONSHIP

#### *A. History of Pesticide Use*

Scientists believe that pesticides have been used by humans for over two thousand years.<sup>173</sup>

Although metals, such as arsenic, lead, and copper were used as pesticides extensively in the early

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

<sup>169</sup> *Id.* at 180.

<sup>170</sup> Ruhl, *supra* note 15 at 540.

<sup>171</sup> FARBER, *supra* note 17 at 182-83. For an excellent analysis of the race to the bottom theory, see Kirsten H. Engel, *State Environmental Standard-Setting: Is there a “Race” and is it to the “Bottom,”* 48 HASTINGS L. J. 271 (1997). For an opposing view of the theory, see Richard L. Revesz, *The Race to the Bottom and Federal Environmental Regulation: A Response to Critics*, 82 MINN. L. REV. 535 (1997).

<sup>172</sup> *Id.*

<sup>173</sup> Homer described how Odysseus used burning sulfur as a fumigant to control pests. HOMER, *THE ODYSSEY* (Edward McCrorie, transl. 2004). For a more complete description of the history of pesticide use, see Clive A. Edwards, *The Impact of Pesticides on the Environment*, in *THE PESTICIDE QUESTION: ENVIRONMENT, ECONOMICS AND ETHICS* 13 (David Pimentel & Hugh Lehman, eds., 1993). Additional documentation of pesticide use, such as the use of arsenic to kill insects, can be found in literature dating back to the time of Christ. There is documentation that arsenic has been used to control insects dating back to the year 70 AD, when Pliny the Elder recommended the use of arsenic to kill insects. Arsenic was also used as a pesticide in 16<sup>th</sup> century China. *Id.*

20<sup>th</sup> Century, most pest control up until that time was accomplished by means of cultural controls, such as cultivation,<sup>174</sup> sanitation,<sup>175</sup> crop rotation,<sup>176</sup> and sowing and harvesting practices.<sup>177</sup> It was not until the latter half of the 20th century that the development of synthetic chemical pesticides led to an explosion of global pesticide use.<sup>178</sup> Because these new synthetic chemical pesticides were spectacularly effective at controlling a wide variety of pests, they quickly gained favor and, before long, were ubiquitous. Estimates of global pesticide use are staggering. More than 1600 types of pesticides are currently available.<sup>179</sup> More than five billion pounds of pesticides, with a value of over 30 billion dollars, are used annually in the world.<sup>180</sup> Pesticide use in the United States accounts for 27 percent of global pesticide usage, with U.S. exports to other countries exceeding 450 million pounds of pesticides per year.<sup>181</sup>

The rapid worldwide adoption of synthetic chemical pesticides began during World War II, with the development of two primary categories of chemical insecticides, the organochlorines and the organophosphates. The organochlorines, which include the notorious pesticide, DDT,<sup>182</sup> were first considered to be highly desirable because, while they are very toxic to a broad range of

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<sup>174</sup> HELMUT F. VAN EMDEN & DAVID B. PEAKALL, BEYOND SILENT SPRING: INTEGRATED PEST MANAGEMENT AND CHEMICAL SAFETY 115-17 (1996). Many pest insects live out at least part of their life cycles in soil, weeds or accumulated crop debris in farm fields. Plowing the top layer of soil kills many of these pest insects. Accordingly, soil tillage historically was a critical component of agricultural pest management. It was not until relatively recently that, as a way to minimize soil erosion, tillage was abandoned in favor of zero or minimum tillage systems, which rely on herbicide usage to control weeds. The demise of tillage as a core component of modern agricultural systems has resulted in a dramatic increase in certain soil-dwelling pests. *Id.* Other cultivation pest control techniques used historically include mulching, compacting and manuring. *Id.*

<sup>175</sup> Sanitation practices are one of the most effective pest control practices used in both ancient and modern agriculture. *Id.* at 117-18. By destroying residues of crops left in fields after harvesting, many pest populations that live in such residues are destroyed. Related practices such as destruction of weed hosts and selective pruning also serve as effective pest control tools. *Id.* at 118-19.

<sup>176</sup> Crop rotation, one of the oldest forms of pest control, is a very effective pest control technique for minimizing soil-dwelling pests. By alternating the planting of different crops in a particular field, populations of soil-dwelling insects that feed on a particular crop will not be able to build up during periods when their food crop is not present. Thus, when the crop eventually is planted, populations of the pest species generally will not be high enough to cause serious problems. *Id.* at 120-21.

<sup>177</sup> Timing sowing and planting dates to avoid pest outbreaks or to ensure the crop plant is in a resistant growth stage when pest outbreaks are likely to occur, as well as carefully tailoring seed and planting rates and early harvesting also can be effective tools for avoiding pest damage to crops. *Id.* at 120-23.

<sup>178</sup> Edwards, *supra* note 173, at 13.

<sup>179</sup> These figures are based on EPA pesticide market estimates for the years, 2000-2001. *See* <http://www.epa.gov/oppbead/pestsales/01pestsales/sales2001.htm> and *See* <http://www.epa.gov/oppbead/pestsales/01pestsales/usage2001-3.htm> (Last visited June 17, 2005).

<sup>180</sup> *See Id.*

<sup>181</sup> Edwards, *supra* note 173, at 13.

<sup>182</sup> DDT is the abbreviation for synthetic insecticide, 1, 1, 1-trichloro-2, 2-bis (*p*-chlorophenyl) ethane. ROBERT E. PFADT, FUNDAMENTALS OF APPLIED ENTOMOLOGY at 755, 3<sup>rd</sup> ed. (1978).

invertebrates, they are not highly acutely toxic to humans or other mammals.<sup>183</sup> These pesticides also are extremely persistent in the environment, which makes them highly effective for long-term effective pest control. However, their persistence in the environment became their downfall when the long-term ecological consequences of these pesticides became apparent. Organochlorine pesticides, such as DDT, are credited with saving thousands of lives from insect borne diseases during World War II.<sup>184</sup> Nevertheless, it soon became evident that these pesticides accumulated in living tissues and bioconcentrated as they moved through the food chain. This resulted in serious impacts to predators at the top of the food chain, including the American Bald Eagle. In consequence, most organochlorine pesticides were either banned or severely restricted, at least in the developed countries of the world.<sup>185</sup>

The other major category of pesticides that was developed during World War II is the organophosphate pesticides. These pesticides were initially developed as wartime nerve gases.<sup>186</sup> Although these pesticides have the environmental advantage of being far less persistent in the environment than are organochlorine pesticides, the organophosphates tend to be highly acutely toxic to humans, other mammals and birds.<sup>187</sup> These pesticides became the pesticides of choice in the United States after most organochlorine pesticides were banned or severely restricted. Organophosphates remain the largest category of chemical insecticide in use in the United States today.<sup>188</sup> In addition to posing risks of acute poisoning to farm workers, these pesticides have been implicated in a large number of avian and wildlife poisonings.<sup>189</sup>

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<sup>183</sup> Edwards, *supra* note 173, at 14.

<sup>184</sup> Andrew P. Morriss & Roger E. Meiners, *Property Rights, Pesticides, and Public Health: Explaining the Paradox of Modern Pesticide Policy*, 14 *FORDHAM ENVTL. L. J.* 1 (2002).

<sup>185</sup> Edwards, *supra* note 173, at 14. A number of international agreements exist to restrict the use of persistent organic pollutants, such as the organochlorine pesticides. For a detailed discussion of such agreements, see Michael P. Walls, *International Chemicals Update 2005*, SK 058 ALI-ABA 661 (2005). It should be noted that there has been a recent resurgence in efforts to loosen restrictions on DDT due to its potential use in combating malaria and other insect-borne diseases. See, e.g., Morriss & Meiners, *supra* note 184.

<sup>186</sup> *Id.* at 15

<sup>187</sup> *Id.*

<sup>188</sup> See <http://www.epa.gov/oppbead/pestsales/01pestsales/usage2001-3.htm> (Last visited June 17, 2005).

<sup>189</sup> *Id.* Other categories of chemical pesticides include the synthetic pyrethroids and carbamates. Pyrethrum is a naturally-occurring pesticide derived from chrysanthemum flowers. *Id.* Synthetic pyrethroids are synthetically produced versions of pyrethrum. These pesticides have the environmental benefit of having very low mammalian toxicity and low environmental persistence. *Id.* Nevertheless, they are highly toxic to a broad range of invertebrates, including many beneficial insects. *Id.* They are also highly toxic to fish and other aquatic organisms. Carbamates are more persistent than organophosphates in the environment and are generally broad-spectrum, having adverse impacts on many different groups of organisms. *Id.* Other commonly used pesticides are: nematicides, which not only are of high mammalian toxicity and broad-spectrum, but also are very transient in soil; herbicides, which generally are not highly toxic to mammals, but travel

Although from an ecological standpoint, narrow-spectrum pesticides are preferable, broad-spectrum synthetic pesticides continue to dominate U.S. pesticide usage.<sup>190</sup> This phenomenon is at least in part attributed to the time and costs associated with bringing a new pesticide to the market. The average time to bring a new pesticide to commercialization is five to ten years, with an associated cost of ten to twenty million dollars.<sup>191</sup> Moreover, the average life-span of a pesticide for a specific use is ten years.<sup>192</sup> Accordingly, pesticide manufacturers may be inclined to adopt research and development strategies that favor broad-spectrum pesticides with broad market opportunities, in order to get the biggest bang for the buck during the limited life span of a pesticide.<sup>193</sup>

In the past ten years, the fastest growing sector of the pesticide industry has been the biotechnology sector. Naturally-existing microbes have been genetically modified to make them toxic to insects and other pests. In addition, agricultural crop plants themselves have been genetically modified to produce substances that have pesticidal effects. These pesticidal living organisms pose novel ecological risks by virtue of their ability to reproduce and spread in the environment.

### *B. Ecological Risks of Pesticides*

Scientists estimate that as many as 10 million species, or 99% of the earth's wild biodiversity, not including cultivated and weedy species, are in a "precarious condition."<sup>194</sup> Causes and contributors to the decline of so many species include indirect habitat destruction through clearing for agriculture and development, the spread of non-native invasive species, pollution, over harvesting of species and disease. Although there is no doubt that direct habitat destruction is the leading contributor of species loss (estimated as being implicated in 85% of U.S. species decline),

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easily in water, where they may be toxic to fish and aquatic organisms; and fungicides, which vary greatly in their toxicity.

*Id.*

<sup>190</sup> WILLIAM H. RODGERS, ENVIRONMENTAL LAW 407 (West, 2d ed. 1994).

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

<sup>192</sup> *Id.* The reasons for the relatively short life span of pesticides include the tendency for pests to develop resistance to pesticides, rendering the pesticides obsolete for that pest and the fact that FIFRA allows for "me-too" registration, which tend to reduce the market share of the original pesticide. A me-too registration allows a pesticide manufacturer, in lieu of developing its own data to support registration, to rely on data generating by a previous registrant provided the me-too applicant makes an offer to compensate the previous registrant for the use of the data. 7 U.S.C. § 136a(c)(1)(F)(iii).

<sup>193</sup> RODGERS, *supra* note 190, at 407-09.

<sup>194</sup> EDWARD O. WILSON, *forward* to DAVID S. WILCOVE, THE CONDOR'S SHADOW: THE LOSS AND RECOVERY OF WILDLIFE IN AMERICA xiv (1999).



pollution, including pesticide pollution is implicated in 24 percent of U.S. species decline.<sup>195</sup> Pesticide poisoning of fish and wildlife is a significant factor in species decline.<sup>196</sup>

Because pesticides are by definition intended to kill or disrupt living organisms, and because they are intentionally released into the environment, often in large quantities over large areas, it is not surprising that pesticides pose a wide array of risks to individual species as well as to overall ecosystem function. Many pesticides are broad-spectrum, affecting diverse species, including many non-target organisms.<sup>197</sup> Others are more narrowly targeted to pest species. However, even these may have significant impacts on non-target species that are closely related to the intended targets.<sup>198</sup> Some pesticides persist in the environment for weeks, months and even years, while others breakdown relatively quickly.<sup>199</sup> Moreover, living organisms vary significantly in their susceptibility to pesticides.<sup>200</sup> The potential ecological risks of pesticide use depend on a number of factors including toxicity or other hazard of the pesticide, method of application, persistence in the environment, amount used and susceptibility of non-target organisms. Moreover, there are not many data available on the environmental effects of pesticide usage on many species. Accordingly, the ecological risks of pesticides cannot be easily described or quantified. Nevertheless, some generalizations can be made.

Many pesticides are highly acutely toxic to some or all non-target mammals, birds, reptiles, amphibians, fish and invertebrates. Many pesticides in current use in the U.S., as well as in other parts of the world, are highly acutely toxic and are known to cause adverse effects on non-target mammals, birds, reptiles, amphibians, fish and invertebrates.<sup>201</sup> Birds and other wildlife may be

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<sup>195</sup> WILCOVE, *supra* note 120, at 8.

<sup>196</sup> Moreover, the spread of non-native species is implicated in 49 percent of U.S. species decline. In one study of the decline of fish species in the United States, Canada and Mexico, it was determined that the destruction of physical habitat was implicated in 73 percent of the decline, the displacement by introduced species was implicated in 68 percent of the decline, the alterations of habitat by chemical pollutants was implicated in 38 percent of the declines, and hybridization with other species and subspecies was implicated in 38 percent of the declines, and over harvesting was implicated in 15 percent of the declines. The numbers add up to more than one hundred because more than one factor is implicated in many of the fish population declines. WILSON, *supra* note 34, at 253-254. Thus, while pesticide usage in itself may not directly destroy habitat (although clearing for agriculture certainly does) chemical pesticides may be a significant contributor to species decline, and pesticidal GMOs, which pose risks of spread in the environment similar to non-indigenous species release, may also be important contributors. Habitat Destruction, spread of nonnatives, pollution, overkill and disease have been referred to as the five horsemen of the environmental Apocalypse. WILCOVE, *supra* note 120, at 8.

<sup>197</sup> See *supra* note 190, and accompanying text.

<sup>198</sup> See Edwards, *supra* note 173, at 17-24.

<sup>199</sup> *Id.* at 17.

<sup>200</sup> *Id.* at 18.

<sup>201</sup> For a detailed discussion of the risks pesticides cause to wildlife species, see Comments on the Proposed Joint

exposed through direct spraying, ingesting pesticide granules, drinking water that has been contaminated by pesticides or eating prey organisms that have been contaminated by pesticides. For instance, the pesticide carbofuran is highly toxic to avian species. While the banning and severe restriction of certain pesticides such as DDT over the past thirty years has dramatically reduced certain risks to wildlife, many risks remain.<sup>202</sup> In addition to effects from direct exposure to pesticides, birds and other wildlife may also be exposed to pesticides by ingesting prey animals that have been contaminated.<sup>203</sup>

Other less visible species also are at considerable risk from exposure to pesticides. For example, for the past decade, there has been considerable concern and debate in the scientific community over the worldwide decline of amphibians. There are now significant data to support a conclusion that certain pesticides, such as the herbicide atrazine, may be contributing to the worldwide decline in amphibian populations.<sup>204</sup>

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Counterpart Endangered Species Act Section 7 Consultation Regulations, filed by Defenders of Wildlife and twenty-nine other commenters, contained in a letter to Gary Frazer, Assistant Director for Endangered Species, U.S. Fish and Wildlife Service, and Phil Williams, Chief, Endangered Species Division, NOAA Fisheries, dated April 16, 2004.

<sup>202</sup> One startlingly example is that when roughly 10,000 dead birds were tested for the presence of West Nile Virus in 2000, the New York State Department of Environmental Conservation determined that pesticides and other chemicals actually were responsible for more bird kills than was the virus. Laura A. Haight, *Local Control of Pesticides in New York: Perspectives and Policy Recommendations*, 9 ALB. L. ENVTL. OUTLOOK J. 37, 51 (2004). As further evidence of the effects on bird populations, studies have shown substantially higher nesting rates of birds, as well as significantly higher bird abundance and avian species richness, on organic farms as compared to conventional farms that use synthetic pesticides. Nancy A. Beecher, Ron J. Johnson, James R. Brandle, Ronald M. Case, and Linda J. Young, *Agroecology of Birds in Organic and Nonorganic Farmland*, 16 CONS. BIOL. 1620 (2002).

<sup>203</sup> The New York State Department of Environmental Conservation has found a number of different avian species, such as screech owls, red-tailed hawks, American kestrels and other raptors that have died as a result of eating small rodents that had consumed rat poison. *Id.*

<sup>204</sup> Haight, *supra* note 202, at 51. For example, in 2002, the organization Californians for Alternatives to Toxics (CATS) filed suit seeking an order requiring the state Department of Pesticide Regulation to reevaluate the state registration of pesticide products containing the pesticidal active ingredients malathion, chlorpyrifos, diazinon, methidathion, endosulfan, chorothonil, and trifluralin. The lawsuit contends that these pesticides may be responsible for significant population declines of several species of amphibians in the Sierra Nevada Mountains. Until very recently, the results of many studies on the effects of pesticides on amphibians have been puzzling because pesticide levels in nature tend to be much lower than levels found to be lethal in the laboratory setting. See Rick Relyea, *Predators Make Pesticides More Lethal*, in CONSERVATION IN PRACTICE, vol. 5, no. 2, 2004, at 5, 5 (excerpting Rick Relyea, *Predator Cues and Pesticides: A Double Dose of Danger for Amphibians*, 13 ECOLOGICAL APPLICATIONS 1515-1521 (2003)). See also Carlos Davidson, H. Bradley Shaffer, and Mark R. Jennings, *Spacial Tests of the Pesticide Drift, Habitat Destruction, UV-B, and Climate-Change Hypotheses for California Amphibian Declines*, 16 Cons. Biol. 1588 (2002). A recent study sheds new light on this dilemma. Scientists have determined that the combination of the pesticide carbaryl and stress from the presence of predators was more lethal in certain amphibian species, than the pesticide by itself. *Id.* In other words, there appears to be a synergistic affect at work between pesticides and predators, making the combination of the two more lethal than the sum of the parts, and resulting in even low concentrations of pesticides in nature being highly lethal to amphibians. Of course, amphibians in nature must cope with other stress such as the presence of predators, in addition to the stress of pesticides. Accordingly, this study demonstrates that amphibians in nature may be significantly more sensitive to pesticides than they

Although the most obvious adverse effects of pesticide use are those to humans and large animals such as mammals and birds, it is likely that the most significant adverse effects of pesticides are those to invertebrates, which are closely related to target pest species.<sup>205</sup> Casualties from this “friendly fire” are widespread in the invertebrate world.<sup>206</sup>

Perhaps equally if not more important than direct acute effects on nontarget organisms are the chronic effects upon growth, physiology, reproduction and behavior.<sup>207</sup> Much less is known about these effects.<sup>208</sup> Even where a pesticide is not toxic enough to kill an organism, it can have very significant sublethal effects on the organism by affecting the organism’s life span, growth, physiology, behavior and reproduction.<sup>209</sup> Moreover, pesticides have been documented to have significant indirect effects on nontarget organisms by reducing the populations of animals or plants that serve as food or cover for other species.<sup>210</sup>

One of the most insidious risks posed by pesticides is the tendency of certain synthetic pesticides to mimic hormones, such as estrogen in humans and wildlife. Only recently has science begun to understand these complex effects.<sup>211</sup> Estrogen mimicking substances include a number of

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are in the sterile isolated confines of the research laboratory. *Id.*

<sup>205</sup> HUNTER, *supra* note 30, at 156-157.

<sup>206</sup> See May Berenbaum, *Friendly Fire*, WINGS: ESSAYS ON INVERTEBRATE CONSERVATION, Spring 2004 at 8-12 (a publication of the Xerces Society). One example is that the insect Order Lepidoptera contains not only many pest moth species, but also contains many non-pest butterfly species. These butterfly species may be beneficial pollinators and may be aesthetically pleasing colorful and interesting species, such as the monarch butterfly. Also, the Order Lepidoptera, contains a number of butterfly species that have been listed as threatened or endangered under the federal Endangered Species Act. 16 U.S.C. §§ 1531 - 1544 (2004). Pesticides that are used to kill pest moth species generally do not discriminate within the Lepidoptera Order, and will also kill non-pest, beneficial butterflies, including endangered species. See HUNTER, *supra* note 30, at 157. Mosquito control pesticides have been indicted as one of the threats to the continued survival of the endangered Miami Blue Butterfly over the past few decades Jaret C. Daniels & Thomas C. Emmel, *Florida’s Precious Miami Blues*, WINGS: ESSAYS ON INVERTEBRATE CONSERVATION, Spring 2004 at 3-7. This recent issue of the Xerces Society publication was devoted exclusively to butterfly conservation; four out the five articles listed pesticides as a significant contributor to butterfly population declines. See *id.* Moreover, recent studies demonstrate a reduction in the abundance of non-target butterflies on conventional farms as compared to butterflies on organic farms. D.J. Hole, *et al.*, Does Organic Farming Benefit Biodiversity has been published electronically by the journal Biological Conservation, available at <http://dx.doi.org/10.1016/j.biocon.2004.07.018> (last visited, August 4, 2005).

