REGULATING EVOLUTION FOR SALE: AN EVOLUTIONARY BIOLOGY MODEL FOR REGULATING THE UNNATURAL SELECTION OF GENETICALLY MODIFIED ORGANISMS

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> Popular accounts of evolution are rife with references to 'progress,' from 'primitive' to more 'advanced' beings, as if describing the evolution of airplanes from the Wright brothers to the Concorde jet. The difference is that there is no Wright brothers in biological evolution.[2]

I. INTRODUCTION –THE WRIGHT BROTHERS APPEAR

In the past ten years there has been an explosion in the genetic manipulation of living organisms to create commercial products. This genetic manipulation has, in effect, been a directed change in the evolutionary process for the purpose of profit.[3] In essence, the commercialization of genetic engineering[4] has added the "Wright brothers" into the equation of natural selection and evolution, thus directing the path and pace of evolution. This deliberate alteration of the path of evolution has brought with it a panoply of novel environmental, human health and economic risks that could not have been foreseen when U.S. environmental and health protection laws evolved. What once took evolution centuries to accomplish can now be done in what seems an instant, prompting one commentator to refer to genetic engineering as "Darwin in hyperspeed."[5] Not only has genetic engineering dramatically accelerated evolution, but it also has accomplished things that probably never could have been accomplished through natural evolution, regardless of the passage of time. Through genetic engineering, DNA can be moved across all biological barriers even at the kingdom level (i.e., between microorganisms,

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[1] Assistant Professor of Law, University of Florida Levin College of Law. I would like to thank Alyson C. Flournoy and Michael A. Wolf for their helpful comments and encouragement, Brenda Appledorn and Kevin Shuler for excellent research assistance, and the University of Florida Summer Research Grant Program for financial assistance.

[2] Philip Johansson, *Crucible of Evolution,* 20 EARTHWATCH INSTIT. J. (2001)

[3] GM plant crops have been planted commercially in the U.S. since 1995. By 2002, more than 88 million acres of genetic engineering-derived crops were being planted annually in the U.S., 67 Fed. Reg. 50578 (August 2, 2002).

[4] Throughout this article, the term "genetic engineering" and "genetic modification" will be used interchangeably and will be used consistently with the USDA definition, which states: "Genetic engineering refers to the process in which one or more genes and other genetic elements from one or more organism(s) are inserted into the genetic material of a second organism using recombinant DNA techniques." *APHIS Biotechnology: Permitting Progress Into Tomorrow,* Biotechnology Fact Sheet, United States Department of Agriculture, Animal and Plant Health Inspection Service (February 2006), available at http://www.aphis.usda.gov/publications/biotechnology/index.shtml (last visited, June 5, 2006).

[5] Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation,* 20 Rev. Litig. 589, 590 (2001).

plants and animals). This dramatic biological barrier-jumping does not occur in nature or through conventional breeding practices.[6]

Many products of genetic engineering have been modified to possess traits that increase their ability to reproduce and survive in the environment. Such traits include insect resistance, viral infection resistance, drought tolerance and temperature tolerance in crop plants. By genetically manipulating microorganisms, plants, and animals to make them more "fit" from an evolutionary standpoint, science has altered the path of evolution to favor not those organisms that have evolved to be more fit for their natural environment, but instead those organisms that have become more fit at the hand of humans for commercialization and profit-making. U.S. environmental law has not evolved to keep pace with these dramatic changes in the evolution of our biological systems. Thus, completely new approaches are needed to address these novel issues. U.S. regulation of genetically modified organisms (GMOs)[7] has occurred in a reactionary, haphazard fashion and has been fraught with political controversy and bureaucratic inertia. Moreover, regulatory agencies have been artificially constrained by early U.S. policy on genetic engineering to rely on existing statutory authorities and to regulate based on the "products" of genetic engineering rather than the "process" by which they are created. Reliance on a mishmash of statutory authorities that predate the advent of genetic engineering and the ensuing interagency turf battles and differing approaches to regulating similar products among different agencies with different missions has resulted in profound regulatory gaps, overlaps, and inconsistencies. With more than 88 million acres of genetic engineering-derived crops being planted annually in the U.S., and more than 130 million acres world-wide,[8] and new and different GM crops continually being developed, the time has come for a serious reevaluation of the

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[6] John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering,* 74 S.Cal. L. Rev. 807, 812 (2001). Conventional plant or animal breeding techniques typically involve cross-fertilization or crossbreeding between varieties or breeds of the same species, and rarely, between species in the same genus. *Id*.

[7] The term genetically modified organism or GMO is commonly used to refer to organisms that are the product of genetic engineering. For a definition of "genetic engineering" *see supra* note 4. Throughout this article, "GM" will refer to "genetically modified."

[8] 67 Fed. Reg. 50578 (August 2, 2002). The Office of Science and Technology Policy states that while the increases in GM crops are most dramatic in the U.S., other nations, such as Canada, Argentina and China, are also experiencing significant growth in the development and use of GM crops. *Id.* In 2004, 40 percent of the corn, 81 percent of the soybeans, and 73 percent of the cotton grown in the United States were genetically engineered. *APHIS Biotechnology: Permitting Progress Into Tomorrow,* Biotechnology Fact Sheet, United States Department of Agriculture, Animal and Plant Health Inspection Service (February 2006), available at http://www.aphis.usda.gov/publications/biotechnology/index.shtml (last visited, June 5, 2006). For a complete list of all GMOs that have been approved to be released in the United States, see United States Regulatory Agencies Unified Biotechnology, available at http://usbiotechreg.nbii.gov/ (last visited August 8, 2006).

U.S. approach to regulating GMOs.

GMOs are typically portrayed as either a panacea, at one end of the spectrum, or the stuff of science fiction horror movies, at the other extreme. The truth, as with most truths, however, probably falls somewhere in the middle. While GMOs hold the promise of important advances in agriculture, medicine and industry, they are not without risk. Further, the elements of risk associated with GMOs are frequently different in kind and degree than are the risks typically addressed by environmental regulatory programs. Although legal scholars, such as Thomas O. McGarity,[9] have analyzed U.S. laws addressing certain elements of risk posed by GMOs, this Article is the first to analyze the complete array of U.S. regulatory programs addressing GMOs and the adequacy of these programs to address the novel elements of risk posed by GMOs. Moreover, this Article is the first ever to propose a new approach to regulation of GMOs utilizing principles drawn from evolutionary biology theory.