<sup>207</sup> Edwards, *supra* note 173, at 24.

<sup>208</sup> *Id.*

<sup>209</sup> *Id.* For example, extreme low doses of some pesticides have been determined to disrupt honeybees’ homing flight behavior, thereby adversely affecting POLLINATION. H.M Thompson, *Behavioural Effects of Pesticides in Bees—Their Potential for Use in Risk Assessment* 12 *Ecotoxicology* 317-330(2003). Available at <http://www.ingentaconnect.com/content/klu/ectx/2003/00000012/F0040001/05112975> (last visited, August 4, 2005).

<sup>210</sup> Edwards, *supra* note 173, at 28-29.

<sup>211</sup> Although the term “environmental estrogen” was coined in the 1970’s, it was not until the past 15 years that any scientific studies were conducted to lend support to the hypothesis that environmental exposure to certain synthetic chemicals could cause estrogenic effects. For a detailed discussion of the risks of endocrine disrupting chemicals and the legal shortcomings in addressing such risks, see generally, Noah Sachs, *Blocked Pathways: Potential Legal Responses to*

pesticides as well as a wide variety of other products in common use, such as toiletries, spermicides and plastics.<sup>212</sup> Exposure to these compounds, particularly when the exposure occurs in the fetus or young children, has been correlated with a large number of effects in humans including decreased sperm counts, breast and testicular cancer, endometriosis, deformed or stunted reproductive organs, neurological defects and low birth weights.<sup>213</sup> In addition to these human health effects, these substances have also been implicated in numerous wildlife impacts including deformed alligators and turtles, and reproductive difficulty in birds, fish and mammals.<sup>214</sup> These estrogenic effects can be extremely complex, unpredictable and difficult to understand.<sup>215</sup>

Another concern is the uncertainty regarding the potential effects of pesticides on ecologically significant microorganisms. Very little is known about the complex ecology of microorganisms.<sup>216</sup> Although there are not many data to suggest that most types of pesticides pose significant risks to microorganisms, soil fumigants, which are designed to destroy soil microorganisms and are applied at very high doses, may pose substantial risks to beneficial microorganisms.<sup>217</sup> For example, the killing of soil microbes and invertebrates resulting from

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*Endocrine Disrupting Chemicals*, 24 Colum. J. Envtl. L. 289 (1999); see also THEO COLBURN ET AL., OUR STOLEN FUTURE: ARE WE THREATENING OUR FERTILITY, INTELLIGENCE AND SURVIVAL? A SCIENTIFIC DETECTIVE STORY (1996); Matthew P. Longnecker, Walter J. Rogan, and George Lucier, *Effects of DDT (Dichlorodiphenyltrichloroethane) and PCBs (Polychlorinated Biphenyls) and an overview of organochlorines in public health*, 18 REV. OF PUB. HEALTH 211 (1997); Louis J. Guillette, Jr., Timothy S. Gross, Greg R. Masson, John M. Matter, H. Franklin Percivil, and Allan R. Woodward, *Developmental Abnormalities of the Gonad and Abnormal Sex Hormone Concentration in Juvenile Alligators from Contaminated and Control Lake s in Florida*, 8 ENVTL. HEALTH PERSPEC. 680 (1994); D. Crews, E. Willingham and J.K. Skipper, *Endocrine Disruptors: Present Issues, Future Directions*, 75 Q. REV. OF BIOL. 243 (2000).

<sup>212</sup> *Id.* AT 302-07.

<sup>213</sup> Sachs, *supra* note 211, at 293-298.

<sup>214</sup> *Id.*

<sup>215</sup> *Id.* at 300. For example, DDT exposure has been demonstrated to cause gulls to begin sharing nests with other females rather than males and young gulls had grossly feminized reproductive tracts. See Susan M. Salvatore, *Estrogens in the Environment*, 69 FLA. B.J. 39, n. 35 (1995). Moreover, a large number of studies on various species of fish exposed to estrogenic compounds have shown effects such as increased time to maturity, smaller gonads and reduced fertility. *Id.* at n. 36. Similarly, declines in the reproductive rates of mammals, such as, minks has been linked to ingesting fish contaminated with estrogenic substances. *Id.* at n. 37. The U.S. Fish and Wildlife Service has reported that between 1985 and 1990, 67% of male Florida panthers were born with one or more undescended testes, compared with only 14% 10 years earlier. *Id.* at n. 38. Although not fully understood, scientists suspect a link with exposure to estrogenic substances in the environment. Perhaps the most widely cited wildlife examples of endocrine dysfunction in wildlife are the feminization of alligators and occurrence of masculinized female fish in Florida. Interestingly, although we are only beginning to understand the estrogenic effects of certain pesticides, in her 1962 book, *Silent Spring*, Rachel Carson predicted such effects: "A substance that is not a carcinogen in the ordinary sense may disturb the normal functioning of some part of the body in such a way that malignancy results. Important examples are the cancers, especially of the reproductive system, that appear to be linked with disturbances of the balance of sex hormones . . . [t]he chlorinated hydrocarbons are precisely the kind of agent that can bring about this kind of indirect carcinogenesis." CARSON, *supra* note 2 at 235.

<sup>216</sup> Edwards, *supra* note 173, at 18.

<sup>217</sup> *Id.*

pesticide use may actually cause crops to become more susceptible to disease and may thereby reduce crop growth. In addition, populations of nitrogen-fixing organisms may be reduced thereby requiring higher levels of fertilizer application.<sup>218</sup> Critical ecological services provided by microorganisms, including decomposition may also be impacted by certain pesticides.<sup>219</sup>

The problem of ecological risk from pesticide exposure is exacerbated by the tendency of certain pesticides to undergo a phenomenon known as bioaccumulation. Bioaccumulation of pesticides become widely recognized during the 1960s as a result of Rachel Carson's book, *Silent Spring*. In her book, Carson explained how DDT and other organochlorine pesticides have the ability not only to persist in the environment for years if not decades, but also to accumulate in the tissue of animals and humans.<sup>220</sup> These pesticides accumulate in animals on the bottom of the food chain and then are passed from prey to predator until they can be found in very high concentrations in top predators. This phenomenon is known as biomagnification. Pesticides that persist, accumulate, and biomagnify are especially insidious in that they can adversely affect organisms far removed in both time and space from the original release of the pesticide into the environment.<sup>221</sup>

Moreover, although agricultural systems in themselves are not natural systems per se, they are generally located in close proximity to natural ecosystems and often contain within their borders, sizable natural and semi-natural ecosystems.<sup>222</sup> Thus, adverse effects from pesticide usage in agricultural systems may negatively impact ecosystems within the farm boundaries as well as nearby ecosystems that may be contaminated by pesticide runoff in water, drift through the air, or movement of contaminated organisms.

As described above, invertebrate nontarget species may be a greatest risk from pesticide use. Loss of invertebrate biodiversity, however, is not the only concern. Equally concerning, is the ecological and economic disruptions that frequently occur as a result of nontarget predator and

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<sup>218</sup> *Id.* at 31.

<sup>219</sup> David Pimentel, *et al.*, *Assessment of Environmental and Economic Impacts of Pesticide Use*, in *THE PESTICIDE QUESTIONS: ENVIRONMENT, ECONOMICS AND ETHICS* 47,68-69 (David Pimentel & Hugh Lehman, eds., 1993)

<sup>220</sup> CARSON, *supra* note 2, at 21-23.

<sup>221</sup> HUNTER, *supra* note 30, at 156. Other risks posed by pesticides have only recently begun to be studied. For example, in recent years, the extent of atmospheric transport of pesticides has come to light. Edwards, *supra* note 173, at 32-33. Moreover, the pesticide methyl bromide has been determined to be a significant contributor to the thinning of the stratospheric ozone layer. *See* 69 Fed. Reg. 76,982 (December 23, 2004).

<sup>222</sup> HUNTER, *supra* note 30, at 276.

parasites being killed by pesticides. Many pest populations are kept in check in nature by the existence of organisms that feed on pest species. Consequently, if these predators or parasites are eliminated or greatly reduced in number, the population of pest species will experience a population explosion. In addition to existing pest species population increases resulting from pesticide usage, new pest species may also be created as a result of this phenomenon.<sup>223</sup>

In the past ten years, a completely new suite of risk concerns have emerged regarding the use of pesticidal genetically modified organisms (GMOs). Although many of the risk considerations for biotechnology pesticides are similar, if not the same, as those for traditional chemical pesticides, these new pesticides pose a number of novel risks not presented by chemical pesticides. One of the most significant novel risk considerations for pesticidal GMOs is the potential for spread of the living organism or the organism's genetic material. For example, plants can reproduce sexually and/or asexually, and as a result, the genetic material that was introduced into the plant and that enables the plant to produce pesticidal substances could spread through agricultural or natural ecosystems. Thus, if a plant that produces a pesticide has the capacity to spread in the environment, or to spread its genetic material to other plants, there would be a greater potential for increased exposure to non-target organisms than there would be for a pesticide produced in plant that can only grow in a limited geographic area or does not have the ability to cross-fertilize with other plants in the environment.<sup>224</sup> This is a particular concern for pesticides produced in plants that have wild relatives in the United States.<sup>225</sup> If these wild relatives acquire the ability to produce the pesticide, through cross-fertilization, many additional nontarget organisms could potentially be exposed to the pesticide.<sup>226</sup> One of the most cited concerns

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<sup>223</sup> *Id.* An example of new pest creation resulting from pesticide use is the bollworm, which is now a major economic pest of cotton. Hunter, *supra* note 30, at 158. Although the bollworm existed previously, it was not a pest until pesticides used to control the boll weevil, another pest of cotton, killed the natural enemies of the bollworm, allowing its population to explode. *Id.*

<sup>224</sup> For a detailed discussion of the potential risks and benefits of pesticidal GMOS, see Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Developments in the EPA's Regulation of Biotechnology*, 7 U. FLA. J. L. & PUB. POL'Y 257 (1996).

<sup>225</sup> *Id.* at 287.

<sup>226</sup> The potential for a GMO or its genetic material to spread from one plant to another raises additional risk issues beyond those of exposure to humans and nontarget organisms. One potential risk of biotechnology products parallels the risk of the introduction of any non-native species into a new environment. David J. Earp, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1666-69 (1994). Even very small genetic manipulations can result in significant changes in an organism's ability to survive and flourish in a particular ecosystem. *Id.* Examples abound regarding the disastrous, but unpredicted, effects of the introduction of non-native species into the environment displacing native species. See J.J. Kim, *Out of the Lab and Into the Field:*

significant concerns regarding pesticidal GMOs is over the potential for the development of "superweeds" through the out-crossing of pesticidal GMOs to wild relatives.<sup>227</sup> Development of such a superweed has the potential to result in substantial disruption of agricultural and natural ecosystems.<sup>228</sup>

Perhaps the most serious concern with pesticidal GMOs stems from the fact that the risks of GMOs are uncertain. Moreover, although the risk of a GMO organism released into the environment creating a new superweed or disrupting the balance of natural ecosystems may be small, the consequences could be disastrous and potentially irreversible.<sup>229</sup> The precise nature and magnitude of the risk is difficult to predict because of the almost infinite variety of potential genetically modified organisms, the ability of GMO's to reproduce and spread, the complexity

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*Harmonization of Deliberate Release Regulations for Genetically Modified Organisms*, 16 FORDHAM INTL. L. J. 1160 (1993). Genetically modified organisms introduced into the environment could have similar impacts See Earp, *supra* at 1653. One of the most significant risks is the risk of a genetically engineered plant becoming a weed or pest itself or outcrossing to related species to create new weeds or pests *Id.* at 1654-55. Once released into the environment, the spread of a GMO may be extremely difficult, if not impossible, to control *Id.*

<sup>227</sup> For example, the ability to produce a pesticide that makes a plant resistant to insect or viral pests can be spread to a wild relative, and subsequently passed on to subsequent generations of that relative. Consequently, the wild relative, by virtue of its newly acquired ability to resist insects or viruses, has the potential to become a hardy weed, or superweed.

<sup>228</sup> For a GMO plant to transfer its genes to related existing weed species, wild relatives of the GMO plant must grow in the geographic areas where the GMO plant is introduced. See Earp, *supra* note 226 at 1666-69. Most crops grown in the U.S. are of foreign origin. Thus, the risk of hybridization between transgenic crops and wild relatives is unlikely in the U.S. Most of the major U.S. crops, including soybeans, corn, and wheat, have been bred to the point where they have lost their ability to compete with wild species in the environment. Thus, these crops are unlikely to become weeds when genetically altered. *Id.* Nevertheless, once these GMOs are exported (intentionally or otherwise) to other parts of the world that have wild relatives of the GMOs, the risks become more profound. Although beyond the scope of this article, the issue of potential risks posed by GMOs to human health, particularly by exposure through foods that have been genetically modified is a significant concern. Another issue that has received considerable attention is the issue of the potential for plant-incorporated protectants in foods to pose a risk of allergenicity to humans. The primary concern appears to be that if a gene that leads to the production of a pesticide is moved from one plant, for example a peanut, into another plant, for example corn, people who know they are allergic to peanuts will not know to avoid the corn plant. Thus, if the pesticide derived from the peanut plant contains an allergen from the peanut plant, allergic consumers could be put at risk. See generally, Judith E. Beach, *No "killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 Food Drug Law 181 (1998) and Celeste Marie Steen, *FIFRA's Preemption of Common Law Tort Actions Involving Genetically Engineered Pesticides*, 38 ARIZ. L. REV. 763 (1996). In addition, the movement of genes from animals to plants may be of concern to subpopulations of people with special dietary preferences such as vegetarians or persons who observe kosher (Jewish) or halal (Muslim) laws. Environmental Defense Fund, *A Mutable Feast: Assuring Food Safety in the Era of Genetic Engineering* (New York 1991). Finally, GMO herbicide tolerant plants may result in increased herbicide usage. Moreover, recently, some studies have shown evidence of a reduction in biodiversity in areas of some GM herbicide tolerant crops due to herbicide use decreasing in weeds and other plants that produce seeds, for insects, birds, and other species. L.G. Firbank, *et al.*, *The Implications of Spring-Sown Genetically Modified Herbicide Tolerant Crops for Farmland Biodiversity: A Commentary on the Farm Scale Evaluations of Spring Sown Crops* (2003), available at <http://www.defra.gov.uk/environment/gm/fse/> (last visited, August 4, 2005).

<sup>229</sup> See John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L.R. 807, 819 (2000-2001).

inherent in natural ecosystems, and the dearth of long term data on the effects of GMOs.<sup>230</sup>

### C. *History of Ecological Issues in Pesticide Regulation*

From its first introduction in the 1930's until its demise in the early 1970's, the pesticide DDT serves as stark illustration of the meteoric rise of a pesticide based on significant economic and human health benefits and subsequent dramatic fall of the same pesticide based on severe ecological and human health risks. Starting in 1939, and continuing through World War II, the military used DDT extensively to control insect vectors of deadly diseases such as typhus.<sup>231</sup> DDT is created with saving millions of lives from such diseases during the war.<sup>232</sup> By 1945, DDT had become a favorite agricultural pesticide, used in most of the world to control a variety of agricultural pests, as well as biting insects such as mosquitoes.<sup>233</sup> At its peak in the 1950's, an estimated 6000 tons of DDT were released into the environment in the U.S. alone.<sup>234</sup> Rachel Carson's 1962 book, *Silent Spring*, brought to the public's attention for the first time the downside of the seemingly miracle pesticide. In her book, Carson raised a number of significant ecological concerns regarding the widespread use of DDT, including the concern that the pesticide killed beneficial as well as pest insects, the disruptive effects of the pesticide in upsetting the natural ecological balance, and the bioaccumulation of the pesticide in the food chain resulting in risks to aquatic organisms, avian species and humans.<sup>235</sup> Carson's book led to a public outcry against the threats of DDT and other persistent pesticides. Once the link between DDT and the dramatic

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<sup>230</sup> See Steen, *supra* note 228 at 764. This discussion of the risks of GMOs, is not intended to suggest that these pesticides have no benefits. In fact, many scientists believe that GMO pesticides may provide a less risky alternative to chemical pesticides. Many GMOs are less toxic than chemical GMOs, more narrowly targeted towards the intended pest and released into the environment in smaller quantities. Nevertheless, the purpose of this discussion on the unique ecological risks posed by GMO pesticides is merely to highlight the complex ecological risks at issue and the large amount of uncertainty regarding such risks. It is worth noting that although there has not been any catastrophic damage caused by the GMOs that have been in the marketplace for the past several years, the pesticidal GMOs which have been commercialized to date are largely relatively innocuous from an ecological standpoint. All of the products in commercialization to date include genes from bacteria and viruses that are non-toxic to humans, that are naturally ubiquitous in the environment and have been applied widely to food crops in their microorganism form for decades. For example, the *B.t.* delta-endotoxin produced by numerous plant incorporated protectants in wide use, is essentially the same *B.t.* toxin that occurs naturally in soil and is ubiquitous in the environment. However, there are literally thousands of GM products in the research and development stage that are not so innocuous or well understood. Research is being done on just about every GM product that human ingenuity can conceive including corn plants that product a spider silk that can be used to make bullet proof jackets and soy plants that produce a scorpion toxin. These new products must be approached with much greater caution.

<sup>231</sup> Morriss & Meiners, *supra* note 184 at 7.

<sup>232</sup> *Id.*

<sup>233</sup> In the Matter of Stevens Industries, Inc, et al., I.F.& R. Docket Nos. 63, et al. (Consolidated DDT hearings, June 2, 1972).

<sup>234</sup> *Id.*



decline of numerous bird species, including the American Bald Eagle, was established, a movement developed to ban the use of DDT. Images of avian egg-shell thinning, deformed birds, and other ecological effects caused by DDT and its relatives fueled the public's new concerns over environmental issues and played a significant role in the development of the environmental movement of the 1960's and early 1970's. In 1969, the U.S. Department of Agriculture, then the agency in charge of pesticide registration,<sup>236</sup> cancelled certain uses of DDT and initiated an intensive review of other uses. Shortly after its creation, the newly formed EPA began a formal review under FIFRA of the remaining uses of DDT. In 1972 EPA issued the final order canceling the registration for most uses of the pesticide DDT.<sup>237</sup> In the final order, EPA concluded that the long-range risks of continued use of DDT were unacceptable and outweighed any economic or societal benefits it provided.<sup>238</sup>

The DDT controversy, which gained attention through the publication of *Silent Spring*, became one of the primary motivators behind the establishment of the EPA in 1970. The controversy also paved the way for a 1972 major overhaul of FIFRA, which had been on the books in a somewhat less ambitious form for over 60 years. The origins of FIFRA can be traced back to the federal Insecticide Act of 1910.<sup>239</sup> The 1910 Act was a consumer protection statute aimed at addressing concerns with false claims about the effectiveness of many pesticide products, which turned out to be useless, and the converse problem of pesticides that were too strong and thus caused crop damage.<sup>240</sup> This consumer protection emphasis carried over into the first enactment of FIFRA in 1947. The 1947 Act contained the first registration requirement for pesticides (referred to by the Act as "economic poisons").<sup>241</sup> The 1947 Act, however, did not establish significant safety standards for pesticides. A pesticide could be registered if the composition of the pesticide was such as to warrant the proposed claims for it and if the pesticide

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<sup>235</sup> See generally, CARSON *supra* note 2.

<sup>236</sup> Prior to the creation of EPA in 1970, the U.S. Department of Agriculture was responsible for administering FIFRA. In 1970, these responsibilities were transferred to EPA. Reorganization Plan No. 3 of 1970, 84 § 2086.

<sup>237</sup> In the Matter of Stevens Industries, Inc, et al., I.F.& R. Docket Nos. 63, et al. (Consolidated DDT hearings, June 2, 1972).

<sup>238</sup> *Id.*

<sup>239</sup> Act of 1910, April 26, 1910, CH. 191, 36 Stat., repealed 61 Stat. 163, 172 (1947).

<sup>240</sup> RODGERS, *supra* note 190 at 412-413.

<sup>241</sup> Ch. 125, 61 Stat. 163 (1947).

and its labeling complied with the requirements of FIFRA.<sup>242</sup> The 1947 Act remained intact until 1972. The 1972 amendments to FIFRA completely overhauled the statute and included provisions aimed at protecting environmental interests for the first time. The 1972 amendments form the backbone of the current FIFRA.

Despite the focus on ecological risks that dominated the DDT controversy and paved the way for the 1972 overhaul of FIFRA, ecological concerns played a much more modest role in the implementation of FIFRA during the 1980s and 1990s. In fact, only a handful of cancellation or suspension actions primarily based on wildlife or other ecological risks were brought by the EPA during that period. The only reported judicial or administrative case in which regulatory action primarily was based on risks to wildlife was *Ciba Geigy v. EPA*,<sup>243</sup> in which EPA proposed canceling of certain uses of the pesticide diazinon on golf course and turf due in large part to its risk to wild birds.<sup>244</sup> In addition to the diazinon case, EPA considered canceling certain uses of pesticides based on risks to wildlife during the 1980s and 1990s. However, EPA failed to take any significant action to address such risks.<sup>245</sup>

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<sup>242</sup> *Id.*

<sup>243</sup> 874 F.2d 277 (5th Cir. 1989).

<sup>244</sup> *Id.* at 278. This case involved the effects on birds of the use of diazinon on golf courses and turf. *Id.* Specifically, the case addressed the question of whether FIFRA requires a precise determination of risk or harm (e.g. the chemical has adverse effects 51% of the time it is used) in order to support cancellation of a registration. *Id.* Another related point of contention was whether devastating effect on bird populations or merely a significant adverse effect will justify cancellation. *Id.* at 280. In this case, the chemical company's contentions, that there should be more exact thresholds and more significant effects on the overall bird population, were rejected by the court. *Id.* The fifth circuit held that FIFRA gives the Administrator sufficient discretion to conclude that recurring bird kills are an unreasonable adverse environmental effect regardless of whether they significantly reduce bird populations. *Id.* Ultimately, the case was remanded to the Administrator to rectify the former administrator's failure to read the word "generally" as meaning "usually", "commonly", or "with considerable frequency." The phrase "generally causes unreasonable adverse effects on the environment" is also read to include any *potential* general causation of adverse effects. *Id.* at 279-280.

Further, despite suffering a stinging defeat in 1989 at the hands of environmental groups claiming that EPA's continued registration of the pesticide strychnine, was a violation of the federal Endangered Species Act, EPA continued to register, and allow the continued registration of, pesticides that pose risks to threatened and endangered species. *Defenders of Wildlife v. EPA*, 882 F.2d 1294 (8th Cir. 1989). In *Defenders*, the court found that EPA's continued registration of the pesticide strychnine constituted a taking under section 9 of the Endangered Species Act, even though there was no evidence as to the chain of possession of the strychnine or other links between EPA's registration of the pesticide and the ultimate death of the listed species. *Id.* at 1301. The court held, in essence, that EPA's decision to allow the registration to remain in effect, rather than suspending or canceling the registration, subjected the agency to Section 9 liability. *Id.* In concluding that "EPA's decision to register pesticides containing strychnine or to continue those registrations was critical to the resulting poisoning" of the endangered species, the court clearly was influenced by the fact that the pesticide could not legally be sold or distributed except under an EPA registration. *Id.*

<sup>245</sup> For example, in 1991, EPA proposed the cancellation of the pesticide ethyl parathion, due to risks to both humans and wildlife from the high acute toxicity of this pesticide. After negotiating with the manufacturers of ethyl parathion, however, EPA accepted a settlement which involved the cancellation of only the ground application uses of the pesticide, which posed significant risks to human farm workers, but did not include the cancellation of aerial application, which posed

In the past few years, there have been a number of controversies over the adverse impacts to wildlife species, including threatened and endangered species, from pesticides. One such controversy started in 2002, when forty environmental groups, including the American Bird Conservancy and Defenders of Wildlife, sent the EPA a Notice of Intent to Sue for Violations of the Endangered Species Act, Migratory Bird Treaty Act, and Administrative Procedures Act Concerning the Registration of the Pesticide Fenthion due to the high risks the pesticide posed to avian species. Later that year, the U.S. Fish and Wildlife Service recommended that EPA cancel existing registrations for fenthion immediately due to unreasonable adverse effects fenthion posed to avian species protection under the Endangered Species Act (ESA)<sup>246</sup> and the Migratory Bird Treaty Act (MBTA).<sup>247</sup> When EPA did not take action to reduce the risks from fenthion, in October of 2002 Defenders of Wildlife, the American Bird Conservancy and the Florida Wildlife Federation filed suit against EPA in federal district court alleging EPA had violated the ESA and MBTA. In 2003 the manufacturer of fenthion voluntarily canceled its registration of fenthion.

In addition, in September of 2004, environmentalists won a significant victory when the Ninth Circuit Court of Appeals issued a decision<sup>248</sup> affirming a district court's 2004 order that found that EPA had violated the ESA because it had failed to take steps to ensure that the registration of 54 pesticides would not jeopardize the survival of listed salmon species. The Court upheld the district court's injunction, which imposed detailed buffer zones restricting the use of more than 30 pesticides along listed salmon-supporting waters in California, Oregon, and Washington states.<sup>249</sup>

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the greatest risks to birds and other wildlife due to spray drift associated with this form of application. *See* 56 Fed. Reg. 65061-01 (Dec. 13, 1991), 57 Fed. Reg.3500-01 (Jan. 29, 1992), and 57 Fed. Reg. 6168-01 (Feb. 20, 1992). In fact, ethyl parathion had been implicated in the deaths of thousands of birds. Nevertheless, EPA declined to take regulatory action to prevent or minimize these risks. *Id.* Ultimately, the remaining uses of ethyl parathion were voluntarily cancelled in 2001, after a concerted campaign led by the American Bird Conservancy in partnership with Defenders of Wildlife, the Pesticide Action Network, and the World Wildlife Fund to pressure EPA and the manufacturer of the pesticide to end all uses. Ethyl Parathion: Notice of Use Cancellation, 66 Fed. Reg. 47667-01 (Sept. 13, 2001). However, despite the fact that ethyl parathion was considered to be one of the most toxic pesticides in current use and had been documented as the cause of thousands of bird kills, and despite decades of study by EPA, the agency itself failed to take regulatory action to protect wildlife.

<sup>246</sup> 16 U.S.C. §§ 1532 - 1544 (2004).

<sup>247</sup> 16 U.S.C. §§ 703 - 711 (2004).

<sup>248</sup> *See* Wash. Toxics Coalition, et al. v. EPA, et al., Case No. C01-013132C, Order issued January 22, 2004. This Order was the third in a series of orders granting injunctive relief to the environmental plaintiffs in this matter. *See* Wash. Toxics Coalition, et al. v. EPA, et al., Case No. C01-013132C, Orders issued July 16, 2003 and August 8, 2003. All of these Orders are available on EPA's website at <http://www.epa.gov/espp/wtc/index.html> (Last visited January 7, 2005).

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

As these recent cases illustrate, EPA has been reluctant to take regulatory action to prevent registration of, or cancel the registration of, a pesticide that poses significant ecological risks. In fact, EPA has failed to take such actions even when challenged by environmental organizations. Instead, such challenges have led to the manufacturers voluntarily canceling its registrations, as in the case of fenthion, rather than EPA taking action to reduce ecological risks. EPA's reluctance to take action to address purely ecological concerns resulting from pesticide use illustrates the broader problem that much of environmental protection law is focused predominantly on human health issues, with ecological concerns receiving little or no attention.

It should not be considered a bold statement to assert that environmental protection law is intended to protect the environment, yet it is. As the illustrations above show, implementation of FIFRA seems largely to have ignored any such intent. And if environmental protection is the goal, it would be logical to expect environmental protection law to be guided by the science of ecology (the study of the interactions of living organisms and their environments). However, after more 30 years of significant public concern over environmental protection and more than 30 years of implementation of numerous environmental protection laws, it is surprising how little these laws have been used to address environmental concerns, and how little ecological science has informed environmental law. Typically, environmental concerns are addressed only where there is a sufficient, independent human health-related motivation. Moreover, many of the first generation environmental laws were developed in an ad hoc way in reaction to the particular environmental crisis of the moment.<sup>250</sup> This collection of piece-meal laws have not kept pace with the scientific world's ever-increasing understanding of ecological systems.<sup>251</sup>

In recent years there have been greater attempts to incorporate ecological principles into environmental law and policy decisions. Professor Dan Tarlock has argued that environmental law derives its legitimacy from science.<sup>252</sup> Toxicology, engineering and other sciences have

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<sup>250</sup> See Brooks, et al., *supra* note 29.

<sup>251</sup> For a proposal to create a single umbrella environmental statute, see Lakshman Guruswamy, *Integrating Thoughtways: Re-Opening of the Environmental Mind?* 1989 WISC. L. REV. 463 (1989).

<sup>252</sup> See generally Tarlock, *supra* note 34. In this article, Tarlock explains how science not only has been used to identify environmental harms, but also to develop ways to remedy such harms. Tarlock argues that science remains the primary justification for environmental protection policy. Without a scientific foundation, Tarlock states, "environmentalism would be the marginal aesthetic movement that it was between the progressive conservation era and the late 1960s." *Id.* at 1136-37. But see Holly Doremus, *Listing Decision Under the Endangered Species Act: Why Better Science Isn't Always Better Policy*, 75 Wash. L. Q. 1029 (arguing that science alone cannot solve difficult environmental policy problems).

certainly played a significant role in environmental law. The role of the ecological sciences, however, has been much more modest. Although the science of ecology has informed certain areas of environmental law, such as endangered species protection,<sup>253</sup> most pollution-focused laws have not undertaken to incorporate ecological principles in any significant way. Indeed, if ecological sciences have significantly informed any area of environmental law, it is in the areas of natural resource management, endangered species protection, and wetlands protection, rather than the myriad of so-called pollution control laws that form the complex regulatory web of environmental regulation. The manner in which EPA has implemented the classic pollution control laws – the Clean Water Act (CWA)<sup>254</sup>, the Clean Air Act (CAA)<sup>255</sup>, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)<sup>256</sup> and the Resource Conservation and Recovery Act (RCRA)<sup>257</sup> – tends to be highly focused on the protection of human health and tends to treat protection of the environment as almost an afterthought.<sup>258</sup> Of course human health protection is of primary concern to most people, and few would place the value of protecting a bird, let alone an insect, above protecting human life. Nevertheless, it should not be forgotten that these environmental protection laws were intended to protect both human health and the environment and that environmental concerns not related to human health provided the impetus for the development of these regulatory programs. Even the bulk of scholarly literature in environmental law has failed to adequately grapple with ecological concerns.<sup>259</sup> In addition to

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<sup>253</sup> See Tarlock, *supra* note 34, at 1125 (describing how environmental law draws on three disciplines: economics, engineering and ecology).

<sup>254</sup> 33 U.S.C. §§ 1251 - 1387 (2004).

<sup>255</sup> 42 U.S.C. §§ 7401 -7671q (2004).

<sup>256</sup> 42 U.S.C. §§ 9601 - 9675 (2004).

<sup>257</sup> 42 U.S.C. §§ 6901- 6992k (2004).

<sup>258</sup> Robert L. Fischman, *Biological Diversity and Environmental Protection: Authorities to Reduce Risk*, 22 ENVTL. L. 435, 441 (1992) (stating that while virtually every statute that EPA is responsible for implementing contains language that would enable EPA to address ecological concerns in its regulatory programs, EPA has failed to utilize these broad authorities to address ecological concerns.) A few of the many examples of EPA's broad authority to address ecological risks include the following: 33 U.S.C. §1314(a)(1) directs EPA to develop water quality criteria that accurately reflecting the latest scientific knowledge on the effect on the health and welfare including plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation, as well as on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes and on biological community diversity. 42 U.S.C. §. 9605(a)(8)(A), EPA's national contingency plan for hazardous discharge clean-up, must take into account the potential for the destruction of sensitive ecosystems. The Clean Air Act requires EPA to promulgate secondary national ambient air quality standards to protect the public welfare. The statute defines the term "welfare" to include the effects of pollution on soils, water, vegetation, animals, wildlife, and the climate. 42 U.S.C. § 7409(a)(1)(B) (2004). For a more comprehensive discussion of EPA's statutory authority to consider ecological concerns in its regulatory programs, *see generally* Fischman *supra*.

<sup>259</sup> Both Professors J.B. Ruhl and Lisa Heinzerling have criticized the scholarly discourse on environmental law as being

the higher priority that human health concerns assume, it is probable that the limited attempts to protect the environment may stem, at least in part, from the fact that despite years of study, the ecological sciences have barely scraped the surface of understanding the complex machinery of the natural world. What little is known teaches us that ecological systems are extremely complex, and ever changing.<sup>260</sup> Accordingly, it is difficult to design regulatory programs to protect what we do not fully understand and what can be perceived as a moving target.

#### IV. FIFRA (A LICENSE TO KILL)

The regulation of pesticides in the U.S. is conducted primarily under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>261</sup> FIFRA requires that all pesticides<sup>262</sup> that are sold or distributed in the United States be registered by EPA.<sup>263</sup> Generally, a pesticide may be registered only if it will not cause an “unreasonable adverse effect on the environment.”<sup>264</sup> Accordingly, in determining whether to register a pesticide, EPA engages in a cost/benefit analysis, weighing the costs or risks associated with the use of a pesticide against the economic and social benefits of the pesticide. A pesticide may be registered only if the benefits of the pesticide outweigh the costs resulting from the use of the pesticide.<sup>265</sup> To determine whether, or the extent to which, FIFRA is eco-pragmatic, or in other words, the extent to which FIFRA

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too focused on human health concern and not focused nearly enough on the important goals of protecting natural systems. Lisa Heinzerling, *Reductionist Regulatory Reform*, 8 FORDHAM ENVTL. L.J. 459, 461 (1997) and J.B. Ruhl, *Working Both (Positivist) Ends Toward a New (Pragmatist) Middle in Environmental Law*, 68 GEO. WASH. L. REV. 522, 541 (2000) (book review).

<sup>260</sup> For a comprehensive discussion of the U.S. Supreme Court’s understanding and use of ecological principles in its decision-making in environmental cases, see Robert W. Alder, *The Supreme Court and Ecosystems: Environmental Science in Environmental Law*, 27 VT. L.REV. 249 (2003).

<sup>261</sup> 7 U.S.C. §§ 136-136(y) (2004).

<sup>262</sup> *Id.* § 136(u) provides that the term “pesticide” means “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. . . .” *Id.* § 136(u).

<sup>263</sup> *Id.* § 136a(a). This subsection provides:

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

*Id.* § 136a(a).

<sup>264</sup> *Id.* § 136a(c)(5). Section 136(j) provides that the term “environment” includes water, air, land, and all plants and man and other animals living therein and the interrelationships which exist among them. *Id.* § 136(j).

<sup>265</sup> Under FIFRA, cost/benefit terminology is used the opposite way it is used in discussing most environmental regulation. Typically, in doing a cost/benefit analysis, the regulatory agency compares the costs of regulation (e.g., the cost of installing pollution controls) to the benefits of regulation (e.g., lives saved or cancers avoided). Under FIFRA, however, the “costs” are considered to be the costs of allowing the use of the pesticide (e.g. cancer deaths), whereas the benefits are considered to be the benefits of allowing the use of the pesticide (e.g., reduction in crop loss from pest insect damage).

addresses the issues of uncertainty, complexity, and change, a close analysis of FIFRA, as well as its implementation by EPA, is warranted.

#### *A. Registration and Other Approval Mechanisms*

FIFRA section 3(a) provides that the Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed its composition is such as to warrant the proposed claims for it, its labeling and other material required to be submitted comply with the requirements of FIFRA, it will perform its intended function without unreasonable adverse effects on the environment, and when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse affects on the environment.<sup>266</sup> Unreasonable adverse affects on the environment is defined by FIFRA to mean any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.<sup>267</sup> Accordingly, when making the determination of whether to register a pesticide, EPA must consider not only any risks the pesticide poses to man or the environment, but also must consider the economic and social implications of using the pesticide. Noticeably, however, in defining unreasonable adverse effect on the environment, while Congress did direct EPA to take into account economic factors, it did not explicitly mandate that EPA conduct a strict cost/benefit analysis.<sup>268</sup> In fact, the legislative history of FIFRA suggests that adverse affects were not intended to be tolerated unless there are “overriding benefits” from the use of the pesticide.<sup>269</sup> Nevertheless, for more than thirty years, EPA has interpreted FIFRA to require a cost/benefit balancing, and this interpretation as been upheld by the court.<sup>270</sup>

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<sup>266</sup> *Id.* §136a(c)(5) provides:

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d) of this section –

- (A)its composition is such as to warrant the proposed claims for it;
- (B)its labeling and other material required to be submitted comply with the requirements of this subchapter;
- (C)it will perform its intended function without unreasonable adverse effects on the environment; and
- (D)when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse affects on the environment.

*Id.* § 136a(c)(5).

<sup>267</sup> Section 136(bb) defines the term “unreasonable adverse effects on the environment” as any “unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. . . .” *Id.* § 136(bb).

<sup>268</sup> SHAPIRO & GLICKSMAN, *supra* note 12, at 32, 29.

<sup>269</sup> *See* RODGERS, *supra* note 190, at 451-53.

<sup>270</sup> *Environmental Defense Fund, Inc. v. EPA* (heptachlor-chlordane), 548 F.2d 998, 1004 (D.C. Cir. 1976), *cert. Denied*

Significantly, although one prong of the test for registration requires EPA to determine that the pesticide “will perform its intended function” without unreasonable adverse effects on the environment,<sup>271</sup> FIFRA expressly states that EPA shall not make any lack of essentially a criterion for denying registration of any pesticide and that where two pesticides meet the requirements for registration, one should not be registered in preference to the other.<sup>272</sup> Thus, to obtain a registration, there is no requirement to demonstrate that a pesticide is essential. Moreover, the availability of alternative pesticides for the same use does not preclude registration. Further, FIFRA expressly authorizes EPA to waive all data requirements pertaining to efficacy and in fact EPA has, by rule, done so.<sup>273</sup>

One of the most important requirements is that the registrant submit data in support of registration.<sup>274</sup> FIFRA gives EPA discretionary authority to register products in certain situations

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431 U.S. 925 (1977) (stating that “to evaluate whether use of a pesticide poses an ‘unreasonable risk to man or the environment,’ [EPA] engages in a cost-benefit analysis . . .”); In the Matter of Chapman Chemical Co., *et al.*, FIFRA Dockets No. 246 *et al.* (EPA 1976) (stating that “before any pesticide can be cancelled under FIFRA [EPA] must be persuaded that the risks to man or the environment from continued use of the pesticide outweigh the benefits of its continued use.”); In the Matter of Protexall Products, Inc., *et al.*, FIFRA Docket Nos. 625, *et al.* (1989) (stating that “the risk-benefit assessment involves a balancing of the risks . . . against the benefits . . .”).

<sup>271</sup> *Id.* § 136a(c)(5)(B).

<sup>272</sup> *Id.* § 136a(c)(5) provides that:

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide’s composition is such as to warrant proposed claims of efficacy.

<sup>273</sup> 40 C.F.R. § 158.640(b)(1). The burden of providing EPA with the necessary information to determine whether the standard for registration is met rests at all times with the registrant or applicant for registration. The procedures for registering pesticides are set forth in the statute and regulations (primarily 40 CFR Part 152) .

<sup>274</sup> 7 U.S.C. § 136a(a) (2004) provides:

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

*Id.* § 136a(c)(2)(a) provides:

(2) Data in support of registration (a) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. . . . In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. . . .