The thesis of this Article is that a new legal approach, which draws on principles of evolutionary biology, is needed to address the novel risks of environmental harm caused by man's intervention in and manipulation of evolution through the development of genetically modified organisms. While most environmental laws have been adopted as a reaction to a particular environmental catastrophe or crisis,[10] this Article asserts that the law should not wait for a GMO catastrophe. This Article builds on the work of leading experts in the science of evolutionary biology, such as E.O. Wilson[11] and Richard Dawkins,[12] and the work of legal scholars, such as William Rodgers,[13] Owen Jones[14] and E. Donald Elliot[15] who have applied evolutionary biology principles to the law. It should be noted that while this Article focuses on a new approach to regulating GMOs, the proposed approach may be equally applicable for the regulation of other livings organism, such as non-indigenous organisms and new types of artificially cultivated organisms, such as farmed fish and endangered species bred to repopulate and amplify

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[9] *See infra* notes 213-215 & accompanying text.

[10] *See* Michael Allan Wolf*, Essay: Environmental Law Slogans For The New Millennium.* 35 U. RICH. L. REV. 91 (2001), stating: "Disasters breed environmental law. One can easily trace the origins of several federal statutory schemes to specific ecological calamities. While it would be an exaggeration to isolate one incident and identify it as the sole cause for a statute, we can legitimately ask whether the United States Code would have contained the Air Pollution Control Act of 1955 28 without the Donora, Pennsylvania disaster and Los Angeles's poisonous smog; the Coastal Zone Management Act 29 without the Santa Barbara oil spill; the Oil Pollution Act of 1990 30 without the Exxon Valdez debacle; or the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) 31 without Love Canal." *See also,* Bradley C. Karkkainen*, Panarchy and Adaptive Change: Around the Loop and Back Again,* 7 Minn. J.L. Sci. & Tech. 59 (2005).

[11] E.O. Wilson's works on evolutionary biology include EDWARD O. WILSON, SOCIOBIOLOGY: THE NEW SYNTHESIS (1975) AND EDWARD O. WILSON, THE DIVERSITY OF LIFE (1992).

[12] Richard Dawkins published the groundbreaking evolutionary biology book, *The Selfish Gene*. RICHARD DAWKINS, THE SELFISH GENE (1976).

[13] *See infra* note 221 & accompanying text.

[14] *See infra* notes 219,224, 233 & accompanying text.

[15] *See infra* notes 229,231,237 & accompanying text.

populations in existing environments. Part II of this the Article sets forth a fact pattern that illustrates the state of genetically modified organisms and highlights the novel elements of risk and amplification of risk that these organisms pose. These novel elements of risk are referred to throughout the Article to illustrate points raised by the Article. Part III describes the types of risks associated with GMOs and identifies how these risks are the same as or similar to other environmental risks, and how risks associated with GMOs are novel. Part IV describes the existing regulatory programs governing GMOs administered by the Environmental Protection Agency, the Food and Drug Administration, and U.S. Department of Agriculture. It demonstrates that these programs have failed to adequately address certain types of risks associated with some GMOs. Part V sets forth the argument that there is a need for a serious reevaluation of U.S. GMO policy and regulation.[16] Part VI describes evolutionary biology theory and explores how it has been employed to help shape many areas of the law. This part further demonstrates the value of drawing on principles of evolutionary biology in developing a new regulatory approach to address the novel risks of pesticidal GMOs. Finally, a new evolutionary biology model for regulating GMOs is presented in Part VII.

II. UNNATURAL SELECTION ANDTHE CASE OF THE "POPCORN SHRIMP"

Consider the following scenario. A genetic engineering company produces genetically engineered corn that contains the gene from a particular type of shrimp, which enables the corn plant itself to produce a toxic normally produced by the shrimp.[17] Although the toxin is not generally particularly toxic to humans and other mammals, it kills corn earworms – a major economic pest of corn – thereby drastically reducing the amount of chemical pesticide that farmers apply to their corn crops. Because the risks of the shrimp toxin to humans have not been fully evaluated, the GM corn is approved only for animal feed and is not approved for human food use. In accordance with current federal pesticide law, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),[18] the EPA conducts a cost-benefit analysis and concludes that the benefits of the GM corn

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[16] Although beyond the scope of this Article, it should be noted that in the past several years there has been a substantial debate, both in the general public and in the scholarly literature, about international trade in GMOs. *See generally,* Serge Frechette, *Biotechnology, Food, and Agriculture Disputes or Food Safety and International Trade,* 26 Can.-U.S. L.J. 253 (2000); Kevin C. Kennedy, *International Trade in Agriculture: Where We've Been, Where we Are, and Were We're Headed*, 10 MSU-DCL J. Int'l L. 1 (2001); Katherine Ives, *The Benefits of Biotechnology, the Intersection of GAT/WTO and Other Trade Issues,* 10 MSU-DCL J. Int'l L. 13 (2001); Holly Saigo, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol,* 12 Geo. Int'l Envtl. L. Rev. 779 (2000); Gerry Kiely, *WTO and Market Access: Subsidies, Tariffication and Barriers to Freer Trade,* 10 MSU-DCL J. Int'l L. 7 (2001); Darren Smitts & Sean Zaboroski, *Trade and Genetically Modified Foods: GMOs: Chumps or Champs of International Trade?*, 1 ASPER REV. INT'L BUS. & TRADE L. 111 (2001); Sabrina Safrin, *Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements*, 96 A.J.I.L. 606 (2002.

[17] Professor Patricia Dilley is credited for being the first to comment that this scenario gives new meaning to the term "popcorn shrimp."

[18] 7 U.S.C. §§ 136 – 136y (2006).

outweigh its risks, provided the bags of seed are labeled to ensure seeds are not planted near water where the GMO can adversely affect aquatic organisms and to prohibit the seeds from being planted in certain parts of the country during bird migration season to limit exposure to migratory birds. EPA is not concerned about the spread of the corn because the biotech company that manufactures it has such a financial stake in selling its product and protecting its research and development investment that it will ensure that the seeds are only sold to farmers who agree to follow all of the regulatory restrictions.

Fast forward. The GM corn makes its way into the animal feed marketplace. The farmers using the engineered corn save money on pesticides and have increased crop yield, and the environment is spared from large amounts of chemical pesticides being sprayed onto farm fields. During the next growing season, some farmers decide to ignore their agreement with the biotechnology company and replant the GM seeds from last year's corn rather buy the expensive new seeds. Some farmers deliver their seed to silos where GM seed is mixed in with non-GM seed. Thus, the next season's GM seed is not properly segregated from non-GM seed and some GM corn makes its way into the human food market. Unwary consumers purchase the corn and consume the shrimp toxin. Although the majority of the population is not affected, people who are allergic to shrimp may have reactions without knowing where they were exposed. Similarly, people who follow dietary laws for religious or philosophical reasons, such as people who keep kosher or vegetarians do not know they are eating food containing a shrimp gene.