Data requirements are found at 40 CFR Part 158, and provide for the submission of health and environmental effects data. The applicant for registration must bear the cost of gathering and generating the necessary data. To avoid duplicative data



even though not all data necessary to make a decision on registration have been generated. This is called "conditional registration." Conditional registration can be used for products with composition and proposed uses identical or substantially similar to currently registered pesticides, products with proposed new uses, or certain products with new active ingredient.<sup>275</sup> For the first two categories, EPA must determine that despite the lacking data, approval of the conditional registration would not significantly increase the risk of any unreasonable adverse effects on the environment.<sup>276</sup> For new active ingredients, EPA must determine that the use of the pesticide during the period of conditional registration will not cause unreasonable adverse effects on the environment and use of the pesticide is in the public interest.<sup>277</sup>

Most environmental risk reduction measures under FIFRA are achieved through labeling restrictions. An applicant for registration must submit all proposed labeling with the registration application.<sup>278</sup> A FIFRA "label" is the written, printed, or graphic matter on, or attached to the pesticide.<sup>279</sup> The term "labeling" under FIFRA includes the label as well as all other written, printed, or graphic matter that accompanies the pesticide or to which reference is made on the label.<sup>280</sup> All registered products must bear a label or labeling setting forth precautionary

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generation, the statute encourages the joint development of data and provides that applicants seeking to reach agreement on the terms of a data development arrangement may seek binding arbitration. *Id.* § 136a(c)(1)(F)(iii). Data already submitted to the Agency to support an existing registration, may be relied upon to support a new registration application provided the applicant for the new registration offers to pay compensation to the registrant who originally submitted the data. Data submitted to support a registration the first time a particular active ingredient is registered is protected by the "exclusive use" provisions of FIFRA and cannot be considered by EPA to support additional registrations for a period of ten years. *Id.* In addition, FIFRA § 10 generally governs the disclosure of information submitted to EPA pursuant to FIFRA requirements. Section 10(d) provides that health and safety data must be made available to the public, except that § 10(g) prohibits disclosure of health and safety data to multinational pesticide producers except during public proceedings under law or regulation. Sections 10(b) and 10(d) provide that other confidential business information ordinarily may not be released and provide specific protection for the formula and information on inert ingredients. Exemptions from these confidentiality protections are provided to avoid imminent public health risks and when the Administrator determines that disclosure is in the public interest during a proceeding to determine whether a pesticide causes unreasonable adverse effects. Any such release of information is subject to procedural protections involving prior notice and opportunity for district court review.

<sup>275</sup> *Id.* § 136a(c)(7), registration under special circumstances, provides:

Notwithstanding the provisions of paragraph (5) --

(A) The Administrator may conditionally register or amend the registration of a pesticide if the administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration

<sup>276</sup> *Id.* § 136a(c)(7)(A).

<sup>277</sup> *Id.*

<sup>278</sup> *Id.* § 136a(c)(1)(C).

<sup>279</sup> *Id.* § 136(p)(1).

<sup>280</sup> *Id.* § 136(p)(2).

statements, warnings, directions for use of the product, and an ingredient statement. A product whose label or labeling does not contain the information required by EPA or which sets forth false or misleading information is misbranded.<sup>281</sup> FIFRA requires users of pesticides to follow all label directions.<sup>282</sup> The requirement for users to follow label instructions is the only obligation placed by FIFRA on users of pesticides. Thus, the label is the only mechanism to regulate user behavior to accomplish risk reduction goals.

Under section 3(d)(1), a pesticide may be classified for either general or restricted use.<sup>283</sup> A restricted use pesticide may be used only by or under the supervision of a certified applicator and is not available for purchase by the general public.<sup>284</sup> A pesticide is classified for restricted use if it would cause unreasonable adverse effects on the environment in the absence of such a restriction.<sup>285</sup> Certification of applicators is primarily a state function. State certification plans must conform to certain standards enumerated in the statute.<sup>286</sup>

FIFRA provides for several forms of pesticide approval in addition to registration under section 3. First, EPA may grant an emergency exemption under FIFRA section 18.<sup>287</sup> Section 18 provides that the Administrator has discretion to exempt any Federal or State agency from any provision (normally, the registration requirement) of the Act if emergency conditions require such an exemption.<sup>288</sup> An emergency condition means an urgent, non-routine situation and is deemed to exist when: no effective pesticides are available under the Act that have labeled uses registered

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<sup>281</sup> *Id.* §§ 136(q) and 136j(a)(1)(E).

<sup>282</sup> *Id.* § 136j(a)(2)(G) provides that it shall be unlawful for any person to use any pesticide in a manner inconsistent with its labeling.

<sup>283</sup> 7 U.S.C. § 136a(d)(1).

<sup>284</sup> *Id.* § 136a(d)(1).

<sup>285</sup> *Id.*

<sup>286</sup> *Id.* § 136i, regarding the use of restricted use pesticides, provides:

Use of restricted use pesticides; applicators

(A) certification procedure

(1) Federal certification

In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides. . . .

(2) State certification

If any State, at any time, desires to certify applicators of pesticides, the Governor of such State shall submit a State Plan for such purpose. The Administrator shall approve the plan submitted by any State [meets certain general conditions regarding the state's legal authority, funding mechanisms, etc.]

*Id.*

<sup>287</sup> *Id.* § 136p.

<sup>288</sup> *Id.*

for control of the pest under the conditions of the emergency; no economically or environmentally feasible alternative practices which provide adequate control are available; and the situation involves the introduction or dissemination of a new pest, will present significant health risks, will present significant environmental risks, or will cause significant economic loss.<sup>289</sup>

In addition to federal pesticide registration under FIFRA, States may issue registrations of pesticide products or uses of such products to meet special local needs under FIFRA section 24(c).<sup>290</sup> A section 24(c) registration may be issued to allow use of a new formulation of a federally registered pesticide, to amend federal registration to permit use on additional crops or pests or at additional sites or to permit use of different application techniques, rates and equipment, to amend federal registration with special label directions necessary to prevent adverse effects or to ensure efficacy under local conditions, or for any other purposes consistent with FIFRA. Valid State registrations are treated as federal registrations under FIFRA.<sup>291</sup>

FIFRA section 5 authorizes EPA to issue Experimental Use Permits (EUP's) for field testing of unregistered pesticides.<sup>292</sup> The Administrator may issue an EUP if she determines that the applicant needs such a permit to accumulate information necessary to register a pesticide under section 3 of FIFRA.<sup>293</sup> Finally, Section 3(a) authorizes EPA, to the extent necessary to prevent unreasonable adverse effects on the environment, to issue regulations limiting the distribution, sale, or use of any pesticide that is not registered under the Act and that is not subject to an EUP under section 5 or an emergency exemption under section 18.<sup>294</sup>

#### *B. Continuing Duties of Registrants*

Once a pesticide is registered, registrants face a number of continuing responsibilities, particularly with regard to supplying additional data. In 1978 Congress added a provision to FIFRA (section 3(c)(2)(B)) giving EPA the authority to require holders of existing registrations to provide data to support the continued registration of a pesticide.<sup>295</sup> Section 3(c)(2)(B) allows the Agency at any time to require additional data to support an existing registration. The penalty for

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<sup>289</sup> *Id.*

<sup>290</sup> *Id.* § 136v.

<sup>291</sup> *Id.* § 136v(c)(1).

<sup>292</sup> *Id.* § 136c.

<sup>293</sup> *Id.*

<sup>294</sup> *Id.* § 136a(a).

<sup>295</sup> *Id.* § 136a(c)(2)(B).

failure to supply this data is suspension of the registration, which results in a prohibition on sale and distribution of the product.<sup>296</sup> Prior to suspension under section 3(c)(2)(B), a registrant has a right to a limited adjudicatory hearing. The only issues to be considered at such a hearing are whether "the registrant has failed to take the action," which is the basis of the suspension and whether the disposition of existing stocks is consistent with the Act.<sup>297</sup>

In addition to information required to be submitted under section 3(c)(2)(B), registrants are under a continuing obligation under FIFRA section 6(a)(2) to submit factual information regarding unreasonable adverse effects on the environment of the pesticide, whenever the registrant has such information.<sup>298</sup> EPA has adopted a rule, which describes specifically the types of information that must be reported, and the time frame for submission of these reports.<sup>299</sup>

The 1972 revisions to FIFRA included a tougher standard for initial registration of pesticides and mandated that the Agency go back and reexamine previously registered pesticides.<sup>300</sup> This reexamination or "reregistration" reflects a congressional determination that previously-registered pesticides ought to be as "safe" as newer ones and a recognition that the data EPA had for these older pesticides was not as complete or up to date as that for newer pesticides. Reregistration has proved to be one of the most critical and one of the most difficult regulatory tasks for EPA's pesticide program.<sup>301</sup> Because reregistration efforts were moving so slowly, in 1988 Congress enacted a new section 4 of FIFRA, which prescribes specific reregistration

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<sup>296</sup> *Id.* § 136a(c)(2)(B)(iii).

<sup>297</sup> *Id.*

<sup>298</sup> *Id.* § 136d(a)(2).

<sup>299</sup> 40 C.F.R. Part 159. In addition to authority to require information reporting, EPA has broad enforcement authority, which it shares with the states under FIFRA. EPA generally is responsible for manufacturer/producer enforcement, while the States have primary responsibility for user enforcement. The manufacturer/producer enforcement provisions give the Agency authority to register pesticide establishments, (7 U.S.C. § 136e). to inspect and to take samples, (*Id.* § 136g). to inspect books and records, (*Id.* § 136f), and to issue "stop sale, use or removal" orders and to institute seizure actions (*Id.* § 136i-2). Pursuant to section 27 of FIFRA, a state must have adequate pesticide laws and regulations and must be implementing such laws and regulations in order to maintain primary enforcement responsibility for pesticide use situations. *Id.* § 136v. The Agency can respond to an emergency requiring immediate action if a state is unwilling or unable to respond. *Id.* § 136w-1. Under section 16(c), the Agency is authorized to seek an injunction against violations of the Act in federal district court. *Id.* § 136n(c). A person who violates any provision of the Act may be subject to civil penalties under section 14(a). *Id.* § 136l. The amount of the penalty is determined by a consideration of the appropriateness of the penalty to the size of the business, the effect on the violator's ability to stay in business, and the gravity of the violation. *Id.* § 136l(a)(4). Moreover, a person who knowingly violates any provision of the Act may be subject to criminal penalties which carry larger fines and the possibility of a prison sentences. *Id.* § 136l(b).

<sup>300</sup> *Id.* § 136a-1.

<sup>301</sup> RODGERS, *supra* note 190, at 431.

requirements intended to dramatically change both the pace and the nature of reregistration.<sup>302</sup> The 1988 amendments require EPA to complete, over a 9-year period, the reregistration review of each registered product containing any active ingredient initially registered before November 1, 1984.<sup>303</sup> The amendments redirected the initial burden of identifying data gaps from EPA to the affected registrants. Moreover, the amendment establishes a multi-phased process with a number of deadlines that ensures that reregistration moves at a more accelerated pace. Failure of registrants to meet the prescribed deadlines may result in suspension or cancellation of registration.<sup>304</sup>

### *C. Cancellation and Suspension*

EPA may cancel or suspend existing registrations based upon certain risk/benefit determinations. FIFRA section 6(b), which specifically addresses cancellation, states that EPA may issue a notice of intent to cancel if a pesticide or its labeling does not comply with FIFRA or if when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.<sup>305</sup> Under section 6(b) there are two types of cancellation actions: section 6(b)(1) -- notice of intent to cancel or change classification; and section 6(b)(2) --notice of intent to hold a hearing to determine whether or not registration should be cancelled or classification changed.<sup>306</sup> For both sections 6(b)(1) and 6(b)(2),

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<sup>302</sup> 7 U.S.C. § 136a-1.

<sup>303</sup> *Id.*

<sup>304</sup> *Id.*

<sup>305</sup> *Id.* § 136d(b). FIFRA requires review of the proposed cancellation notice by the Secretary of Agriculture (USDA) and the FIFRA Scientific Advisory Panel (SAP). The statute dictates that the notice must be submitted to USDA and the SAP 60 days prior to notification of the registrant or publication (whichever comes first). If USDA and the SAP do not submit comments within 30 days, EPA may publish the notice. If USDA and the SAP do submit comments, EPA may, after reviewing such comments, withdraw the notice, issue a final notice without modification, or modify the notice, as appropriate.

Once the notice is published, persons adversely affected have 30 days to request a hearing. If no such hearing is requested, the notice of intent to cancel becomes final. If a hearing is requested, the hearing is considered a formal adjudicatory proceeding and is held before an ALJ. Such a proceeding is governed by the Agency's rules at 40 CFR Part 164.

<sup>306</sup> *Id.* § 136d.

Administrative review, suspension

(b) Cancellation and change in Classification

If it appears to the Administrator that a pesticide or its labeling . . . does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either-

(1) to cancel its registration or to changes it classification together with the reasons (including the actual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

. . . In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into

EPA must make a finding that the risks appear to outweigh the benefits. For section 6(b)(2), however, a hearing may be held when the Administrator's judgment concerning the risks and benefits of a pesticide is only tentative.<sup>307</sup> Before taking final action under section 6(b), the Administrator must determine whether any unreasonable risks posed by a pesticide's use can be sufficiently reduced by regulatory measures short of cancellation. Such measures include the imposition of additional labeling restrictions and/or the classification of the pesticide for restricted use. If the Administrator determines that adequate risk reduction cannot be achieved by such regulatory measures, the registration of the pesticide for that use must be cancelled. An EPA Final Order on a cancellation is reviewable in District Court.<sup>308</sup>

FIFRA also authorizes EPA to suspend the registration of a pesticide based on certain findings. FIFRA provides for two types of suspension proceedings -- "ordinary" and "emergency" suspension.<sup>309</sup> Ordinary suspension is issued where such action is necessary to prevent an

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account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy.

. . . The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication of a notice . . . , unless within that time either (I) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. . . In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

*Id.* § 136d(b).

<sup>307</sup> There is no distinction between § 136d(b)(1) and § 136d(b)(2) hearing in the manner of conduct, burden of proof, or nature of initial decision by ALJ. One issue generally considered as part of the cancellation process is whether the Agency should allow the continued sale and use of existing stocks of the pesticide.

<sup>308</sup> Of the more than 60 pesticide cancellations and suspensions, only approximately one third have been judicially reviewed. RODGERS, *supra* note 190, at 480. EPA's refusal to initiate proceedings to cancel or suspend a registration is considered a final order reviewable in District Court. *See* *Envtl. Defense Fund v. EPA*, 465 F.2d 528 (D.C. Cir. 1972).

<sup>309</sup> 7 U.S.C. §136d(c) (2004) - Suspension

(1) Order

If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3) no order of suspension may be issued under this subsection unless the Administrator has issued or at the same time issues, a notice of intention to cancel; the registration, or change the classification of the pesticide under subsection (b) of this section. Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard." The registrant shall then have an opportunity . . .for an expedited hearing before the Administrator in the question of whether an imminent hazard exists.

(2) Expedited hearing

If no request for a hearing is submitted to the Administrator within five days of the registrant's receipt of the notification . . . , the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Administrator

imminent hazard during the time required for cancellation proceeding. "Imminent hazard" is defined as a substantial likelihood of serious harm during the duration of cancellation proceedings.<sup>310</sup> The term is not limited to a concept of crisis. The function of a suspension action is to assess the evidence required to determine the risks and benefits for the period involved, not an ultimate resolution of the cancellation issues.<sup>311</sup> In an ordinary suspension, notification to the registrant of the intent to suspend and an opportunity for a hearing is required prior to effectiveness of suspension. Only a registrant may request an adjudicatory hearing. The order becomes effective either after a favorable decision following a hearing, or 5 days after notification if no hearing is requested.<sup>312</sup> If no hearing is requested, the suspension order is not reviewable by a court.<sup>313</sup> If a hearing is requested, an expedited administrative adjudicatory hearing is held before an ALJ, in which interested persons can intervene. The sole issue at the hearing is whether an imminent hazard exists.<sup>314</sup>

An emergency suspension order, which is effective immediately, may be issued if an emergency exists that does not permit even an expedited hearing before suspension takes place.<sup>315</sup>

Registrants have 5 days to request an expedited hearing and the hearing must begin within 5 days of the Agency's receipt of such a hearing request.<sup>316</sup> If an expedited hearing is requested, the emergency order remains in effect until the issuance of a final suspension order following the hearing.<sup>317</sup> No party other than the registrant and the Agency may participate in the expedited hearing, except for the filing of briefs.<sup>318</sup> An emergency suspension order is subject to immediate

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agree that it shall commence at a later time.

(3) Emergency order

Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notice to the Registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) . . . In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of the final order on suspension, and (b) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules.

<sup>310</sup> *Id.* § 136(l).

<sup>311</sup> *Id.* § 136d(c)(1).

<sup>312</sup> *Id.* § 136d(c)(2).

<sup>313</sup> *Id.*

<sup>314</sup> *Id.*

<sup>315</sup> *Id.* § 136d(c)(3).

<sup>316</sup> *Id.*

<sup>317</sup> *Id.*

<sup>318</sup> *Id.*

review in District Court.<sup>319</sup>

#### *D. Enter GMOs*

Pesticidal GMOs are regulated under FIFRA in much the same way as are traditional chemical pesticides.<sup>320</sup> For pesticidal GMOs, this means using FIFRA to regulate the “pesticide”

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<sup>319</sup> *Id.* § 136d(c)(4). The export of pesticides is regulated under section 17 of FIFRA. Section 17 reflects a somewhat limited role for EPA in the export of pesticides. The primary emphasis of this section is on the provision of information to foreign governments. Section 17 (a) provides that no pesticide intended solely for export to any foreign country shall be deemed in violation of the Act if it is prepared or packaged according to the specifications or directions or the foreign purchaser and in the case of unregistered pesticides, if prior to export the foreign purchaser signs a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States. In addition, section 17 (b) mandates notice to all countries of certain regulatory control actions taken by EPA (section 17(b)). Specifically, section 17(a) provides:

(a) Pesticides and Devices Intended for Export. -- Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act (1) when prepared or packed according to the specifications or directions of the foreign purchaser . . . ; and (2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

*Id.* § 136o(a).

Section 17(b) provides:

(b) Cancellation Notices Furnished to Foreign Governments. -- Whenever a registration, or cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.

*Id.* § 136o(b).