Meanwhile, out in the farm field, because the GM corn is a living organism, it can reproduce and spread in the environment. The GM corn pollen is carried by the wind where it fertilizes other cornfields, including nearby "organic" cornfields. If the corn is tested and discovered to be genetically modified the organic farmer will suffer severe economic loss because she cannot legally sell GM food as "organic."[19] The pollen also fertilizes a grassy weed that is a close genetic relative of the corn. The weed now contains the shrimp toxin and is protected from predation by insect pests that normally keep the weed population in check. The weed now has a selective advantage in the wild and takes over as a "superweed" crowding out all of the indigenous plants that normally grow in the area. The seeds of the weed also are food for seed-eating migratory birds flying through the area on their yearly migration, which are now exposed to the toxin and suffer ill effects. Finally, although the original seed bags warned farmers not to plant seed within 100 feet of streams due to the toxicity to aquatic organisms, such warnings do not prevent the new superweeds from spreading along streambeds. Moreover, subsequent generations of seeds that farmers sent to silos or saved to replant will not contain such warning. Thus, unsuspecting farmers may plant seeds in inappropriate places during bird migration season, thereby creating risk to a number of protected avian species. Finally, there are now so many plants (corn and weeds) pumping out the shrimp toxin on a continual basis, that the corn earworm begins to develop resistance not only to the shrimp toxin, but also to a commonly used chemical pesticide that has a similar

[19] *See* 7 C.F.R. §205.202.

chemical structure. As with the phenomenon of antibiotic resistance, an important pesticide is rapidly losing its efficacy.

This fact pattern, although fictional, illustrates the far-reaching potential risks from the release of GMOs that have been modified to be more "fit" from an evolutionary standpoint. Some of these risks arise from the fact that a living organism is being introduced into an environment in which it has not naturally evolved to exist. Similar risks can result from introduction non-native species into an environment or from increasing the population of a naturally-occurring species beyond natural levels. But some of these risks are of a type that simply would not exist if it weren't for the genetic manipulation of organisms. Only through genetic manipulation can a shrimp toxin be produced by a corn plant and only through genetic manipulation can a corn plant pass on such genes to a weedy relative, thereby dramatically improving its evolutionary fitness, and turning it into a "superweed." While this scenario may seem far-fetched or worst-case scenario, it is not. Many of the events described actually have occurred in the past few years as a result of the commercialization of pesticidal GMOs.

Probably the most well-known example of problems that can arise from the release of pesticidal GMOs into the environment is the recent case involving StarLink corn. StarLink corn contained a protein that was similar to a protein found in peanuts; peanuts contain many proteins that can cause severe allergies in humans. Thus, the StarLink corn was approved only for animal feed and was not approved for human food use. Despite this limited approval, testing by an environmental organization revealed the presence of the StarLink gene in large batches of taco shells and other human food corn products.[20] Farmers throughout the U.S. were forced to destroy their crops. The farmers filed class action lawsuits. [21] In addition, consumers alleging fraud, negligence and breach of warranty for recklessly exposing millions of consumers to these unapproved and potentially dangerous products filed class action lawsuits. Moreover, corn products with the gene showed up as far away as Japan and Korea, leading to a dramatic decline in imports of U.S. corn products in these countries.[22]

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[20] StarLink Corn: How it Reached the Food Supply, A.P., Dec. 4, 2002, *available at* http://archive.showmenews.com/2000/dec/20001204busi011.asp; *See* Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons from the Starlink Corn Fiasco.* 27 Wm. & Mary Envtl. L. & Pol'y Rev. 593, 628-33 (2003); William Lin, Gregory K. Price & Edward Allen, *Starlink: Impacts on the U.S. Corn Market & World Trade*, *available at* www.ers.usda.gov/briefing/biotechnology/starlinkarticle.pdf (last visited June 24, 2006)

[21] *In re* StarLink Corn Prods. Liab. Litig., 212 F.Supp. 2d 828 (N.D. Ill. 2002). The defendants, Aventis CropScience USA Holdings and Garst Seed Company, moved for dismissal, arguing that the farmers' claims were pre-empted by FIFRA and that the economic loss rule barred recovery. *Id.* at 833. The trial court held that FIFRA did not pre-empt the farmers' claims, that the contamination of crops by neighboring GM-crops provided a claim to which the economic loss rule did not apply, and that the plaintiffs had properly alleged claims based on negligence, public nuisance and private nuisance. *Id.* at 852.

[22] *See* Lin, et. al. *supra* note 20; Bratspies, *supra* note 20; Rebecca M. Bratspies, *Consuming Fear of Corn: Public Health and Biopharming*, 30 AM. J.L. AND MED. 371, 387 (2004).

Other documented instances of the risks illustrated by the popcorn shrimp hypothetical include a case where the British government ordered the destruction of experimental fields of herbicide-tolerant oilseed rape plants because the genetically engineered forms had successfully pollinated nearby "natural" plants. Such spread might have created a new breed of "superweeds" resistant to herbicides and capable of displacing other plant life.[23] In Canada, GM corn cross pollinated a neighboring field of "organic" corn, which could no longer be sold as "organic."[24] GM corn pollen has been found to cause significant risk to monarch butterfly larvae in laboratory conditions.[25] Moreover, a number of insect pests have demonstrated resistance to Bacillus thuringensis, an important low-risk non-engineered biological pesticide that is a naturally occurring soil bacterium,[26] which has been genetically engineered into a wide variety of crops including corn, potatoes and cotton.

III. THE RISKS OF GENETICALLY MODIFIED ORGANISMS

The concept of risk includes elements of hazard and exposure. GMOs present hazards and exposures that are different in both type and degree than are the hazards and exposures presented by traditional environmental chemicals. Toxicity is the typical hazard presented by most traditional environmental chemicals. With regard to GMOs, hazards are expanded well beyond toxicity to include hazards such as the creation of

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[23] "Farmers advised to destroy GM crops," BBC News Online: UK Politics (May 27, 2000), *available at* http://news.bbc.co.uk/1/low/uf_politics/766539.stm.

[24] Thomas Hayden, "Bad Seeds in Court: When Genetically Modified Plants Contaminate Their Crops, Organic Farmers Fight Big Biotech," US NEWS & WORLD Report, Science & Tech., Jan. 28, 2002. For an interesting twist on the economic consequences of genetic contamination *see* Monsanto Canada Inc. v. Schmeiser, 2004 CarswellNat 1391 (Supreme Court of Canada 2004). Schmeiser, a farmer in Saskatchewan, was sued by Monsanto for patent infringement when his canola crop was found to contain the company's patented modified genes which made the crops herbicide-resistant. Schmeiser did not have a license for use and did not purchase the company's crop, yet 95 to 98 percent of his 1998 crop consisted of the genetically modified canola. The Supreme Court of Canada upheld the patent infringement claim, but struck down the damages award as Schmeiser used the canola solely for feed purposes and did not gain any particular advantage from his usage of herbicide-resistant crops. Schmeiser countersued Monsanto for the contamination of his non-GM crops with the herbicide-resistant canola.

[25] Wendy Thai, *Transgenic Crops: The Good, the Bad, and the* Laws, 6 MIN. J. L. SCI, & TECH. 877 (2005); JJE Losey, *Transgenic Pollen Harms Monarch Larvae*, 399 Nature 214 (1999). At least one other study has found negligible harm to monarch butterflies. Marc Kaufman, *2nd Study Links Gene-Altered Corn, Butterfly Deaths*, WASH. POST, Aug. 22, 2000, at A2; *Gene-Spliced Corn no Big Threat to Butterflies, Studies Say*, S.F. CHRON. (East Bay Edition), Nov. 3, 1999, at A11. EPA has prepared a document evaluating risks to Lepidoptera in general from *B.t.* PIPs, which can be viewed at http://www.epa.gov/pesticides/biopesticides/pips/executive_summary_and_preface.pdf (last visited August 8, 2006).

[26] Researchers at Texas A&M have studied methods of enhancing the resistance effects of *Bt* cotton, but have also noted that the increasing pest-resistance qualities have a drawback- namely those pests that survive the natural toxin will propagate and lead to an increasing population of Bt-resistant budworms and bollworms. *See* Steve Hill, "Science Hopes to Keep One Step Ahead of Adaptive Bugs," September 6, 1996, *available at* http://agnews.tamu.edu/stories/ENTO/adbugs.htm (last visited April 14, 2006).

superweeds or pest resistance. In addition, pathways for exposure to hazards may be much greater and more widespread because GMOs are living organism spreading and reproducing in the environment. Accordingly, there are a number of different types of risks associated with GMOs. Some are very similar to the risks associated with traditional pesticides and chemicals, some are similar to the risks associated with the introduction of non-indigenous organisms into new environments, and some are novel and result from the fact that that many GMOs are intentionally genetically modified to give them an evolutionary selective advantage.

The traditional types of risks that are associated with some GMOs include the toxicity of the organism or a chemical produced by the organism, which could be toxic either to humans or to wildlife. The second category of risks is similar to the risks produced when non-indigenous organisms are introduced into new environments. For GMOs, even a small change in the genetic material of an organism can cause the organism to behave or reproduce in new ways, or both. In other words, even a small change in an organism can create a new organism, which when released into a new environment may behave differently than either the original host or recipient organisms. A third type of risk, distinctive to GMOs, is created by the selective advantage provided to certain GMOs. In particular, GMOs that are designed to have enhanced abilities to protect themselves may have an evolutionary selective advantage in the environment. For example, GM crops, such as those genetically enhanced to resist disease, pests, or climatic conditions, will be able to out-compete their non-enhanced relatives. By intentionally imposing selective advantages into the organisms, humans have given the organisms the potential to spread in the environment and pass their traits onto future generations. In this way the evolutionary process is accelerated. The organisms which have been enhanced may be more evolutionarily "fit," and therefore, more likely to survive. Because of the very different types of risks associated with GMOs, any regulatory system that does not take into consideration these risks is inherently skewed. Accordingly, a new system should be designed to address each type of risk rather than conflating these different risks into one regulatory approach.

A. *Traditional Risks: GMOs as Chemicals*

Many of the risk considerations for GM plants are similar to, if not the same, as those for traditional chemicals. GM plants typically have been modified by inserting genetic material into the DNA of the plant that enables the plant to produce chemical substances with some commercial purpose. Examples include GM plants that produce pesticides that protect the plant from insects or other pests, and GM plants that produce industrial or pharmaceutical chemical substances that can be extracted from the plants and used commercially. As with any chemical risk assessment, the underlying considerations of analyzing risk posed by GM plants are the potential for non-target organisms and humans to be exposed to the substance produced by the GM plant, and the hazard (usually toxicity) of such substance to non-target organism, humans, and the

environment. Such hazard is determined by the chemical and toxicological properties of the substance. [27] Although the risk of direct harm posed by exposure to toxins may be familiar, exposure considerations can be very different for GM plants than for traditional chemicals. For traditional chemicals, the primary factors in determining exposure are the amount of chemical that is introduced into the environment and the likelihood that humans or other non-target organisms will come into contact with the chemical.

One of the major risk concerns associated with GMOs is their potential risks to human health, particularly through dietary exposure. A human dietary issue that has received considerable attention is the potential of GMO foods to pose a risk of human allergenicity. [28] The primary concern appears to be that if a gene is moved from one

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[27] In addition to risks posed by the GMO itself, one category of GMOs may result in the increased use of chemical pesticides, thereby increasing risks associated with such chemicals. A number of crop plants have been genetically modified to increase their resistance to certain herbicides. As a result of this increased crop resistance to herbicides, farmers can apply herbicides at stages of crop growth when they will be the most effective in killing weeds. However, if GMO herbicide-tolerant plants cause farmers to use more herbicides or apply herbicides more frequently, there may be an increase in environmental risk associated with the increased use of the herbicide. In fact, recent studies show a reduction in biodiversity in areas of some genetically modified herbicide-tolerant crops due to increased herbicide usage resulting in a decrease in weeds and other plants that produce seeds that are normally food sources for insects, birds, and other species. 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.

[28] A full discussion of the human health risks associated with GMOs is beyond the scope of this Article. Most of the public outcry against GMOs, as well as much of the scholarly literature on GMO issues, has focused on the human health risks. Issues relating to the safety of GMOs for human food use have been at the forefront of the public debate on GMOs. *See generally,* Marc Lappe, *Biotechnology and Agriculture,* 10 MSU-DCL J. Int'l L. 39 (2001); Jack Laurie, *Biotechnology and Agriculture,* 10 MSU-DCL J. Int'l L. 29 (2001); Emily Robertson, *Note: Finding a Compromise in the Debate Over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U.J. Sci & Tech. L. 156 (2003); Katherine Van Tassel, *The Introduction of Biotechnological Food to the Tort System: Creating a New Duty to Identify*, 72 U. Cin. L. Rev. 1645 (2004). In fact, in 2001, The New York Times Review of Books writer, Richard Lewontin, commented that he had nineteen recent books and a fifteen-pound stack of articles on his desk relating to genetically engineered foods. *See* Richard C. Lewontin, *Genes in the Food!,* The New York Times Review of Books (June 21, 2001)(reviewing four books on the risks and benefits of GMOs in food.) One of the hotly debated issues is whether foods containing GMOs should be labeled as such so that consumers can make informed choices about the foods they eat. *See generally,* Lauren Zeichner, *Product v. Process: Two Labeling Regimes for Genetically Engineered Foods and How They Relate to Consumer Preferences*, 27 Environs Envtl. L & Pol'y J. 467 (2004); Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. Rev. 733 (2003); Frank J. Miskiel, *Voluntary Labelling of Bioengineered Food: Cognitive Dissonance in the Law, Science and Public Policy*, 38 Cal. W. L. Rev. 223 (2001); Sarah L. Kirby, *Genetically Modified Foods: More Reasons to Label Than Not*, 6 Drake J. Agric. L. 351 (2001). To date, the United States has not required such labeling. In 2001, in response to intense public concern over GMOs in the public food supply, as well as requests from the GM industry for guidance on labeling GM foods, the FDA published a notice in the Federal Register providing guidance to assist manufacturers who wish to voluntarily label their foods to indicate whether they contain GM ingredients. 66 Fed. Reg. 4839 (January 18, 2001). This notice does not require food labeling, but merely provides guidance on appropriate labeling for those producers who elect to label their food products. *Id.*