<sup>320</sup> The decision to treat GMOs similarly to traditional pesticides is rooted in the early U.S. biotechnology policies of the 1980's. The United States Government's first systematic attempt to address the regulation of biotechnology in a comprehensive fashion was with the publication of the 1984 document entitled "Proposal for a Coordinated Framework for Regulation of Biotechnology." Notice of Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,8566 (1984). The purpose of this document was "to provide a concise index to U.S. laws related to biotechnology, to clarify the policies of the major regulatory agencies that will be involved in reviewing research and products of biotechnology, to describe a scientific advisory mechanisms for assessment of biotechnology issues, and to explain how the activities of the Federal agencies in biotechnology will be coordinated." *Id.* In 1986, the Office of Science and Technology Policy ("OSTP") published in the Federal Register "Coordinated Framework for Regulation of Biotechnology: Announcement of Policy and Notice for Public Comment" ("the coordinated framework"). 51 Fed. Reg. 23,302 (1986). This approach was based on a belief that rDNA technology in itself does not create risk. *See Steen, supra* note 228, at 766. Instead, certain types of products of biotechnology may pose risks that can be addressed in the same fashion as regulatory agencies address the risks posed by traditional chemical products. During the 1980s and early 1990s, the executive branch of the US government was focused on promoting biotechnology as the US's hope for strong economic future. The feeling at the time was that the US had allowed Japan to beat it in the electronics industry. The federal government was determined not to allow this to happen with the biotech industry. The message was clear that regulatory agencies were not to stand in the way of biotechnology. There would not be any new biotechnology legislation and agencies would continue to rely on existing regulatory programs. For pesticidal GMOs this meant FIFRA. Moreover, a raging debate ensued over whether regulatory agencies should be regulating the “process” of genetic engineering or the “products” of genetic engineering. At that time, it was determined that from a risk standpoint, the process was irrelevant and that agencies should regulate only products of biotechnology. Under the coordinated framework, the regulatory approach taken by U.S. regulatory agencies, including EPA, has been to rely on existing statutes and to focus on the “product” rather than the



rather than targeting regulation at the process by which the pesticide is created.<sup>321</sup> GMOs that are intended to kill, disrupt, repel or mitigate pests are regulated in much the same way as traditional chemical pesticides under FIFRA. As described above, section 2(u) of FIFRA defines the term "pesticide" as: "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliator, or desiccant \* \* \* ." This definition is very broad and can include living organisms and substances produced by living organisms as well as traditional chemical pesticides. The definition of "pesticide" in FIFRA does not depend on the process by which a particular pesticide is produced. EPA has interpreted this definition to include biological pesticides and genetically modified pesticides. Thus, pesticidal GMOs must be registered under FIFRA prior to sale or distribution in the U.S. The standard for registration is the same for pesticidal GMOs as for traditional chemical. EPA has developed some data requirements specifically geared to address potential risks from microbial pesticides, including microbial GMOs.<sup>322</sup>

One category of pesticidal GMOs regulated by EPA under FIFRA includes microbial GMOs. EPA has regulated naturally-occurring microbial pesticides, such as *B.t.*, for many years. Microbial pesticides are regulated in much the same way as traditional pesticides at the large-scale testing and registration stages. EPA has expressed concern about the potential for adverse effects associated with small-scale environmental testing of certain microbial pesticides, both naturally-occurring and genetically engineered. Small-scale testing of most traditional pesticides generally is considered to pose very limited risks, and thus, typically is not regulated by EPA. Because microbial pesticides are living organisms that have the potential to reproduce and spread in the environment, however, even small-scale testing has the potential to present unreasonable adverse

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"process" used to create the product. *Id.*

<sup>321</sup> EPA's primary authority for regulating agricultural biotechnology products be found in two statutes: FIFRA, 7 U.S.C. § 136-136y (2004), and FFDCA, 21 U.S.C. § 301 *et seq.* (2004). Under FIFRA, EPA has the authority to address all environmental and human health issues associated with pesticide use. Under FFDCA, EPA has the authority to set tolerances for pesticide residues in or on food. EPA also regulates biologicals and biotechnology products that are not pesticides, food, or drugs under the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§ 2601-2692 (2004). TSCA grants EPA the authority to screen new chemical substances and impose controls to prevent unreasonable risks, and, through rulemaking, to acquire information and impose restrictions to prevent unreasonable risks on existing chemical substances. Although some agricultural biotechnology products may fall within the purview of TSCA, the majority of agricultural biotechnology products regulated by EPA are considered pesticides under EPA's broad definition of the term, and thus, are regulated under FIFRA and FFDCA.

effects on the environment.<sup>323</sup> Thus, EPA has promulgated a rule that requires notification prior to any small scale testing of certain microbial pesticides, including microbial GMOs.<sup>324</sup>

Another category of pesticidal GMOs regulated by EPA under FIFRA are pesticidal genetically modified plants, or “plant incorporated protectants.”<sup>325</sup> In July 2001, EPA published its long-awaited rule for the regulation of plant-incorporated protectants under FIFRA.<sup>326</sup> The plant-incorporated protectant rule took approximately 10 years to develop. Countless public hearings, scientific advisory council meetings, Congressional hearings and interagency negotiations were held.<sup>327</sup> Despite all of these efforts, however, the resultant rule is quite modest and does not really tackle the complex and novel risks of GMOs. The thrust of the new rule is merely to define the scope of what types of pesticidal GMOs EPA believes warrant regulation.<sup>328</sup> EPA has identified several categories that it has exempted from any FIFRA regulation because they are low risk.<sup>329</sup> One such category is GMOs that so closely resemble the types of plants that could be created

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<sup>322</sup> The data requirement for microbial pesticides can be found at 40 C.F.R. § 158.740 (2005).

<sup>323</sup> See 59 Fed. Reg. 45,600 (1994) (codified at 40 C.F.R. § 172).

<sup>324</sup> 40 C.F.R. § 172.

<sup>325</sup> A plant-incorporated protectant is defined as a pesticidal substance that is intended to be produced in a living plant, or in the produce thereof, and the genetic material necessary for its production. 40 C.F.R. § 152.3.

<sup>326</sup> 66 Fed. Reg. 37772 (2001) (codified at 40 C.F.R. Parts 152 and 174). EPA does not yet have any rules governing GM animals. For an historical discussion of the Plant-Incorporated Protectant Rule, see Angelo, *supra* note 224.

<sup>327</sup> 66 Fed. Reg. 37772 (2001).

<sup>328</sup> Under EPA's definition of plant-incorporated protectants, all substances produced by plants and intended for a pesticidal purpose are within EPA's jurisdiction, regardless of whether the plant is genetically modified. However, not all plant-incorporated protectants within EPA's jurisdiction warrant regulation under FIFRA. EPA believes that many plant-incorporated protectants do not warrant any regulation under FIFRA because they pose low probability of risk and will not cause unreasonable adverse effects on the environment. For example, in 1982, EPA promulgated a regulation under FIFRA § 25(b) that exempted all biological control agents from the requirements of FIFRA, except for certain microorganisms. 40 C.F.R. § 152.20(3). This exemption was promulgated because EPA found that macroorganisms used as biological control agents were adequately regulated by other federal agencies, such as the U.S. Department of Agriculture.

<sup>329</sup> EPA's first attempt to describe its plans to regulate plant-incorporated protectants was in early 1994. On January 21, 1994, EPA held a joint meeting of a sub-panel of the Agency's Scientific Advisory Panel and the Biotechnology Science Advisory Committee to address certain scientific issues related to the regulation of pesticidal substances produced in plants. For the meeting, EPA made available to the public a draft proposal of a comprehensive policy and four draft proposed rules (together referred to as the "draft proposal") that were developed under FIFRA and FFDCA. On November 23, 1994, EPA published in the Federal Register somewhat modified versions of these draft documents (together referred to as "the proposal"). 59 Fed. Reg. 496 (1994); 59 Fed. Reg. 60,519 (1994); 59 Fed. Reg. 60,535 (1994); 59 Fed. Reg. 60,542 (1994); and 59 Fed. Reg. 60,545 (1994). The proposal was intended to clarify the status of plant-incorporated protectants (referred to as "plant-pesticides" in the 1994 proposal and later renamed plant-incorporated protectants) under FIFRA and FFDCA and outline the scope of what types of plant-incorporated protectants EPA believed warranted regulation based on risk/benefit considerations. Under the proposal, many plant-incorporated protectants would not be subject to regulation because they pose a low potential for risk to humans and/or the environment. Others would be subject to regulation, but would be regulated somewhat differently than conventional pesticides because of the unique nature of plant-incorporated protectants. The proposal outlined how EPA intended to assess plant-incorporated protectants at different stages of environmental testing and at the sale and distribution stage. The final plant-incorporated protectant rule, promulgated in

naturally or through traditional plant breeding. An example of this would be introducing a substance normally produced by one variety of corn in to another variety of corn versus introducing a substance normally produced only in bacteria into corn. This type of plant-incorporated protectant would be exempt because it is not posing any new risks that would not have evolved naturally or through traditional breeding.<sup>330</sup> If a pesticidal GMO does not meet one of these exemptions, however, the regulatory process, is virtually identical to the regulatory process for all pesticides - namely, registration based on a cost/benefit analysis and labeling restrictions on use.<sup>331</sup> EPA has not yet established specific data requirements for genetically modified plants that act as pesticides.<sup>332</sup>

## V. IS FIFRA ECO-PRAGMATIC?

Although the basic regulatory framework of FIFRA dates back to 1972, with some of its provisions such as the misbranding prohibition dating back to the early consumer-protection statutes of the early 20<sup>th</sup> century, and despite the fact that a statute with the word “rodenticide” in it would hardly be expected to be cutting-edge, FIFRA is surprising eco-pragmatic. In fact, somewhat ironically given the state of pesticide regulation today, the earliest applications of FIFRA have threads of eco-pragmatism running through them. Even by today’s standards, the 1972 DDT cancellation decision represents a fairly sophisticated ecological analysis focused on: the tendency of DDT and its metabolites to persist in the soil and aquasphere, the tendency of DDT to be readily transported by leaching, erosion, run-off and volatilization, DDT’s fat soluble characteristic which enables it to collect and concentrate in animal fat tissue, the fact that DDT can bioaccumulate as it moves up the food chain, and the fact that once accumulated DDT is toxic to animals and humans and inhibits the ability of fish and other wildlife species to regenerate.<sup>333</sup> EPA did not shy away from tackling the difficult issue of how to take into account the risks may occur in the future due to the persistent nature of the pesticide. EPA also was not paralyzed by a lack of certainty in data. For example, even though EPA recognized that the degree of

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2001, adopted some, but not all of the exemptions proposed in 1994.

<sup>330</sup> 40 C.F.R. § 174.25.

<sup>331</sup> EPA has not adopted any specific registration, data or labeling requirements for plant-incorporated protectants. *See generally*, 66 Fed. Reg. 37772 (2001).

<sup>332</sup> *Id.*

<sup>333</sup> In the Matter of Stevens Industries, Inc, et al., I.F.& R. Docket Nos. 63, et al. (Consolidated DDT hearings, June 2, 1972).

transportability of DDT was unknown, EPA utilized data showing that DDT was found in remote areas of the world and in ocean species, such as whales, as providing enough evidence from which a logical reference could be drawn that DDT is readily transported in the environment.<sup>334</sup> Moreover, EPA concluded that persistence and biomagnification in themselves were a “cause of concern, given the unknown and possibly forever undeterminable long-range effects of DDT in man and the environment.”<sup>335</sup> Thus, even in 1972, EPA recognized the uncertainty surrounding ecological effects data, while at the same time employing a precautionary approach to prevent uncertain, possibly devastating effects that may occur in the long term.

When the group petitioners who opposed cancellation argued that DDT is only one toxic substance in a polluted environment and that therefore whatever its laboratory effects, it cannot be shown as the causative agent of injury to wildlife, EPA responded that this argument “does not redeem DDT, but only underscores the magnitude of effect that will be necessary for cleaning up the environment.”<sup>336</sup> Persuaded by evidence showing metabolites of DDT cause eggshell thinning in certain bird species despite some contradictory evidence, EPA found it sufficient that there was “laboratory data and observation data, and in addition, a scientific hypothesis, which might explain the phenomenon.”<sup>337</sup> EPA further found that there were no label restrictions that could completely prevent effects on nontarget organisms, persistence and transport in the environment, or biomagnification. Accordingly, cancellation was the only available risk-reduction measure.

EPA’s analysis of the benefits of DDT in formulating its decision to cancel was also fairly sophisticated and in some ways did a better job of considering benefits than many more recent EPA decisions regarding cancellation or suspension of pesticides. The benefits analysis focused on the availability of alternatives including non-chemical pest management programs and the fact that the crops protected by DDT were not in short supply. EPA found that DDT was not necessary to ensure an adequate supply of cotton at a reasonable cost, given that only 35 percent of the cotton-producing acreage at the time was treated by DDT.<sup>338</sup> In contrast to many recent EPA decisions, where non-chemical pest control alternatives and emphasis on availability of crops are conspicuously absent, or at least play a very minimal role, in the decision-making process, EPA’s

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<sup>334</sup> *Id.*

<sup>335</sup> *Id.*

<sup>336</sup> *Id.*

<sup>337</sup> *Id.*

1972 DDT cancellation decision takes a broader look at the cost/benefit analysis than merely counting up dollars and cents on each side of the equation. In fact, EPA's 1972 DDT cancellation decision has other indicia of an eco-pragmatic approach. For example, in the final order, EPA's statement that "the risk/benefit equation is a dynamic one" can be viewed as a foreshadowing of the arguments for flexibility and adaptive management that are at the center of eco-pragmatic scholarship.

Subsequent to the DDT cancellation, EPA brought a number of cancellation and suspension actions, through which the agency's interpretation of the statutory standard, "unreasonable effects on man and the environment," was further developed.<sup>339</sup> This series of FIFRA cancellation and suspension cases cemented the interpretation of FIFRA as containing a cost/benefit balancing standard, rather than the open-ended balancing standard that, at least arguably, it was intended to be.<sup>340</sup> As Professor William Rodgers has described the legislative history of FIFRA, the "unreasonable adverse effects" language was intended to be an environmentally stringent standard for registration.<sup>341</sup> The Senate Commerce Committee, which created the standard, described it as not tolerating any adverse effects, "unless there are overriding benefits from the use of a pesticide."<sup>342</sup> Accordingly, it appears that the standard contemplated by the Senate drafters of the 1972 FIFRA amendments intended that, although economic and social factors should be considered and balanced against environmental risks, the balancing would not be a simple accounting of dollars and cents on two sides of the equation, with the pesticide winning the right to registration as long as the scale was tipped, no matter how slightly in favor of the benefits provided by the pesticide. Instead, the Senate drafters appeared to intend that, where environmental risks exist, the analysis would favor registration only where the risks were outweighed by "overriding benefits." An example of an overriding benefit might be where a

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<sup>338</sup> *Id.*

<sup>339</sup> *Environmental Defense Fund, Inc. v. EPA* (heptachlor-chlordane), 548 F.2d 998, 1004 (D.C. Cir. 1976), *cert. Denied* 431 U.S. 925 (1977); *In the Matter of Chapman Chemical Co., et al.*, FIFRA Dockets No. 246 *et al.* (EPA 1976); *In the Matter of Protexall Products, Inc., et al.*, FIFRA Docket Nos. 625, *et al.* (1989).

<sup>340</sup> *See, e.g.*, *In the Matter of Chapman Chemical Company* (canceling certain uses of mercury in pesticides based on a finding that the risks of continued use outweighed the benefits); and *In the Matter of Protexall Products, Inc., et al.*, FIFRA Docket Nos. 625, *et al.* (1989) (describing the registrant's burden in challenging a proposed cancellation as requiring a showing that the "benefits of continued use justify the risks").

<sup>341</sup> RODGERS, *supra* note 190 at 451.

<sup>342</sup> *Id.* (quoting Senate Comm. on Commerce, Federal Environmental Pesticide Control Act of 1972, S.Rep. No. 970, 92d Cong., 2d Sess. 11 (1972)).

particular pesticide is important to fighting a significant public health problem such as West Nile Disease, and where other less risky control alternatives are not available or are too costly.<sup>343</sup> Other overriding benefits might include situations where a particular pesticide is necessary to the maintenance of a segment of agriculture, where nonchemical or less risky alternatives are not available and to grow the crop without the pesticide would result in severe economic losses or dramatically increased food prices. However, an overriding benefit would not be found in a situation where, if the pesticide were taken off the market, the evidence showed only that chemical companies would lose money or farmers would have to switch to other existing alternative pest control practices, which might involve some additional cost. If FIFRA were amended to make clear that only overriding benefits could outweigh significant environmental risks, then potential registrants would face a more stringent standard and pesticides that posed significant risk would not routinely be registered.

Certainly there is much that can be done to mold FIFRA into a more eco-pragmatic law. Nevertheless, eco-pragmatic themes such as adaptive management and an ecological integrity baseline run throughout the existing statute. The concept of an ecological baseline can be found in a numbers of places in FIFRA. Specifically, the standard for registration under FIFRA is designed to address a large array of ecological concerns, as well as human health concerns. FIFRA's regulatory standard is aimed at preventing "unreasonable adverse effects on the environment."<sup>344</sup> The word "environment" is defined very broadly by FIFRA to included water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these."<sup>345</sup> Thus, FIFRA not only broadly includes land, water, air and plant and animal resources, within the definition of "environment," but also includes the "interrelationships" among these resources as encompassed within the definition.

Moreover, FIFRA contemplates an ecological baseline in its premarket evaluation. Under FIFRA, a registration is required prior to the sale, distribution or commercialization of any

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<sup>343</sup> The importance that pesticides can play in preventing significant public health problems is specifically addressed by FIFRA. The definition of "unreasonable adverse effects on the environment" provides that "The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides, In weighing and regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide." 7 U.S.C. § 136(bb) (2004).

<sup>344</sup> See, e.g., *id.* § 136(l), § 136(x), § 136(ee)(2).

<sup>345</sup> *Id.* § 136(j).

pesticide product. Moreover, except for in limited circumstances qualifying for an exemption, some level of regulatory review is required prior to the release of any pesticide into the environment even if only for experimentation purposes. Unlike some other environmental regulatory programs, such as the Toxic Substance Control Act (TSCA),<sup>346</sup> FIFRA imposes a somewhat precautionary approach in that pesticides, in that they are by definition intended to kill or disrupt living organisms, are presumed to pose unreasonable risks, and therefore, they cannot be sold or distributed without a premarket environmental review.<sup>347</sup>

Moreover, FIFRA's precautionary approach is manifest in its allocation of the burden of proof. While not expressly stated in the language of FIFRA, pursuant to a series of administrative and judicial decisions, the burden of proof that a pesticide does not pose an unreasonable adverse effect of the environment remains at all time on the proponent of registration or continued registration.<sup>348</sup> Thus, a proponent of registration is required to demonstrate it meets this burden prior to a pesticide being registered. Further, if EPA proposes cancellation of a pesticide or use of the pesticide, the burden of proof rests on the proponent of continued registration during any cancellation or suspension hearing that may ensue.

With regard to adaptive management, FIFRA also shows surprising signs of being eco-pragmatic. Many of FIFRA's provisions are specifically designed to seek new information, to adapt to new information or to tailor the level of regulation to the level of certainty of risks based on the sufficiency of available data. For example, FIFRA establishes two different levels of registration – full registration and conditional registration. EPA may conditionally register a pesticide under certain circumstances, despite the fact that sufficient data have not been generated to support full registration. As described above, such circumstances may be where a new use is proposed for a pesticide that is already registered for another use. In such a situation, sufficient

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<sup>346</sup> 15 U.S.C. §§ 2607-2629 (2004).

<sup>347</sup> In contrast, new non-pesticide chemicals entering the marketplace do not require a premarket environmental review under TSCA. *Id.* § 2604. Instead, prior manufacturing these new non-pesticide chemical substances under TSCA, all that is required is a 90-day notification to EPA. *Id.* § 2604(a). During the premarket notification period, EPA conducts a cursory review of the proposed new chemical, but unless a determination is made that for a particular chemical generation of new data rare required, EPA typically does not require environmental testing. *Id.* § 2604. If a non-pesticide substance is later found to pose unforeseen risks, EPA can, by regulation, require additional testing to be conducted or impose regulations to reduce the risk from such a substance under sections 4, *Id.* § 2603 and 6, *Id.* § 2606, of TSCA, respectively.

<sup>348</sup> *Environmental Defense Fund, Inc. v. EPA (heptachlor-chlordane)*, 548 F.2d 998, 1004 (D.C. Cir. 1976), *cert. Denied* 431 U.S. 925 (1977); *Environmental Defense Fund, Inc. v. EPA (DDT II)*, 439 F.2d 584 (1971); *Stearns Elec. Paste Co. v. EPA*, 461 F.2d 293, 304 (7<sup>th</sup> Cir. 1972).

data exists to support the existing use, but additional data may be required to support full registration of the newly proposed use. Under such circumstances, EPA may conditionally register the pesticide for the new use if EPA determines that the conditional registration would not significantly increase the risk of any unreasonable adverse effects on the environment. Accordingly, through the conditional registration process, a degree of flexibility is built into FIFRA, allowing products to be used in new ways prior to full data generation.<sup>349</sup>

Other provisions of FIFRA that allow unique circumstances and changing information to be taken into consideration include the emergency exemption provisions, the state registration provisions and the experimental use permit provisions. The emergency exemption provision of section 18 of FIFRA authorizes EPA to grant an emergency exemption to any state or federal agency if emergency conditions – i.e., urgent non-routine conditions for which no economically or environmentally feasible alternative practices that provide adequate control are available. Thus, section 18 provides flexibility to adapt to changing circumstances, which could include the outbreak and spread of a new pest or the spread of a public health disease. In such circumstances, EPA is authorized to act quickly to control the problem before the pest or disease vector is widely disseminated and to minimize the harm, without waiting for a full data set to be produced to support registration.

The state registration provision in section 24(c) authorize states to issue registration to meet special local needs. Accordingly, this provision allows states to take into consideration local circumstances that may warrant the use of pesticide products or uses that are not generally approved under FIFRA for nationwide use. Thus, in a state where a particular pest causes more severe harm than in other states, the cost/benefit analysis for the use of the pesticide in that state may have a different result from the nationwide cost/benefit analysis for that use, and accordingly, a special local needs registration may be granted for that state only. In this way, FIFRA's flexibility allows registrations to be tailored to the special agricultural, environmental, economic or other needs of a state.