organism to which a certain segment of the population has an allergy to another food organism which is not otherwise allergenic, allergic persons will not know that the GM food is potentially allergenic to them. Consider, for example, the popcorn shrimp scenario set forth above, in which a gene from shrimp is inserted into corn plants. A certain segment of the human population is allergic to shrimp. Those persons know to avoid eating shrimp or other food products are likely to contain shrimp products, (such as seafood gumbo). The allergic individuals, however, have no way of knowing, or even suspecting, that by eating products that contain corn (such as tortilla chips), they may be exposing themselves to the shrimp proteins to which they are allergic.[29] Eliminating this risk would require mechanisms to segregate the GMO corn and warn consumers that the GM corn may be allergenic to people allergic to shrimp. Without such protections, consumers will not be aware that by eating corn products they may be exposed to substances normally produced by shrimp and allergic consumers could be put at risk.

Risk considerations for GMOs become even more complex with regard to the likelihood of non-target (human or wildlife) exposure to any hazardous substances produced by the genetically modified organisms. Exposure considerations for GMOs are dependent, in large part, on the biological characteristics of the modified organism itself. For example, exposure to a substance produced by a GM plant is determined in part by factors such as which particular plant parts (e.g., leaves, stems, fruit, or roots) produces the substance and what organisms consume or are associated with those plant parts. Moreover, one of the most significant exposure considerations for GM plants not seen for chemical pesticides is the potential for spread of the living plant or the plant's genetic material. 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 the substance could spread through agricultural or natural ecosystems. Thus, the capacity of a plant that has been genetically modified to produce a particular pesticidal, industrial or pharmaceutical chemical substance to spread in the environment, or to spread its genetic material to other plants, increases the risk of potential exposure to non-target organisms as compared to a chemical substance produced in a 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. This is a particular concern for GM plants that have wild relatives in the

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[29] *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 concern subpopulations of people with special dietary preferences such as vegetarians or persons who observe kosher (Jewish) or halal (Muslim) laws or may raise ethical, philosophical or religious concerns. Environmental Defense Fund, A Mutable Feast: Assuring Food Safety in the Era of Genetic Engineering (New York 1991). Other philosophical issues that have been raised include a concern that the prospect of "human-made" organisms, even if they pose no risk to humans or the environment, may threaten the concepts of "wildness" and wilderness." *See, e.g.,* MARGARET MELLON, NATIONAL WILDLIFE FEDERATION, BIOTECHNOLOGY AND THE ENVIRONMENT: A PRIMER ON THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 32(1988).

U.S. If these wild relatives acquire the ability to produce the plant-pesticide through cross fertilization, many additional non-target organisms could be exposed to the chemical substance.[30]

B. *Novel Risks: GMOs as "Darwin in Hyperspeed"*[31]

When organisms are genetically modified to take on new traits, such modification can be viewed as intentional "mutation." In other words, the types of random mutations that occur in nature may enhance selective advantage, reduce selective advantage, or be neutral. In the case of genetic modifications that are intended to impose protections on the plant itself, such as pest or disease resistance, the changes are by their nature mutations that impose selective advantage on the organisms. Moreover, such changes may be much more dramatic in type and magnitude than the types of mutations typically occurring in nature. Such dramatic mutations, from an evolutionary standpoint, may be analogous to the types of rapid evolutionary changes that can occur in response to catastrophic events or unusually harsh environmental conditions.[32]

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 non-target organisms. One potential risk of genetic engineering products parallels the risk of the introduction of any non-native species into a new environment.[33] Even very small genetic manipulations can significantly change an organism's ability to survive and flourish in a particular ecosystem.[34] Examples abound regarding the disastrous but unpredicted effects of introducing non-native species into the environment, displacing native species.[35] Introducing GMOs into the environment could have similar impacts.[36] One of the most significant risks is the risk of a genetically engineered plant becoming a weed or pest itself or out-crossing to related species to create new weeds or pests.[37] Once released into the environment, the spread of a GMO may be extremely difficult, if not

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[30] Other areas of potential adverse effects on the environment center on specific plant-pesticides or categories of plant-pesticides. For example, plants that are modified to produce viral coat proteins by inserting viral genetic material into the plant's DNA may have the potential to result in the development of new unintended viruses. *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, 286 (1996).

[31] Deacon and Paterson, *Emerging Trends in Biotechnology Litigation*, *supra* note 5.

[32] For an excellent discussion of how catastrophic events and harsh environmental conditions can accelerate the pace of evolution, *see generally* JONATHAN WEINER, THE BEAK OF THE FINCH (1994).

[33] 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).

[34] *Id.*

[35] *See* J.J. Kim, *Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms,* 16 FORDHAM INTL. L. J. 1160 (1993).

[36] *See* Earp, *supra* note 33 at 1653.

[37] *Id.* at 1654-55.

impossible, to control.[38] 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 the relative's subsequent generations. 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."

One consideration in the superweed risk analysis is that 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.[39] Most major crops grown in the United States are of foreign origin.[40] Thus, hybridization between GMO crops and wild relatives is unlikely in the United States. Moreover, many 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.[41] Thus, these crop plants are unlikely to become weeds themselves when genetically altered.[42] However, many U.S. minor crops do have wild relatives in the U.S.[43] Further, once the GMO crops are reproducing and spreading in the environment, they can end up in geographic locales far from the point of initial release or planting. Perhaps of even greater concern is that once these GMOs are exported (intentionally or otherwise) to other parts of the world that do have wild relatives of the GMOs, the risks become more profound.

C. *Economic Risks: Contamination of Organic Crops and Pesticide Resistance*

Another type of novel risks posed by the potential for GM plants to cross-pollinate other plants is an economic risk. One economic cost that has arisen due to GMO's ability to outcross with non-GMO crops is the genetic contamination of organically grown crops with GM pollen. USDA regulations on Organic Labeling prohibit foods containing GMOs from being labeled "organic."[44] Organic farmers who

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[38] *Id.*

[39] *See* Earp, *supra* note 33, at 1666-69.

[40] *See* JANE RISSLER & MARGARET MELLON, THE ECOLOGICAL RISKS OF ENGINEERED CROPS 113 (1996). (showing geographic origin for rice (southwest Asia), soybean (northeast Asia), wheat (Middle East) and corn (Central America)).