Finally, the experimental use permit provision continued in FIFRA section 5 is another example of the flexibility afforded by FIFRA in tailoring the amount of data necessary to the level

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<sup>349</sup> Of course, should the new data demonstrate that the new use does not meet the standards for full registration, full registration will not be granted.



of risk resulting from a particular use. FIFRA section 5 authorizes EPA to issue permits for the field testing of pesticides necessary to generate data to support full registration. Thus, as the risk from exposure to a pesticide increases (i.e., as it moves from lab testing, to small-scale field testing, to full-scale use), progressively greater data requirements attach to ensure that sufficient data are available to make an unreasonable adverse effects determination for each level of use. Similarly, the ability for EPA to classify a pesticide as either general or restricted use allows EPA to adapt the amount of regulation required to the risks associated with the particular pesticide. By classifying a pesticide as restricted use, EPA ensures that users of the pesticide will have at least some level of training and supervision to reduce the risks associated with the use of that pesticide.

With regard to taking advantage of new information as it develops – or requiring new information as new testing methodologies become available or new risk scenarios are understood—FIFRA also contains some relatively eco-pragmatic approaches. Because hundreds of pesticides on the market were registered prior to the current registration data requirements being in place, FIFRA section 4 contains a detailed “reregistration” process designed to ensure that older pesticides are reexamined in light of more stringent regulatory standards and more sophisticated testing methodologies that have come into existence since the times of the early registrations of many pesticides. The current reregistration provisions include a multi-phased process with a number of deadlines, which must be met to avoid suspension or cancellation. This reregistration approach has been an extremely time-consuming, burdensome and expensive process. If future changes to the registration standard, data requirements or testing methodologies warrant another round of reregistration, it also could be extremely costly in terms of time and resources. Nevertheless, such a process may be the only way to comprehensively address significant changes.

While reregistration applied to all pesticides registered prior to 1984, there are a number of FIFRA data requirements that apply to previously registered pesticides in a more targeted manner. For example, FIFRA section 3(c)(2)(B) authorizes EPA to require holders of existing registrations to provide additional data support the continued registration of a pesticide whenever EPA finds that “additional data are required to maintain in effect an existing registration of a pesticide.”<sup>350</sup> Finally, under section 6(a)(2) of FIFRA, if at time after the registration of a pesticide, the

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<sup>350</sup> 7 U.S.C. § 136a(c)(2)(B) (2004).

registrant obtains in any way factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant is required to submit such information to EPA. Unreasonable adverse effects information submitted to EPA may lead to EPA requesting additional data under section 3(c)(2)(B), EPA initiating a cancellation or suspension action, EPA reclassifying a general use pesticide as a restricted use pesticide, or some other form of regulation to ensure that the pesticide will not cause unreasonable adverse effects on the environment. Thus, FIFRA contemplates a process of ongoing evaluations of pesticide risks as new information becomes available. With regard to pesticidal GMOs, EPA has taken the section 6(a)(2) approach a step farther to require ongoing reporting of adverse environmental effects data, not only for registered pesticides, but also for pesticides that qualify for a plant-incorporated protectant exemption.<sup>351</sup> In its plant-incorporated protectant rule, EPA requires that any person who produces, for sale or distribution, a plant-incorporated protectant exempt under the rule, who obtains any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant, must submit such information to EPA.<sup>352</sup>

## VI. REINVENTING FIFRA THROUGH ECO-PRAGMATISM

Notwithstanding all of these promising elements, FIFRA has not lived up to its eco-pragmatic promise. As described more fully below, a combination of statutory shortcomings, unfortunate interpretations, and problems with implementation and enforcement, have resulted in FIFRA's lack of success as an environmental protection statute. Accordingly, there is considerable room for improvement. By revising FIFRA to follow the eco-pragmatic approach and to more consciously incorporate ecological principles, the statute could be improved substantially.

### *A. Reinventing the Cost/Benefit Balancing*

For FIFRA to be reinvented in an eco-pragmatic mold, a number of changes are indicated. First, as described above, EPA's cost/benefit approach to registration and cancellation under FIFRA, must be replaced with an open-ended balancing approach, which appears to be Congress'

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<sup>351</sup> 40 C.F.R. § 174.1.

<sup>352</sup> 40 C.F.R. § 174.71 (2005). This rule goes on to explain that for the purposes of plant-incorporated protectants, "[a]dverse effects on human health or the environment means at a minimum information about incidents affecting humans or other nontarget organisms where both: (1) The producer is aware, or has been informed, that a person or nontarget organism allegedly suffered a toxic or adverse effect due to exposure to (e.g., ingestion of) a plant-incorporated protectant. (2) The producer has or could reasonably obtain information concerning where the incident occurred." *Id.* § 174.71(b).

intent in drafting the “unreasonable adverse effects on man and the environment” standard. Under such an approach, although economic and social costs would be factors to be considered in determining whether to allow a pesticide to be sold or distributed in the U.S., they would not be used to “balance” away significant human health or environmental risks. Such risks would only be permitted in cases where there are overriding benefits of the pesticide, taking into account a number of specified considerations in the open-ended balancing.

The plain language of FIFRA, as it currently stands, does not mandate a strict cost/benefit balancing. Instead, as Shapiro and Glicksman have suggested, on its face, FIFRA could be read to contain a open-ended balancing standard. As described above, FIFRA’s definition of “unreasonable adverse effects on the environment” means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. Congress’ only direction to EPA was to “take into account” economic and social as well as environmental considerations. Nevertheless, EPA has interpreted and implemented this standard as more of a strict cost/benefit balancing.<sup>353</sup> However, at least with regard to the registration of pesticides, EPA does not really engage in a true cost/benefit analysis because it does not require applicants to demonstrate the benefits of the pesticide. Moreover, as described above, EPA generally does not require efficacy data prior to registering a pesticide. EPA has, by rule, waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans.<sup>354</sup> Accordingly, at the time of a registration decision, EPA does not know how efficacious a particular pesticide is. Further, at the time of registration, EPA does not conduct an analysis to determine whether more efficacious alternatives, including non-chemical alternatives, exist. Thus, at the time of registration, EPA does not know the extent of the benefits

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<sup>353</sup> *Environmental Defense Fund, Inc. v. EPA (heptachlor-chlordane)*, 548 F.2d 998, 1004 (D.C. Cir. 1976), *cert. Denied* 431 U.S. 925 (1977); *In the Matter of Chapman Chemical Co., et al.*, FIFRA Dockets No. 246 *et al.* (EPA 1976); *In the Matter of Protexall Products, Inc., et al.*, FIFRA Docket Nos. 625, *et al.* (1989).

<sup>354</sup> 40 C.F.R. § 158.640 (2005). The only pesticides for which EPA requires efficacy data are pesticides intended to control microbial organisms that affect human health and certain vectors of public health diseases. *See id.* (containing product performance data requirements for antimicrobial agents, products for treating water systems, and pesticides intended to kill or repel rodent, avian, and bat vectors). However, EPA has reserved the right to require, on a case-by-case basis, submission of efficacy data for other pesticides. *Id.*

of the pesticide. Instead, benefits are assumed.<sup>355</sup> When coupled with the limited cost data that EPA considers, it can be seen that EPA's cost/benefit analysis to support registration is not a true cost/benefit analysis and is flawed in many respects.

Technology-based approaches, which have worked well in other areas of pollution control law,<sup>356</sup> may not work so well where the goal is to release substances into the environment with the intent to kill living organisms. Thus, a different approach may be necessary. FIFRA differs from many other environmental laws in that the environmental risks that are sought to be reduced by other such laws are by-products of activities that are intended to produce some other product or service (e.g., air pollution from energy production), whereas, with FIFRA, the pesticide that poses the risk is the intended product. Accordingly, under FIFRA, the imposition of technology to reduce risks would take a different form than with other technological controls that seek, for example, to reduce air pollution emissions. The FIFRA analogue of the technology-based standard, therefore, is an alternative reduced risk method of pest control. Such an alternative can be either a lower risk chemical pesticide, or other non-chemical methods of pest control, such as biological control or cultural control.<sup>357</sup>

FIFRA's balancing standard should be revised to make clear that it is an open-ended balancing rather than a strict cost/benefit balancing. In addition to the economic considerations that the statutory standard directs EPA to consider in conducting this balancing, the statute should be revised to explicitly direct EPA to take into consideration additional factors aimed at ensuring that ecological concerns are adequately valued in the balancing. For example, considerations such as the degree of uncertainty regarding risks, the level of probability or risk, the degree of harm that could occur, the likelihood of a pesticide to spread or reproduce in the environment, either through biological means as in the case of GMOs or physical means,<sup>358</sup> are all factors that should be given serious consideration in any open-ended cost/benefit balancing.

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<sup>355</sup> In determining whether to register a pesticide, EPA assumes that a manufacturer would not invest the resources necessary to support registration and commercialization of the pesticide unless the pesticide was efficacious and thus has benefits. Of course, one need only look at the glut of weight loss products, anti-balding products, and wrinkle cream on the market, and the billions of dollars consumers spend each year on such products to conclude that marketability and efficacy are not necessarily one in the same.

<sup>356</sup> See generally Wagner, *supra* note 94.

<sup>357</sup> Biological controls include predator or parasites of pest insects. Cultural controls include as cultivation, sanitation, crop rotation, and sowing and harvesting practices. See *supra* notes 174-177 and accompanying text.

<sup>358</sup> Physical means of environmental dissemination include the tendency of a pesticide to move great distances through

Another recommended revision to EPA's cost/benefit approach to FIFRA registration is to require that the benefits provided by a pesticide actually be demonstrated. As discussed above, FIFRA does not mandate, and EPA has opted not to require that efficacy data be provided when registering a pesticide<sup>359</sup>. Nor does EPA require that applicants for pesticide registration provide data showing that there are not cost-effective alternative pest control methods available. Likewise, EPA does not require applicants to provide information demonstrating that their proposed pesticide is relatively beneficial, either environmentally or economically over other existing pesticides or pest control methods that are available to address the target pest. EPA merely assumes that a pesticide manufacturer would not incur the costs of developing and marketing a pesticide if it was not efficacious and did not have benefits and that any pesticides that are not beneficial will be eliminated through market forces. Consequently, a manufacturer could obtain a registration for a pesticide without ever having to show that the pesticide works for its intended purpose, let alone that the pesticide is necessary for combating particular pests or that existing chemical or non-chemical alternatives are not available. Virtually no chemical pesticide is without at least some risk. Thus, it is at least possible, if not likely, that pesticides are being registered that pose some risks, but have not been demonstrated to have any significant environmental, economic or societal benefit.

It is not until EPA begins to consider whether to cancel the registration of a pesticide that EPA evaluates the benefits of the pesticide and whether there are viable alternatives available. In determining whether EPA should proceed with cancellation, EPA necessarily makes a threshold determination that the risks posed by a pesticide are significant. Once that determination is made, EPA conducts a full cost/benefit analysis. It is only at this point that EPA takes a look at the economic benefits of the pesticide. However, when conducting a benefits analysis, EPA's analysis of alternatives is typically limited to looking at other registered pesticides for the same use (which are assumed to be efficacious if they are registered). EPA's consideration of non-chemical alternative pest control techniques such as cultural control, biological control or organic farming

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soil, water or air, and the tendency of a pesticide to bioaccumulate.

<sup>359</sup> The lack of a requirement for efficacy data is in contrast to other licensing statutes, such as the licensing provisions of the FDCA governing the approval of new drugs, which explicitly requires a finding that a drug is "effective" as part of the premarket review process. A new drug is considered to be "effective" if there is a general recognition among experts, founded on substantial evidence, that the drug in fact produces the results claimed for it under prescribed conditions. 21 U.S.C. § 111 (2004).

practices has proven to be extremely limited and cursory. Moreover, when evaluating whether existing chemical alternatives are available for the target pest, EPA does not conduct a comparative risk analysis, which leads to the situation where a less risky pesticide may be cancelled because other alternatives exist, but as more and more pesticides are cancelled, the benefits of the remaining pesticides grow. Thus, the benefits of the “last pesticide standing” will be very high because no alternatives exists. Accordingly, the last pesticide standing will have benefits that outweigh the risks, even if the risks are relatively high. This problem could be solved by requiring a true benefits analysis for each registered pesticide, including a consideration of non-chemical alternatives, and conducting relative risk analysis, that compares the risks of pesticides targeted toward a particular pest.

It should be noted that although EPA does not routinely consider the relative risks of alternative pesticides when making registration or cancellation decisions, EPA has implemented certain policies to encourage the development and registration of lower risk pesticides. In 1997, EPA issued Pesticide Registration (PR) Notice 97-3, which sets forth EPA’s policy for the expedited review of conventional pesticides under the reduced risk initiative and of biological pesticides.<sup>360</sup> The goal of the policy is to encourage the development, registration and use of lower-risk pesticides products “which would result in reduced risks to human health and the environment, when compared to existing alternatives.” To accomplish this goal, EPA offers the incentive of an expedited registration review for qualifying products. Qualifying pesticides include those that may reasonably be expected to accomplish one or more of the following: (I) Reduce the risks of pesticides to human health; (ii) Reduce the risks of pesticides to nontarget organisms; (iii) Reduce the potential for contamination of groundwater, surface water or other valued environmental resources; and (iv) Broaden the adoption of integrated pest management strategies.”<sup>361</sup>

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<sup>360</sup> This policy was developed partially in response to the 1996 Food Quality Protection Act mandates to develop procedures and guidelines for expedited pesticide review. The policy supersedes EPA’s prior reduced-risk criteria published in 57 Fed. Reg. 32140 (July 20, 1992) and 58 Fed. Reg. 5854 (Jan. 1993) and PR Notice 03-9 (July 21, 1993).

<sup>361</sup> These criteria are found in FIFRA § 3(c)(10), 7 U.S.C. § 136a(c)(10). EPA has further interpreted these criteria to develop a list of factors that will most significantly contribute to EPA’s decision to grant reduced risk status. These factors include, in descending order of importance: very low mammalian toxicity; toxicity generally lower than alternatives (10-100X); displaces chemicals that pose potential human health concerns [e.g., organophosphates, probable carcinogens (B2s)]; reduces exposure to mixers, loaders, applicators and reentry workers; very low toxicity to birds; very low toxicity to honeybees, significantly less toxicity/risk to birds than alternatives; not harmful to beneficial insects, highly selective pest

Moreover, with regard to the costs side of the equation, EPA's analyses, although more complete than for benefits, does not fully address the suite of environmental risks posed by pesticides.<sup>362</sup> Most of the indirect environmental and economic costs of pesticide use are not considered.<sup>363</sup> Environmental and economic costs which are not typically addressed in any meaningful way in pesticide cost/benefit analyses includes: domestic animal poisonings and contaminated products, destruction of beneficial natural predators and parasites, honeybee and wild bee poisonings and reduced pollination, crop and product loss, ground and surface water contamination, fishery losses, adverse effects on wild birds and mammals, adverse effects on microorganisms and invertebrates, and adverse effects on ecosystem services. In 1993, Cornell Professor David Pimentel estimated that if the full environmental and social costs of pesticide use are taken into account, including indirect effects, the environmental and social costs of pesticide use would be significantly greater than \$8 billion/year.<sup>364</sup> Pimentel estimated that of this \$8 billion/year, users of pesticides in agriculture pay only approximately \$3 billion, leaving the remaining \$5 billion/year to be borne by society.<sup>365</sup> Moreover, Pimentel points out that many of the true costs of pesticide use are either not well understood or difficult to quantify. Thus, the true cost of pesticide use may be even higher. Unfortunately, very few of these costs are considered by EPA when conducting the cost/benefit analysis it relies on to register a pesticide. Moreover, the way that EPA has interpreted FIFRA, even a very small risk may warrant cancellation of a

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impacts; very low toxicity to fish; less toxicity/risk to fish than alternatives; potential toxicity/risk to fish mitigatable/similar toxicity to fish as alternatives, but significantly less exposure; low potential for groundwater contamination; lower use rates than alternatives, fewer applications; low pest resistance potential (i.e., new mode of action); highly compatible with IPM; efficacy. PR 97-3 at 3-4.

<sup>362</sup> It is not clear why EPA has focused its attention on human health risks, and has given short shrift to ecological concerns.

While EPA certainly has the legal authority to regulate to address ecological concerns, its focus continues to be human health concerns. Nowhere is this more apparent than in the area of pesticide regulation. Professor Holly Doremus has raised the issue of whether EPA's emphasis on human health concerns, as opposed to ecological concerns, stems from the institutional setting of EPA's pesticide program. Holly Doremus, Personal Correspondence, July 27, 2005. Although a full evaluation of this issue is beyond the scope of this article, the history of the EPA pesticide program may be a factor in creating such a bias. Prior to the creation of the EPA, pesticides, to the extent they were regulated, were under the jurisdiction of the U.S. Department of Agriculture. When EPA was formed, many of the USDA employees working on pesticide issues moved over to the EPA pesticide office. Perhaps this created a culture focused on promoting agriculture even at the expense of ecological harm. Another explanation for this institutional bias may simply be that, from a political standpoint, it is easier to justify imposing costs on industry or farms to protect human health than it is to protect ecological resources

<sup>363</sup> See generally, Pimentel, *supra* note 219.

<sup>364</sup> *Id.* at 72.

<sup>365</sup> *Id.*

pesticide, provided that the benefits are very low.<sup>366</sup> Conversely, presumably, even a very high risk may not trigger cancellation if the economic benefits to be achieved are very high. By this logic, if a pesticide poses a great economic benefit, high risks to vulnerable species or ecosystems will be tolerated.

Another area in which EPA's current approach to regulating pesticides is lacking is with regard to threatened and endangered species. The Center for Biological Diversity recently released a report that found that EPA has approved registrations for pesticides that put more than 375 Endangered Species Act (ESA) listed species at risk.<sup>367</sup> In the past several years, EPA has come under considerable attack for its failure to adequately address risks to certain species listed under the ESA<sup>368</sup> from pesticide uses. Since the 1989 *Defenders of Wildlife* case, in which EPA was found liable for a take under the ESA for allowing the continued registration of pesticides containing strychnine, which harmed certain listed species, it has been clear that EPA not only has an obligation to comply with the consultation requirements under the ESA when making decisions regarding pesticide registration, but the agency also has an obligation to ensure that the permitted use of a registered pesticide will not result in an unauthorized take of a listed species.

Nevertheless, in the years since the *Defenders of Wildlife* decision, EPA's actions with regard to the protection of listed species from pesticides have been limited and have failed to carry out the mandates of the ESA. EPA's policy regarding pesticides and endangered species has consisted of requiring certain pesticide products labels to direct users to County Bulletins, which identify on a map the range of listed species in that County. In the past several years, EPA has come under increasing criticism for its failure to fulfill its obligations under the ESA.<sup>369</sup> In

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<sup>366</sup> In the Matter of Protexall Products, Inc., et al., FIFRA Docket Nos. 625, et al (1989) (upholding cancellation of sodium arsenate ant baits which posed a small risk of minor illness to children because the benefits of the pesticide were minimal).

<sup>367</sup> Brian Litmans & Jeff Miller, *Silent Spring Revisited: Pesticide Use and Endangered Species* (A Center for Biological Diversity Report, 2004), available at <http://www.biologicaldiversity.org/swcbd/Programs/science/pesticides/> (Last visited, August 4, 2005).

<sup>368</sup> 15 U.S.C. §§ 1531-1599 (2004).

<sup>369</sup> While a detailed discussion of the issues related to the relationship between pesticide laws and the Endangered Species Act is beyond the scope of this article, those issues are the subject of a forthcoming article by the author. For a further discussion of these and related issues, see Patti A. Goldman, *Protecting Endangered Species From Pesticides: Making the ESA Work or Finding Loopholes*, SJ023 ALI-ABA 31 (2003); Pierre Mineau, *Birds and Pesticides: Are Pesticide Regulatory Decisions Consistent With the Protection Afforded Migratory Bird Species Under the Migratory Bird Treaty Act?*, 28 WM & MARY ENVTL. L. & POL'Y REV. 313 (2004). See also, Marcilynn A. Burke, *Klamath Farmers and Cappuccino Cowboys: The Rhetoric of the Endangered Species Act and Why it (Still) Matters*, 14 DUKE ENVTL. L. & POL'Y F. 441, 487-491 (2004) (discussing a number of regulatory attempts to weaken the consultation process including with regard to pesticide registration).



particular in September of 2004, environmentalists won a significant victory when the Ninth Circuit Court of Appeals issued a decision affirming a January 2004 U.S. District Court for the Western District of Washington order which found that EPA had violated the ESA, because it had failed to take steps to ensure that the registration of 54 pesticide would not jeopardize the survival of listed salmon species. The Court's ruling upheld the District Court's injunction, which imposed detailed buffer zones restricting the use of more than 30 pesticides along listed salmon supporting waters in California, Oregon, and Washington states.<sup>370</sup>

EPA's response to the criticisms regarding its failure to fully comply with the ESA, as well as its recent court loses, has been to amend the joint regulations for consultation under section 7 of the ESA.<sup>371</sup> On August 5, 2004, EPA published in the Federal Register Final Rules that in essence allow EPA to avoid consultation with the federal wildlife agencies regarding whether new pesticides could cause harm to species listed under the ESA. Under the new rules, EPA will conduct its own reviews, which will simplify the process.<sup>372</sup> The agencies' purported rationale for the new rules is to provide a more efficient approach to make decisions on whether new pesticides will "adversely affect" a listed species.<sup>373</sup> However, environmental groups fear that the new rules will undercut the ESA and put listed species at greater risk. Consequently, a number of environmental organizations have filed suit alleging that the new rules violate the ESA.<sup>374</sup>

Concerns with rare or sensitive species or ecosystems can be addressed by an open-ended balancing approach, where the agency is directed to consider costs, but not in a strict cost/benefit monetized balancing. Under such an approach, although costs would be taken into consideration, the agency could be directed to afford greater weight in its balancing to other specified factors

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<sup>370</sup> See Wash. Toxics Coalition, et al. v. EPA, et al., Case No. C01-013132C, Order issued January 22, 2004. This Order was the third in a series of orders granting injunctive relief to the environmental plaintiffs in this matter. See Wash. Toxics Coalition, et al. v. EPA, et al., Case No. C01-013132C, Orders issued July 16, 2003 and August 8, 2003. All of these Orders are available on EPA's website at <http://www.epa.gov/espp/wtc/index.html> (Last visited January 7, 2005).

<sup>371</sup> EPA adopted the new regulation as a joint regulation along with the two ESA consulting agencies, the U.S. Fish and Wildlife Service and National Marine Fisheries Service, and the U.S. Department of Agriculture. Joint Counterpart Endangered Species Act Section 7 Consultation Regulations, 69 Fed. Reg. 47,732 (Aug. 5, 2004) (to be codified at 50 C.F.R. pt. 402).

<sup>372</sup> According to EPA officials, the consultation process was not working. EPA frequently ignored the consultation requirements because it the "complexity of considering thousands of chemical's potential effects on 1,200 ESA-listed species." See [Http://www.eenes.net/Greenwire/searcharchive](http://www.eenes.net/Greenwire/searcharchive) (last visited December 1, 2004).

<sup>373</sup> See *id.* FWS and NMFS have completely only approximately 12 consultations on pesticides in the past 10 years. Since 2002, EPA has sent the wildlife agencies approximately 30 pesticide consultations, but very few have been completed. *Id.*

<sup>374</sup> On September 23, 2004, a coalition of eight environmental groups filed suit challenging the Joint Counterpart Endangered Species Act Regulation. *Id.*

such Environmental Justice concerns, risks to threatened or endangered species, risks to rare species, or risks to vulnerable ecosystems. It should be noted, however, that under this proposal, the analysis would not end with the open-ended balancing. A second step, described more fully below, would require the consideration of local factors, such as the presence of threatened or endangered species, which could be effected by the use of the pesticide in that location.<sup>375</sup>

FIFRA's cost/benefit approach also raises concerns with regard to the pesticidal GMOs.<sup>376</sup> EPA's cost/benefit approach raises particular concerns with regard to pesticidal GMOs that are exported, or that naturally spread, to other parts of the world. For example, one risk concern with plant-incorporated protectants is whether a favorable ecological niche exists for the modified plant in its new environment that will enable the plant to thrive, and perhaps become a pest or disrupt the balance of ecosystems. EPA may evaluate a particular pesticidal GMO under FIFRA and may

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<sup>375</sup> Although the possibility of harm to threatened or endangered species should be considered and afforded weight in the open-ended balancing analysis, it would be noted that under the ESA, jeopardy to listed species can not be "balanced" away by cost considerations. Accordingly, in the second-step localized decision-making process, specific risk to listed species from the application of the particular pesticide in that particular locale must be evaluated under the ESA. Pesticide applications that do not comply with the ESA would be prohibited.

<sup>376</sup> The world-wide concern over the safety of biotechnology products is evidenced by the significant role that biotechnology played in the negotiations of the United Nations Convention on Biological Diversity. The agreement that was eventually reached contained a number of provisions that were relevant to biotechnology. Two provisions in particular, Article 8 (In-situ Conservation) and Article 19 (Handling of Biotechnology and Distribution of its Benefits) were directed at addressing international concerns with biotechnology products. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (2000). Article 8 of the Convention requires that Contracting Parties establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from of biotechnology that could affect the conservation and sustainable use of biological diversity. Neither FIFRA's export provisions nor EPA's plant-incorporated protectant rule address the broader concern of risk to biological diversity internationally. It is conceivable that a pesticide, particularly a plant-incorporated protectant, that does not pose an unreasonable risk in the U.S. could pose an unreasonable risk in another country. As discussed above, many of the risk issues associated with plant-incorporated protectants relate to their ability to outcross to wild relatives. This is a very different situation than that of conventional pesticides. For conventional chemical pesticides, the risks posed by the substance will tend to be the similar regardless of the country or part of the world. For example, if a pesticide is highly toxic to humans or other mammals in the United States, it will also be highly toxic to humans or mammals in other countries. The risks associated with plant-incorporated protectants, on the other hand, may vary more with location depending on a number of factors such as the presence of wild relatives. It would be extremely difficult, if not impossible, for EPA to evaluate all risks of a plant-incorporated protectant in every country in the world. Moreover, to conduct the unreasonable adverse effects analysis required by FIFRA, EPA also must look at the societal benefits associated with the pesticide. It would seem infeasible for EPA to conduct such an analysis for every importing country. EPA is not in a position to evaluate, and place value on, the economic and societal benefits that an importing country derives from a particular pesticide or chemical substance. Another impediment to EPA addressing risks of plant-incorporated protectants in countries other than the United States is that FIFRA provides EPA with very limited authority to regulate exported pesticides. The export of pesticides is regulated under section 17 of FIFRA. See 7 U.S.C. § 136o (2004). The primary emphasis of this section is on the provision of information by EPA to foreign governments. *Id.* Section 17 mandates two systems of notification: a notice to the government of an importing country of the export of unregistered pesticides, *id.* § 136o(a)(2), and a notice to all countries of cancellation or suspension actions taken by EPA, *id.* § 17o(b). Beyond these notification provisions, FIFRA does not

find that it will not pose an unreasonable environmental risk in the U.S. because a suitable niche does not exist for the modified plant in the U.S. that would allow the creation of a pest. To determine whether the pesticidal GMO poses an unreasonable risk in another country, however, the exporting company (or EPA) would be required to identify the types of ecosystems that exist in that country and the likelihood that the modified plant would thrive or spread in that environment. To do this, the exporting company (or EPA) would have to address a wide array of issues to determine whether the pesticide produced by the plant gives it a selective advantage in the new environment. Such a determination would depend on a number of considerations such as whether the modified plant has wild relatives in the new environment, how the modified plant is affected by factors such as climate, what selective pressures (e.g., viruses or other pathogens that normally keep the plant population in check) exist in the new environment, and how the modified plant interacts with the types of species present in the various ecosystems of the importing country. It appears to be unreasonable to require such a site-specific risk assessment for every country that imports U.S. pesticides. Nevertheless, international concerns could be averted if the United States were to participate in international efforts to provide advanced informed consent prior to exporting GMOs to other countries. Such a process is contemplated by the Rio Convention on Biodiversity, as well as the Cartagena Biosafety Protocol, to neither of which the United States is a party.<sup>377</sup>

#### *B. An Ecological Integrity Baseline*

As described above, one of the cornerstones of eco-pragmatism is an environmental baseline. By incorporating ecological principles into eco-pragmatism, the notion of ecological integrity as the environmental baseline emerges. With such a baseline, any action taken under FIFRA can be measured against the reference point of the baseline. As with any baseline, however, such comparisons cannot be made without good data and ongoing monitoring. To ensure that pesticide usage does not undermine ecological integrity, a number of revisions to the FIFRA program are necessary.

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provide EPA with the authority to regulate exports.

<sup>377</sup> Article 19(3) of the United Nations Convention on Biodiversity provides: “The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organisms resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.” The Cartagena Protocol on Biosafety implements this directive by including a provision which requires advanced informed agreement by the Importing Party prior to the first international transboundary movement of living modified organisms for intentional introduction into the environment. Article 7(1) of the Cartagena Protocol on Biosafety.

Perhaps most importantly in this regard, EPA's data requirements must be revised to require data better designed to evaluate risks to wildlife species, and in particular ESA listed species, as well as ecosystem services such as pollination, decomposition, nitrogen fixation, and other ecological services provided by organisms that may be affected by pesticides. Currently, EPA's data requirements for pesticide registration only address a limited number of these concerns.<sup>378</sup> EPA's data requirements for testing for ecological effects are limited and many such data requirements have not yet been developed. In addition to substantial data requirements related to product chemistry,<sup>379</sup> much of EPA's requirements regarding data necessary to support the registration of a pesticide are focused on human health effects. For example, EPA has extensive data requirements related to residue chemistry to estimate human exposure to pesticides, acute human hazard, subchronic human hazard, chronic human hazard, mutagenicity, metabolism studies, reentry hazard, spray drift evaluation, as well as oncogenicity, teratogenicity, neurotoxicity, and reproductive effects in humans.<sup>380</sup>

EPA's environmental fate data are designed to "assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources, and assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides."<sup>381</sup> Environmental fate studies include studies to determine the rate of pesticide degradation,<sup>382</sup> metabolism studies to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide,<sup>383</sup> mobility studies pertaining to leaching, adsorption/desorption and

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<sup>378</sup> The minimum data requirements for registration, experimental use permits, and reregistration are set forth in 40 C.F.R. § 158 (2005). More detailed standards for conducting tests, guidance on evaluation and reporting of data and additional guidance is provided in a series of advisory documents that EPA makes available to applicants and the public. *See id.* § 158.20(c). In its data requirement rules, EPA identifies some data as required and other data as "conditionally required." Conditionally required data are required only if the product's proposed pattern of use, results of other tests, or other factors meet the criteria specified in the rules. *See id.* §§ 158.25(a) and 158.101. EPA's rules also allow certain data requirements to be waived if that are not applicable to the particular pesticide or use. *See id.* § 158.25(b) (setting forth policy on flexibility and waiver); 40 CFR 158.35 (describing the flexibility in data requirements) and § 158.45 (regarding waiver of data requirements). In addition, EPA's rules set forth varying data requirements for minor use of a pesticide (i.e., used on a minor crop) and biochemical and microbial pesticides. *See id.* §§ 158.60 and 158.65, respectively.

<sup>379</sup> *See id.* §§ 158.150, 158.153, 158.155, 158.160, 158.162, 158.165, 158.167, 158.170, 158.175, 158.180, and 158.190.

<sup>380</sup> *See id.* paragraphs 158.202(a), (c), (e), (f), and (g) and *id.* §§ 158.240, 158.390, 158.440 and 158.340. *See also, id.* § 158.34 (providing that certain human health effects data d=submitted to EPA must be flagged as indicating potential adverse effects).

<sup>381</sup> *Id.* § 158.202(d)(1).

<sup>382</sup> *Id.* § 158.202(d)(2).

<sup>383</sup> *Id.* § 158.202(d)(3).

volatility of pesticides,<sup>384</sup> dissipation studies<sup>385</sup> and accumulation studies.<sup>386</sup> Perhaps because environmental fate data are used to evaluate human exposure to pesticides, as well as wildlife exposure, these data requirements appear to be fairly comprehensive. However, EPA's data requirements regarding effects on wildlife and nontarget organisms are considerably less comprehensive.

With regard to ecological effects, EPA has, by rule, developed limited data requirements designed to evaluate wildlife and aquatic organisms, environmental fate, and nontarget insects. EPA's data requirements for effects on wildlife and aquatic organisms, include avian toxicity studies<sup>387</sup> and freshwater fish and invertebrate acute toxicity studies<sup>388</sup> for most pesticides intended for outdoor use. Wild mammal toxicity, avian reproduction, simulated and actual field testing of mammals and birds, acute toxicity to estuarine and marine organisms, fish early life stage, aquatic invertebrate life cycle, fish life cycle and aquatic organisms accumulation and simulated or actual field testing of aquatic organisms are only conditionally required<sup>389</sup> for most outdoor uses. As can be seen by EPA's primary focus on acute toxicity testing, EPA does not generally require data related to potential adverse effects of pesticides on wildlife behavior, neurology, reproduction, birth defects, or other non-acute effects. Moreover, EPA's data requirements do not contain any studies aimed at evaluating effects on other species, such as amphibians or reptiles or other species not specifically identified in the rules. Accordingly, EPA's wildlife data requirements should be revisited to determine what additional data requirements should be included to more fully address the wide range of potential effects on fish and wildlife that may result from exposure to pesticides.

Likewise, EPA's data requirements for nontarget insects are limited. EPA does conditionally require acute toxicity testing for honey bees and other pollinators, if the proposed use will result in honey bee or other pollinator exposure, however, EPA does not have any data

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<sup>384</sup> *Id.* § 158.202(d)(4).

<sup>385</sup> *Id.* § 158.202(d)(5).

<sup>386</sup> *Id.* § 158.202(d)(6). *See also id.* § 158.290.

<sup>387</sup> Avian oral LD50 and dietary LC50s are required using the preferred test animal species, the mallard and the bobwhite. *Id.* § 158.490.

<sup>388</sup> Freshwater fish LC50 studies are required, with the preferred test species being the rainbow and bluegill fish and acute LC50 studies are required on freshwater invertebrates, with the preferred test species being *Daphnia*. *Id.* § 158.490.

<sup>389</sup> *Id.* § 158.490. Conditionally required studies are required only on a case-by-case basis depending on the results of lower tier studies, such as acute and subacute testing, intended use pattern and environmental fate characteristic or if certain specified criteria are met.

requirements related to honeybee subacute feeding studies,<sup>390</sup> nontarget aquatic insects, or nontarget predatory or parasitic insects.<sup>391</sup> Moreover, EPA does not have any data requirements whatsoever related to soil microorganisms, which provide critical ecological services, such as decomposition and nitrogen fixation, or any data requirements designed to evaluate the effects of pesticides on any other ecological services.

Although EPA's data requirements do include some studies designed to evaluate risks to fish, wildlife, aquatic organisms and nontarget insects, EPA's primary purpose in requiring such studies is not to determine *whether* to register a pesticide product, but instead is to "provide data which determines the need for (and appropriate wording for) precautionary label statements to minimize the potential adverse effects to nontarget organisms."<sup>392</sup> However, label requirements do not always provide sufficient protection against the environmental harms resulting from pesticides use.

Despite all of the testing and labeling that EPA imposes, large numbers of birds, insects, amphibians, and aquatic species, including threatened and endangered species, continue to be harmed by EPA-registered pesticides.<sup>393</sup> While many label requirements that EPA imposes are aimed at protecting human users of pesticides,<sup>394</sup> as well as other humans such as children<sup>395</sup> from accidental poisonings, EPA does require certain environmental hazard information to appear on pesticide labels. For example, if a pesticide intended for outdoor use contains an active ingredient with a specified level of acute mammalian or avian toxicity, the label must bear a precautionary statement, such as "This pesticide is toxic to wildlife."<sup>396</sup> If either accident history or field studies

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<sup>390</sup> In its data requirements rule, EPA identifies this type of requirement as "reserved pending development of test methodology." 40 C.F.R. § 158.590 (2005).

<sup>391</sup> In its data requirements rule, EPA identifies these types of requirements as "reserved pending further evaluation to determine what and when data should be required, and to develop appropriate test methods." *Id.* § 158.590.

<sup>392</sup> *Id.* § 158.202(h)(1).

<sup>393</sup> See Brian Litmans & Jeff Miller, *Silent Spring Revisited: Pesticide Use and Endangered Species* (A Center for Biological Diversity Report, 2004), available at <http://www.biologicaldiversity.org/swcbd/Programs/science/pesticides/> (Last visited, August 4, 2005).

<sup>394</sup> See *id.* §§ 156.10 (general labeling requirements); 156.60 (human hazard and precautionary statements); 156.62 (human hazard toxicity categories); 156.64 (signal words for human hazard toxicity categories); 156.68 (first aid statement); 156.70 (precautionary statements for human hazards); 156.78 (precautionary statements of physical or chemical hazards); and §§ 156.200 -156.212 (worker protection statements).

<sup>395</sup> See *id.* § 156.66 (child hazard warning).

<sup>396</sup> The specified level of acute toxicity for mammals warranting such a statement is an oral LD50 of 100mg/kg or less. The specified level of acute toxicity for fish warranting such a statement is an LC50 of 1ppm or less. The specified level of acute toxicity for birds warranting such as statements an oral LD50 of 100 mg/kg or less or a subacute dietary LC50 of 500

demonstrate that the use of the pesticide may result in fatality to birds, fish or mammals, the pesticide label must bear the precautionary statement, such as “This pesticide is extremely toxic to wildlife (fish).”<sup>397</sup> Similarly, if a product intended for certain uses contains an active ingredient that is toxic to pollinating insects, the label must bear an appropriate label caution.<sup>398</sup> Finally, if a product is intended for outdoor use other than aquatic applications, the label must bear the precautionary statement “Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.”<sup>399</sup>

Although EPA does require these precautionary statements on labels, it is unclear what effect they have in practice. For example, if a farmer intends to apply a particular pesticide to combat a particular pest of her crops and the pesticide label indicates it is toxic to wildlife, how will this information influence the farmers' behavior? It is unlikely that the farmer will choose not to apply the pesticide, because virtually all of the major chemical pesticides use in agriculture today are acutely toxic to at least some nontarget organisms. It is difficult to imagine that a statement on a label indicating that a product is toxic to wildlife will have any significant influence on user behavior. Without more specific directions about when, where or how it is appropriate to apply the pesticide to minimize risks to wildlife, the farmer is left with an essentially useless warning. The lack of more useful directions to minimize risk is likely due to the fact that because most chemical pesticides are acutely toxic to at least some wildlife, it is impossible to release them into the environment in large amounts, without creating the possibility for harm to wildlife.

### *C. Addressing Uncertainty and Change*

As described above, eco-pragmatism argues in favor of feasibility approaches rather than cost/benefit approaches. While this article proposes a modified cost/benefit analysis (open-ended balancing) for the registration of a pesticide under FIFRA, it also proposes that a feasibility analysis be conducted for significant pesticide “use.” Currently, there is no federal system in place, and only very limited state or local systems in place, that regulate the “uses” of pesticides registered under FIFRA other than the label instructions on each registered pesticide. These label instructions generally are the same nationwide. Thus, there is not currently a widespread system

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ppm or less. *Id.* § 156.85(b) paragraphs (1), (2) and (3), respectively.

<sup>397</sup> *Id.* § 156.85(b)(4).

<sup>398</sup> *Id.* § 156.85(b)(5).

<sup>399</sup> *Id.* § 156.85(b)(6).

for considering local factors to determine what pest control method should be used in what location under what circumstances.

As described above, for an environmental regulatory system to be eco-pragmatic, it must be flexible and able to adapt to new information and changed circumstances. Transferring some decision-making authority to a local level is one way to accomplish this goal. The consideration of local factors in making the determination of whether or how to use a specific pesticide in a specific location is of particular import. The benefit of local control over pesticide use is that decision can be made based on local factors. Such factors could include presence of threatened, endangered or otherwise rare species, presence of sensitive species, soil conditions, climatic conditions, proximity to environmentally sensitive lands, types of crops grown, types of farming practices used, severity of pest infestations, or other relevant site-specific factors.<sup>400</sup>

There are a variety of potential mechanisms available for achieving local decision-making regarding actual pesticide use. One such mechanism is to encourage local government regulation of pesticide use. Another mechanism is to provide better training to certified applicators in IPM and non-chemical controls, and better information regarding endangered species, ecological processes, the role of predators and parasites, and other local environmental conditions. Similarly, better training could be provided to local agricultural extension agents. A variation on this theme would be to empower local officials – whether they be local government officials or extension agent officials to make case-by-case, or season-by season decisions on the actual use of pesticides.