[41] Mary Jane Angelo, *Embracing Uncertainty, Complexity, and Change*: *An Eco-Pragmatic Reinvention of a First-Generation Environmental Law*, 33 ECOLOGY L.Q. 105, n.235 (2006).

[42] *See* Earp at 1654..

[43] Meeting Minutes: FIFRA Scientific Advisory Panel Meeting, December 6-8 2005, *A Set of Scientific Issues being Considered by the Environmental Protection Agency Regarding: Plant-Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the proposed Rule,* SAP Report No. 2006-01 (on file with author).

[44] *See generally* 7 C.F.R. § 205 (2006). The rule requires product labels to differentiate between 100% organic, organic, made with organic materials. The product must meet varying statistical amounts of organic constituents (i.e., a product to be labeled as "Organic" must consist of at least 95% organic ingredients, excluding water and salt). The product cannot contain sulfites, and the non-organic constituents are either non-organic agricultural products that are not commercially available in an organic

have fields near fields where GMO crops are grown, and whose crops become contaminated with low levels of pollen drift from the GMO crops may not be able to sell their crops as organic, which may result in lost revenue to organic farmers who are forced to sell such crops on the lower-priced non-organic market. For an organic farmer to demonstrate that her crop does not contain GMOs, the farmer will have to conduct expensive genetic testing. A recent survey found that eleven percent of the major organic soybean and corn growers are now regularly spending $300.00 per test to determine the level of GMOs in their crops.[45] Moreover, many buyers of agricultural crops, such as major food producers, have a zero tolerance standard for GMOs due to strong consumer preferences. Perhaps the most significant blow to the U. S organic farming industry may be that European organic producers are increasing exports of organic crops to the U.S. These European organic crops are lower-priced because organic growers in Europe do not have to pay for genetic testing because GMO crops are not widely grown in European Union countries.[46]

In addition, serious concerns have arisen regarding the risk that plants producing pesticidal substances such as the *B.t.* toxin[47] on a continual basis may hasten the development of pest resistance to these beneficial pesticides. Many non-GMO biological pesticides, such as the naturally-occurring *B.t.* microbe are relied on by organic and non-organic growers alike. These microbial pesticides are very effective pesticides, and are a relatively low risk to non-target organism. They are applied to crops on an as-needed basis. When a crop plant is genetically engineered to produce a pesticide, such as the *B.t.* toxin, in its tissue, it continually produces the toxin in all of its cells over the course of its life. With tens of millions of acres of GM crops continually producing these toxins, pest species are continually exposed to the toxin. Resistance to toxins will tend to develop more quickly in populations of pest species that are continually exposed to the toxin than in populations of species that are only sporadically exposed.[48] Evidence already exists that GM crops producing the *B.t.* toxin may be responsible for the development of *B.t.* resistance in certain pest species, such as the diamond-backed moth.[49] If such resistance continues to develop in other pest species, growers will lose an important tool in their

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form, or are products that are permitted under 7 C.F.R. § 205.605 (2006). *See* "Labeling Packaged Products", available at http://www.ams.usda.gov/nop/ProdHandlers/labelTable.htm (last visited April 3, 2006).

[45] Survey by the Organic Farming Research Foundation., *available at* http://www.ofrf.org/press/Press%20Clippings/Washington.Post.060503.AP.Elias.1pg.pdf.

[46] Rick Gush, *Organic Farming vs. Genetic Engineering,* Hobby Farms 28 (Januarys/February 2006).

[47] *Bacillus thuringiensis,,* or *B.t.*, is a naturally-occurring soil microbe. This microbe acts by forming a protein crystal, referred to as the delta endotoxin, which is toxic to insects when ingested. *See* R.E. PFADT, FUNDAMENTALS OF APPLIED ENTOMOLOGY 239 (3rd Ed. 1978).

[48] Matthew Rich, *The Debate Over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. 889, 893-95 (2004). This is a similar phenomenon to the bacterial resistance that is occurring with regard to the overuse of antibiotics. *See generally* Michael Misocky, *The Epidemic of Antibiotic Resistance: A Legal Remedy to Eradicate the "Bugs" in the Treatment of Infectious Diseases*, 30 AKRON L. REV. 733 (1997).

[49] Rich, *supra* note 48.

pest management arsenal. This is of particular concern to organic growers, for whom naturally-occurring microbial pesticides such as *B.t.* are among the few pesticides available to them that allow them to sell their crops as "organic."[50]

D. *Uncertain Risks: New Technology and Lack of Experience*

Perhaps the greatest concern with GMO crops is simply the fact that there is substantial scientific uncertainty regarding the potential risks that could arise from genetically modifying crops and introducing them into the environment and the human diet. Given the relatively recent emergence of GM technology, our experience is extremely limited. Although there has been widespread use of certain GMO crops for approximately ten years, the GMOs that are in widespread use are primarily a few limited types, such as *B.t.*, viral coat proteins, and herbicide tolerance, in a few very well understood crops, such as corn and soy. The fact that there have not been widespread environmental or human health problems resulting from the use of the GMOs is not surprising. This limited universe of GMOs is generally considered to be fairly innocuous.[51] Moreover, it may take many years to fully understand the existence and extent of any ecological disruptions that may be occurring as a result of introducing these novel organisms in to the environment. What is perhaps of greater concern than the GMOs in current widespread use, however, are the many GMO products in the research and development stage that may pose much more significant risks. For example, research is being conducted on a variety of GMO crops that have been engineered to produce new types of pesticides and pharmaceutical and industrial products.[52] If these GMOs are not properly contained and are allowed to spread in to the environment, humans and wildlife alike could be unwittingly exposed to hazardous pharmaceutical or industrial substances.[53]

This discussion of the risks of GMOs is not intended to suggest that GMOs have no benefits. For instance, many scientists believe that GMO pesticides may provide a less risky alternative to chemical pesticides because many GMOs are less toxic than chemical GMOs, more narrowly targeted towards the intended pest, and released into the

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[50] 7 C.F.R. §205.

[51] Moreover, as some have noted, if some humans are experiencing health problems from consuming GMOs, or if these GMOs are causing some ecological disruptions, it may be very difficult to draw a causal connection between the adverse effect and the GMO. For example, because GMO foods are not labeled, a human who is having health problems may not even be aware that she is consuming GMOs let alone be able to correlate consumption of the GMO with the health effect. *See* http://www.ucsusa.org/food_and_environment/genetic_engineering/environmental-effects-of-genetically-modified-food-crops-recent-experiences.html

[52] *See APHIS Biotechnology: Permitting Progress into Tomorrow*, Biotechnology Regulatory Services Fact Sheet, United State Department of Agriculture, Animal and plant Health Inspection Service (February 2006), *available at* http://www.aphis.usda.gov/brs (last visited, June 4, 2006).