For example, a local official could be required to evaluate the local conditions, including the particular pest concerns, the climatic conditions and a wide variety of local environmental factors, before “prescribing” that a particular pesticide be used. This idea is similar to that of a medical doctor prescribing that a patient take a particular medication. Prior to issuing such a prescription, the doctor would consider a number of factors such as the patient’s overall health, other medical conditions, other medications the patient is taking, any allergies or sensitivities the patient may have to certain types of medications, the patients age, the patient’s health and lifestyle objectives and the patient’s willingness to accept certain risks to achieve such goals. Moreover, the doctor could adjust the type or amount of medication over time to fine-tune the treatment in

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<sup>400</sup> Because ecological impacts are necessarily contextual and local, whereas, human health impacts are not, EPA’s failure to adequately address local ecological effects of pesticides may be further evidence of an institutional bias away from



accordance with changing circumstances or new information. A prescription-type approach to pesticide application could similarly be adjusted over time to take into consideration changed local conditions, or new information about local environmental factors. Of course, the physician-prescribe pharmaceutical system is not without its shortcomings. High pressure sales tactics by representatives of the pharmaceutical industry, glossy advertisements on television and in magazines promising a wonderful life can be achieved merely by popping a pill, the public's desire for an "easy fix" in the form of a pill, and industry-sponsored research all may contribute to the trend over physicians over prescribing medications. It is likely that even with a pesticide prescription system in place, pesticide manufacturers will be able to convince decision-makers to prescribe their pesticides. Nevertheless, such a system, if properly instituted, could result in at least some level of informed decision-making prior to the release of large amounts of pesticides into the environment.

The likely criticisms of such a system would be that to institute such a system could entail high costs and possibly the creation of a new bureaucracy. However, the possibility exists of relying on existing infrastructure to facilitate such a system without the need for a completely new institution or significant additional personnel. The existing agricultural extension services could potentially be used to administer such a system. Alternatively, existing state requirements for certified applicator training and certification could be expanded to better educate applicators on local environmental factors that should be taken into account and on non-chemical alternative pest control mechanisms that in many cases may be preferable to chemical approaches. additional and expense. Such and approach might also be able to rely on existing extension infrastructure and resources.

Although FIFRA provides a regulatory system that applies to any pesticide sold or distributed in the United States, FIFRA does not generally preempt state or local government regulation of pesticide use. In 1991, the right of a local government to regulate pesticide use was clearly established by the U.S. Supreme Court in the case of *Wisconsin Public Intervenor v. Mortier*.<sup>401</sup> In that case a Wisconsin local government had adopted an ordinance, which required a permit from the local government prior to certain types of pesticide use. Prior to the *Mortier*

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ecological protection. See *infra* note 362 & accompanying text.

<sup>401</sup> 501 U.S. 597 (1991).

decision, only a small number of states had in place laws that preempted local governments from regulating pesticide use. After *Mortier*, all but 11 states have laws preempting local regulation of pesticides.<sup>402</sup>

Justice White, writing for the majority in the *Mortier* decision, recognized the benefit of local decision-making for the actual use of pesticides when he wrote: “FIFRA nowhere seeks to establish an affirmative permit scheme for the actual use of pesticides. It certainly does not equate registration and labeling requirements with a general approval to apply pesticides throughout the Nation without regard to regional and local factors like climate, population, geography, and water supply.”<sup>403</sup> And yet, this is in practice what FIFRA does. Once a pesticide receives a FIFRA registration, unless a particular state actively seeks to further regulate such a pesticide, it can be used anywhere in the United States with the only limitation being that it must be used in accordance with the FIFRA label instructions. As is described more fully below, most states do not have detailed environmental permitting requirements for pesticide use.<sup>404</sup> Although EPA attempts to impose risk reducing measures on users through detailed labeling requirements, a set of instructions on a container that have been drafted to apply to the entire United States is a poor substitute for a site-specific, circumstance-specific decision on what pesticide to use where, when and how.

The issue of localized decision-making regarding pesticide use has arisen in another context in recent years. Beginning with the case of *Headwaters, Inc., v. Talent Irrigation District*<sup>405</sup> in 2002, the courts, as well as EPA have been grappling with the issue of whether and under what circumstances a National Pollutant Discharge Elimination Systems (NPDES) permit is required under the Clean Water Act for the application of pesticides into waters of the United States.<sup>406</sup> Historically, EPA had not required NPDES permits for such pesticide applications.

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<sup>402</sup> Haight, *supra* note 202, at 39. The U.S. Supreme Court recently addressed FIFRA preemption again in *Bates v. Dow Agrosciences, LLC.*, 125 S. Ct. 1788 (2005) (holding that FIFRA does not preempt claims for defective design, defective manufacture, negligent testing, breach of express warranty, and violation of Texas Deceptive Trade Practices Act, and remanding the issue of whether FIFRA preempts fraud and failure-to-warn claims).

<sup>403</sup> 501 U.S. 597 (1991).

<sup>404</sup> See *infra* notes 412-414 & accompanying text.

<sup>405</sup> 243 F.3d 526 (9<sup>th</sup> Cir. 2001)(holding that the application of an aquatic pesticide to irrigation canals in compliance with the registration and labeling requirements under FIFRA, did not eliminate the need for an NPDES permit).

<sup>406</sup> For a detailed discussion of the judicial decisions and EPA’s position on the issue of requiring NPDES permits for aquatic pesticide application, see Kelly C. Connelly (case note), *Pesticides and Permits: Clean Water Act v. Federal Insecticide, Fungicide and Rodenticide Act*, 8 GREAT PLAINS NAT. RESOURCES J. 35 (2003) and Paul Herran, (case note),

Thus, although EPA, at least arguably, has the legal authority to require permits for applications of pesticides to waters, which would take into consideration localized environmental factors, EPA has chosen not to do so. Even after the *Headwaters* decision, EPA has steadfastly refused to require NPDES permits for the application of pesticides directly to waters of the U.S. for the purpose of controlling pests in or over such waters.<sup>407</sup>

In addition, as described above, nationwide decision-making regarding pesticides can lead to disproportionate risks being placed on vulnerable populations of people, as well as on vulnerable species or ecosystems. While an overall cost/benefit analysis for a particular pesticide may weigh in favor of use of the pesticide, geographic or ecological “hot spots” may occur where the risks outweigh the benefits on those localized geographic areas or for those particular species. Without some way to bring localized concerns into the decision-making process, risks will continue to fall disproportionately on the most vulnerable human and ecological resources. Although over one half of all registered agricultural pesticides are restricted use pesticides,<sup>408</sup> which must be applied only under the supervision of a certified applicator, the certified applicator requirement does not provide the level of oversight, consideration of local ecological factors and consideration of lower risk alternatives that would be needed to adequately address ecological risks. First, certified applicators do not necessarily directly oversee the application of pesticides, but instead typically serve as “arm chair” supervisors.<sup>409</sup> Second, certified applicators are not required to receive any particular training in local ecological systems and their vulnerability to particular pesticides.<sup>410</sup> Finally, although FIFRA section 11 requires EPA and states to make available to certified applicators at their request instructional materials concerning Integrated Pest Management (IPM), the statute expressly states certified applicators are not required to receive instruction on IPM and are not required to be shown to be competent with respect to such techniques.<sup>411</sup> Thus, certified

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*Headwaters, Inc. V. Talent Irrigation District: Application of Aquatic Pesticides to Irrigation Canals, a Discharge, Which Requires a Clean Water Act Permit?*, 25 HAW. L. REV. 629 (2003).

<sup>407</sup> See 68 Fed. Reg. 48,385 (August 13, 2003).

<sup>408</sup> RODGERS, *supra* note 190, at 458.

<sup>409</sup> See *infra* note 414 & accompanying text.

<sup>410</sup> For a description of certified applicator training programs, see RODGERS, *supra* note 190, at 462-63.

<sup>411</sup> 7 U.S.C. § 136i(c) (2004), regarding instruction in integrated pest management, provides:

Standards prescribed by the Administrator for the certification of applicators of pesticides under subsection (a) of this section, and state plans submitted to the Administrator under subsection (a) of this section, shall include provisions for making instructional materials concerning integrated pest management techniques available to individuals at their request in accordance with the provisions of section 136u(c) of this title, but such plans may not require that any individual receive

applicators are not required to know about less risky pest control techniques, let alone to consider them in making decisions regarding which options to choose to control a particular pest. In fact, a certified applicator's job is not to decide what approach to take to control a pest, but is merely to ensure that once a particular pesticide is chosen, it is applied properly in accordance with label instructions.

Unfortunately, despite compelling reasons for considering local conditions in determining what pesticides to use in what locations and under what conditions, and the fact that FIFRA allows state and local governments to regulate pesticide use, state regulation of pesticides tends to be minimal. Most states do not have regulatory systems in place that are much more environmentally protective than FIFRA's basic nationwide protections. Most states do not have any significant regulations addressing the use of pesticides under localized conditions. For example, most states do not require site-specific permits to be obtained before a pesticide can be applied, even for large scale agricultural pesticide application into the environment.<sup>412</sup> Likewise, most states do not require anyone with specialized knowledge of the presence of threatened or endangered species or rare or sensitive ecosystems to make any evaluation prior to the release of pesticides into the environment. What state pesticide regulatory programs generally do is treat farmers as "private applicators," who are required to obtain a state certification that demonstrates that they have attained a level of practical knowledge of pesticide use and hazards, before such farmer is allowed to apply pesticides. Some states have more stringent requirements for chemigation, fertigation and aerial application,<sup>413</sup> but generally, once a farmer has obtained the required training and

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instruction concerning such techniques or to be shown to be competent with respect to the use of such techniques. The Administrator and States implementing such plans shall provide that all interested individuals are notified on the availability of such instructional materials.

<sup>412</sup> Some states do have limited permitting requirements for pesticide use, however these requirements generally apply only to aerial application of pesticides and generally a permit is not issued for each application. For example, in Hawaii, a permit is required prior to aerial application of pesticides. *See* HAW. ADMIN. RULES § 4-66-64 (2004). However, the permit can be issued for repeated uses or for a specified length of time. *Id.* at § 4-66-64 (a)(4). Consequently, changing local environmental conditions are not likely to be adequately addressed for each application. In Massachusetts, a permit is required for the aerial application of pesticides, however, the permit is for a one-year duration and is not specific to the date or time of application. *See* MASS. REGS. CODE tit. 333, § 13.05(3)(b) (2004). Nevertheless, a site inspection is required prior to permit issuance, which presumably means that local conditions are assessed prior to issuing the permit. *Id.* In addition, in Massachusetts, a special permit is required for application of restricted use pesticides to an area greater than twenty-five acres. *See id.* § 13.03(18). Similarly, in Vermont, one-year duration permits are required for aerial application of pesticides. *See* VT. CODE R. 20 031 012 § IV (5) (2003).

<sup>413</sup> *See, e.g.,* FLA. ADMIN. CODE ANN. r. 5E-9.019(2)(a) (2005) (aerial applicators require a separate certification); HAW. ADMIN. RULES § 4-66-64(6) (2004) (mandating a notice requirement prior to any aerial application); IDAHO ADMIN. CODE 02.03.03.310, 02.03.03.320 (2004) (placing specific restrictions on aerial application geared primarily toward minimizing

certification, he is free to apply pesticides at will provided it is done in accordance with FIFRA or state label directions and restrictions. What's more, generally the certified private applicator can "supervise" the application of pesticides by non-certified persons. In most states, "direct supervision" means that the certified private applicator is within a telephone call away from his supervisees.<sup>414</sup> Some states do have specific pesticide regulations aimed at protecting groundwater or surface water bodies. However, even these states do not generally require any form of site-specific permitting evaluation prior to pesticide use. By establishing a prescription-type system to large-scale pesticide use, not only will local environmental factors receive due consideration, but the system would have the flexibility necessary to adapt to changing circumstances and new information.<sup>415</sup>

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spray drift); 302 KY. ADMIN. REGS. 27:050 § 2(8) (2003) (requiring separate certification for aerial applicators); LA. ADMIN. CODE tit. 7, Part XXII § 145 (A)(iii-vii) (2005) (detailing specific requirements regarding aerial application, including the requirement to adjust flight patterns to avoid sensitive areas and prohibitions on aerial application if wind velocity exceeds 10 mph or if it is raining or rain is imminent); MASS. REGS. CODE tit. 333, § 13.05(3)(b,c) (2004) (requiring a permit for aerial application, as well as prohibiting aerial application within 400 feet of a water body and requirements that aerial spraying cease if spray drift occurs); MICH. ADMIN. CODE r. 285.637.10 (2005) (detailing specific requirements regarding aerial spray drift, including a requirement for applicators to have a written spray draft plan in place and restrictions to protect sensitive areas including all water bodies); NEB. ADMIN. CODE tit. 25, chp. 2 005.03 (2002) (mandating separate certification requirements for application of restricted-use pesticides via chemigation); N.C. ADMIN. CODE tit. 2, r. 9L.1002, 9L.1003 (2004) (detailing spray drift control regulations and a prohibition on aerial application to restricted areas, including water bodies); VT. CODE R. 20 031 012 § IV (1)(b) (2003) (detailing rules regulating pesticide drift); WASH. ADMIN. CODE §§ 16-202-2001 - 16-202-2021 (2004) (detailing rules regulating fertigation); WIS. ADMIN. CODE § 29.50(2) (2003) (listing restrictions to prevent significant spray drift).

<sup>414</sup> See, e.g., FLA. STAT. ANN. § 487.021(64) (2004) ("under direct supervision" means that the licensed applicator is available "if and when needed"); IDAHO CODE § 22-3401(34) (2004) (stating that a supervisory certified applicator must be available as needed, even though the "certified applicator is not physically present at the time and place the pesticide is applied"); NEB. REV. STAT. § 2-2642(5)(c)(iv) (2002) ("direct supervision" defined as being available by voice or electronic means and the ability to be physically present if needed); VA. CODE ANN. § 3.1-249.27 (2004) ("under the direct supervision of" means the certified applicator is responsible for supervisees' actions); and WIS. STAT. § 94.67(10m) (2003-2004) (allowing private applicators to "direct the use of" restricted-use pesticides, provided they are available if and when needed during the application); MD REGS. CODE tit. 15.05.01.01(b)(23)(b) (2005) (stating that the supervisory certified applicator must be available is needed); N.J. ADMIN. CODE tit. 7, § 30-1.2(2005) (defining "available if and when needed" to mean that the direct supervisor is in constant voice contact and no more than 3 hours away via ground transportation); OR. ADMIN. R. 603-057-0001(10) (2004) ("immediate supervision" defined as no more than five minutes away). Nevertheless, a few states do have more stringent supervisory requirements for certified applicators. See e.g., IND. ADMIN. CODE tit. 355, r. 4-2-3 (2004) (stating that, if an applicator has never worked with a pesticide before or is not a "registered technician", the certified applicator must be both physically present and in direct voice contact during the application; for registered technicians, the certified applicator can be available through telephone or walkie-talkie); MASS. REGS. CODE tit. 333, § 10.07 (1996) (requiring that the supervision of non-certified applicators increase based upon the hazard of the given pesticide being used); N.Y. COMP. CODES R. & REGS. tit. 6, § 325.7 (2004) (defining "under the direct supervision" to mean that the certified applicator must be physically present and within voice contact); and VT. CODE R. 20 031 012 § I(7)(17) (2003) (certified applicators must be physically present and actively supervise non-certified applicators).

<sup>415</sup> A possible alternative to a registration approach, would be imposing a reporting requirement on farm. Such an approach would be similar to the Toxics Release Inventory under the Emergency Planning and Community Right-to-Know program. 42 U.S.C. §§ 11001-11050 (2004). J.B. Ruhl has suggested such an approach as a way to provide regulators and

As described above, one of the cornerstones of eco-pragmatism, as well as conservation biology, is adaptive management. Because of the complexity and changing nature of ecological systems, as well as our ever-increasing understanding of those systems, it is necessary that any system designed to address ecological risks, be flexible and able to adapt to changed circumstances and new information. Accordingly, a prescription approach, whereby a prescription for pesticide use is written based on a feasibility analysis for each large-scale application (or perhaps series of applications during a growing season), could serve as an adaptive management approach. Each time a localized decision must be made to determine what pesticide to prescribe, current local conditions can be evaluated to determine the pest control that would maximize ecological protection to the extent feasible.<sup>416</sup> Moreover, as new pesticides and non-chemical pest control techniques are developed, they can be considered when determining what to prescribe.<sup>417</sup>

## VIII. CONCLUSION

Despite its early successes in protection of ecological resources at the beginning of the environmental movement in the United States, FIFRA has virtually lain dormant with regard to protection of ecological resources for the past 25 years. Ironically, if any area of environmental law should be tailored specifically to address ecological concerns, it is with pesticide law, where substances that are intend to kill and disrupt species and natural systems are intentionally released

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local communities with information on pesticide releases. See J.B. Ruhl, *Farms, Their Environmental Harms, and Environmental Law*, 27 Ecology L.Q. 263, 337-338 (2000). Although such an approach would not directly require the consideration of local ecological factors prior to use of a pesticide, by providing bringing pesticide releases under the scrutiny of regulators and communities, such an approach could result in long-term changes to pesticide usage.

<sup>416</sup> For example, if in year two, an American Bald Eagle, or other listed species, builds a nest near the field to be sprayed, it may not be appropriate to prescribe the same pesticide that was used on the field in year one, if that pesticide is toxic to avian species. Likewise, if a listed species is no longer present near the field, it may be appropriate to go back to the more toxic pesticide. Similarly, if new information about the surrounding ecosystem is discovered, it could effect the decision of what pesticide to prescribe.

<sup>417</sup> Although a detailed analysis of discounting environmental benefits is beyond the scope of this article, as described in Part IV, above, many risks of pesticides are long-term risks. For example, the tendency of certain pesticides to bioaccumulate as they work their way up the food chain, poses risks that may not be realized for many years after the initial release of the pesticide into the environment. Similarly, the harms from certain pesticides that pose reproductive effects, such as the endocrine disruptors, may not be to the animals exposed, but may instead be to the offspring, or even subsequent generations of the animals exposed. Moreover, many of the potential harms to ecological systems and ecological services that pesticides pose, including disruptions of predator/prey relationships, harm to pollinators, harm to microorganisms that perform decomposition and nutrient cycling services, may not be evident in the short-term, but may have significant long-term impacts. Accordingly, any pesticide regulation that reduces these long-term harms, may not demonstrate have immediate benefits. Consequently, as Farber suggests, it is important to ensure that the long-term benefits of pesticide risk reduction measures are adequately valued through the use of low discount rates. The idea of intergenerational equity further supports this notion. To ensure that future generations inherit functioning ecosystems, including functioning agricultural systems, it is incumbent upon this generation to ensure that the long-term benefits of

in to the environment in large quantities. Moreover, pesticide law has failed to keep pace with recent advances in ecological study and the field of conservation biology. The eco-pragmatic framework proposed by Professor Daniel Farber, and elaborated upon by others may serve as useful approach to reinventing pesticide law to better address ecological concerns. To accomplish this, several steps are required. First, the prevailing interpretation of FIFRA's "unreasonable adverse effects standard" as mandating a strict cost/benefit balancing should be reevaluated and readjusted to be more of an open-ended balancing standard, as contemplated by the drafters of the standard. Related to this idea, EPA's approach to evaluating whether a particular pesticide poses an unreasonable adverse effect on the environment should be modified so that registrants are required to demonstrate the true benefits of a pesticide, by demonstrating efficacy and by evaluating the benefits of the pesticide in relation to the benefits provided by other pest control methods that are available, including lower risk chemical pesticides as well as non-chemical pest control methods. Moreover, a mechanism, such as the prescription approach, should be developed to allow for localized decision-making on which pesticide is best for a given situation taking into account local environmental factors to determine the maximum level of environmental protection that is feasible for any given situation. Second, to account for the uncertainties and long-term effects of pesticides on the environment, a low discount rate should be used in conducting the open-ended balancing analysis. Third, to ensure that pesticides released into the environment do not undermine a baseline of ecological integrity, the data requirements under FIFRA should be strengthened to require information about the potential effects on a wider variety of wildlife species, as well as ecological services such as pollination, decomposition, and nitrogen fixation. Finally, an adaptive management approach should be developed to allow for flexibility and adjustments to the choice of pest control method appropriate for a given situation. An adaptive management mechanism could be based on a medical prescription model, which would allow for fine-tuning and adjustment as circumstances change over time or as new information becomes available. The eco-pragmatic approach may provide the necessary framework for modifying U.S. pesticide law just enough so that we "do the best we can" to protect critical ecological resources.

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pesticide-risk reduction measures are properly valued though appropriate low discounting.