[53] *See generally*, Wendy Thai, *Transgenic Crops: The Good, the Bad, and the Laws*, 6 MINN. L. J. SCI. & TECH. 877 (2005).

environment in smaller quantities.[54] This discussion on the unique ecological risks posed by GMO pesticides highlights the complex ecological risks at issue and the large amount of uncertainty regarding such risks to permit evaluation of the extent to which the existing framework is poorly designed to address these risks.

IV. U.S. REGULATION OF GMOS

A. History (Coordinated Framework)

Whether and how the United States would regulate GMOs was not addressed until 1984, when the Office of Science and Technology Policies (OSTP) published a document entitled "Proposal for a Coordinated Framework for the Regulation of Biotechnology."[55] The stated purpose of the document was "to provide a concise index to US laws related to

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[54] Products of genetic engineering have the potential of providing significant benefits to society through new or improved pharmaceuticals, foods, industrial compounds and substitutes for traditional chemical pesticides. For example, traditional chemical pesticides often are of relatively high toxicity and often are toxic to a broad range of organisms, including humans. In addition, the manner in which traditional pesticides are applied – often sprayed over large areas – typically results in significant exposure to non-target organisms. GM pesticides, on the other hand, are generally of lower toxicity, target-specific, and produced in relatively small quantities in the organism. Consequently, non-target organisms are not as likely to be exposed to these pesticides as they are to pesticides that are sprayed over large areas. Moreover, even if non-target organisms are exposed to plant-pesticides, because these pesticides are often of low toxicity and are generally target specific, non-target organisms are not as likely to be adversely affected by these pesticides as they are with pesticides that are more highly toxic or toxic to a broad spectrum of organisms. For example, the *B.t.* toxin is specific to specific groups of insects (e.g., Lepidoptera) and is not toxic to humans or other mammals. Another example of where a plant-pesticide is believed to have the potential for significant environmental benefits is viral coat protein-mediated resistance. By genetically modifying plants to produce certain viral coat proteins, researchers have been able to produce plants that are resistant to infection by particular viruses. For viruses spread by vectors such as insects, the most common agricultural practice for preventing viral attack is the use of chemical pesticides to control the insect vector that spreads the virus. It is believed that the use of viral coat protein-mediated resistance would reduce the need for these chemical pesticides. In addition to the environmental benefits of viral coat protein-mediated resistance, there is a high potential for significant economic benefits. Another potential environmental benefit is the reduction of run-off of agricultural chemicals such as pesticides and fertilizers, which can contaminate surface and ground water. For example, rDNA technique may be used to create plants with improved photosynthetic and nitrogen fixation capabilities, thereby reducing the need to apply fertilizers. *See generally* Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Developments in the EPA'S Regulation of Biotechnology*, 7 FL. J. LAW & PUB. POL'Y 257 (1996); EPA, Statement of Policy: Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act 37-38 (Dec. 20, 1993).

[55] Notice of a Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50, 856 (1984) (hereinafter Notice of Coordinated Framework). Although commonly used interrelatedly with genetic engineering, the U.S. government has defined the term "biotechnology" as: "[t]he use of various biological processes, both traditional and newly devised, to make products and perform services from living organisms or their components." Notice of the Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment., 57 Fed. Reg. 6753, 6754 (1992).

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 mechanism for assessment of biotechnology issues, and to explain how the activities of the federal agencies in biotechnology will be coordinated."[56] In 1986, the OSTP published the final "Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment" (hereinafter "Coordinated Framework").[57]

The Coordinated Framework articulated two major policy choices that set the stage for at least the next twenty years of U.S. regulation of biotechnology. First, the document stated that biotechnology could be adequately regulated under existing legal authorities and that new legal authorities were not necessary to address emerging technologies.[58] Second, the document articulated a policy position that the "products" of biotechnology would be regulated rather than the "process" by which such products were created.[59] Specifically, the Coordinated Framework stated that "[t]echniques of biotechnology are not inherently risky in that biotechnology should not be regulated as a process, but rather that the products of biotechnology should be regulated in the same way as the products of other technologies." [60] In other words, the Coordinated Framework set forth the position that the potential risks of genetic modification were not dependent on the process by which such modification was made, but instead only depended on the ultimate product that was produced regardless of the process or technology used. In addition, the Coordinated Framework outlined the relationship and coordination between five federal agencies possessing legal authority in the regulation of

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[56] Notice of Coordinated Framework*, supra* note 55.

[57] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986) (hereinafter Coordinated Framework).

[58] *Id.* at 23,306. The document stated "Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part these laws as currently implemented would address regulatory needs adequately." *Id.* at 23,303.

[59] *Id.* at 23,302-04. The document provides "The manufacture by the newer technologies of food, the development of new drugs, medical devices, biologics for humans and animals, and pesticides, will be reviewed by FDA, USDA and EPA in essentially the same manner for safety and efficacy as products obtained by other techniques." *Id.* at 23,304. The process versus product debate extends beyond the regulation of GMOs. For an interesting discussion of the issues, *see generally* Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulations of Consumer Choice,* 118 HARV. L.REV. 525 (2004).

[60] *Id.* During the 1980s and early 1990s, the executive branch was focused on promoting biotechnology as the US's hope for a 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. During this time, Vice President Quayle's Council on Competitiveness became intensively involved in planning for the commercialization of biotechnology. The message was clear that regulatory agencies were not to stand in the way of biotechnology and were not to develop any new regulatory programs. *See* Vice President's Council on Competitiveness, *Report on National Biotechnology Policy* (Feb. 19, 1991); *see generally* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733 (2003).

biotechnology. These agencies include the Environmental Protection Agency (EPA), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Occupational Safety and Health Administration (OSHA).[61] The two federal agencies identified in the Coordinated Framework as having the primary authority to regulate environmental risks posed by genetically modified organisms are the Environmental Protection Agency and the United States Department of Agriculture.[62] The primary agency identified as having the authority to address risks from GMO food is the Food and Drug administration.[63]

B. Environmental Protection Agency Authority

The United States Environmental Protection Agency (EPA) is the primary federal agency charged with the regulation of environmental risk-producing activity in the U.S. EPA regulates biotechnology products under at least three separate statutory authorities. For pesticidal GMOs (e.g., plants or microorganisms that have been genetically modified to produce pesticidal substances), EPA's authority is derived from the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA governs the manufacture, sale and distribution of pesticides in the U.S., and addresses both environmental and human health risks associated with such pesticides.[64] The reach of EPA's authority under FFDCA, on the other hand, extends only to pesticides in food, and only addresses the human health risks associated with such pesticides.[65] EPA's third authority for regulating GMOs is found in the Toxic Substances Control Act (TSCA), which is EPA's "catch-all" authority for regulating substances that do not fall within the jurisdictional bounds of its other authorities.[66] Although none of the three statutes expressly addresses GMOs, and in fact, GM products were not even contemplated at the time the statutes were initially passed, EPA has nonetheless interpreted them as providing authority to regulate certain categories of GMOs.

The primary federal statute that regulates the environmental risks associated with pesticides, whether conventional chemical pesticides or organisms that have been genetically modify to exhibit pesticidal characteristics, is FIFRA.[67] The origins of FIFRA are in the 1910 Federal Insecticide Act, which was a classic consumer protection statute.[68] It was designed to address grievances from consumers, primarily farmers, that pesticides sold to them were either too weak and therefore didn't kill the pests, or too

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[61] Coordinated Framework, *supra* note 57.
[62] *Id.*
[63] *Id.*
[64] 7 U.S.C. §136-136y (2006).
[65] 21 U.S.C. §342 (2006).
[66] 15 U.S.C. §2601-2629 (2006).
[67] 7 U.S.C. §136-136y (2006).
[68] *See generally* CHRISTOPHER J. BOSSO, PESTICIDES & POLITICS (1987).

strong, thereby harming the crops themselves.[69] The act relied heavily on labeling provisions to ensure claims about the pesticides were accurate and also to provide information on the proper use of the pesticide.[70] The statute was not designed to address risks to the environment. The act remained virtually unchanged until 1972. During the crest of the environmental movement and in response to the environmental concerns regarding pesticides that were raised in Rachel Carson's *Silent Spring*, attempts were made to bring environmental concerns into the statute.[71] The most significant aspect of the 1972 FIFRA was the addition of the cost/benefit balancing criteria, which a pesticide must meet to receive and maintain a registration. Despite some Congressional tinkering over the years, the 1972 FIFRA continues to form the current backbone of pesticide law in the U.S.

FIFRA's primary regulatory tools are the requirement for every pesticide to be registered and the use of labeling restrictions to minimize adverse impacts to humans and the environment.[72] Section 3 of FIFRA provides that no person may distribute or sell in the United States any pesticide that is not registered under the Act.[73] FIFRA section 3(c)(5) requires that, before a pesticide may be registered, the applicant has the burden of demonstrating that when used in accordance with widespread and commonly recognized practice, the pesticide will not generally cause "unreasonable adverse effects on the environment."[74] FIFRA defines the term "unreasonable adverse effects on the environment" as any unreasonable risk to humans or the environment, "taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[75] Thus, FIFRA involves a balancing of the risks presented by the use of the pesticide against the benefits associated with the use of that pesticide.[76]

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[69] CHRISTOPHER J. BOSSO, PESTICIDES & POLITICS (1987).

[70] CHRISTOPHER J. BOSSO, PESTICIDES & POLITICS (1987).

[71] Compared to other areas of environmental law, pesticide law is unique in that it attempts to address the risks of substances that are intentionally released into the environment for the sole purpose of destroying living organisms. Other areas of environmental law address controlling substances that are released into the environment by accident or as a byproduct of contained processes. These types of releases can be prevented or minimized to acceptable levels through technological fixes and legal systems that deter behavior that leads to unacceptable releases. Once an unacceptable release occurs, steps can be taken to mitigate the release and, if necessary, clean up the contamination. In other cases, less toxic substances can be used in commercial processes so that if releases do occur, the affects will be minimized. With pesticides, however, releases of the toxic substance are not just an unfortunate consequence, they are the goal. *See* Mary Jane Angelo, *Embracing Uncertainty, Complexity, and Change: An Eco-pragmatic Reinvention of a First-Generation Environmental Law,* 33 ECOLOGY L.Q. 105, 109 (2006).

[72] 7 U.S.C. §136a(a) (2006).

[73] 7 U.S.C. §136a(a). *Id.*

[74] 7 U.S.C. §136a(c)(5) (2006).

[75] 7 U.S.C. §136(bb) (2006).

[76] The plain language of FIFRA does not mandate a strict cost/benefit balancing. The statute merely requires that EPA "take into account" economic and social as well as environmental considerations. Nevertheless, EPA has consistently interpreted and implemented this standard as a strict cost/benefit

EPA generally relies on labeling requirements to impose risk reduction measures on the use of traditional pesticide products. For example, EPA regulations at 40 CFR 156.10 contain extensive labeling requirements addressing, among other things, warnings, precautionary statements and directions for use. [77] Other labeling restrictions are imposed, case-by-case, through the registration process. Restrictive labeling may include anything from requirements that personal protective equipment such as gloves and respirators be used to reduce the risk to pesticide users, to the requirement that a buffer zone be provided around fields to prevent risks to bystanders from spray-drift, to geographic restrictions on the use of certain pesticides to reduce the risk to endangered species or other beneficial organisms that occur in a limited geographical area.[78] These labeling restrictions are translated into use restrictions via FIFRA section 12(a)(2)(G), which provides that it is unlawful for any person to use any registered pesticide in a manner inconsistent with its labeling.[79]

EPA has stated that it recognizes that many types of restrictive labeling that it relies on to regulate traditional chemical pesticides may not be appropriate for pesticidal GMOs.[80] For example, geographical limitations on the use of the GMO may not be

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balancing, and this interpretation has been upheld in a number of administrative and judicial decisions. *See, e.g.,* Envtl. Def. Fund, Inc. v. EPA (heptachlor-chlordane), 548 F.2d 998, 1004 (D.C. Cir. 1976), *cert. denied,* 431 U.S. 925 (1977); In re Chapman Chem. Co., FIFRA Docket No. 246, 1 E.A.D. 199 (EPA 1976); In re Protexall Prod., Inc., FIFRA Docket No. 625, 2 E.A.D. 854 (EPA 1989).

[77] 40 C.F.R. §156.10 (2006).

[78] 40 C.F.R. §156.10 (2006).

[79] 7 U.S.C. §136j(a)(2)(G) (2006). EPA regulations require that every pesticide bear a label that states "It is a violation of federal law to use this product in a manner inconsistent with its labeling." 40 C.F.R. § 156.10(2)(ii).

[80] 59 Fed. Reg. 60496 (November 23, 1994). If a pesticide is found to pose an unreasonable adverse effect on the environment after it is registered and in commerce, FIFRA provides mechanisms for the cancellation of the pesticide registration, or in the case of imminent risk, for the immediate and temporary suspension of the registration. 7 U.S.C. §136d(b) (2006). EPA is authorized to cancel or suspend existing registrations based upon certain risk/benefit determinations. 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. *Id.* 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 imposition of additional labeling restrictions and/or classification of the pesticide for restricted use. *Id.* 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. 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. 7 U.S.C. §136d(c) (2006). Ordinary suspension is issued where such action is necessary to prevent an imminent hazard during the time required for cancellation proceeding. *Id.* "Imminent hazard" is defined as a substantial likelihood of serious harm during the duration of cancellation proceedings. 7 U.S.C. §136(l) (2006). 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. An emergency suspension order, which is effective immediately, may be issued if an emergency exists that does not permit even an expedited hearing

meaningful if the organism that produces the pesticide can reproduce and spread in the environment beyond those geographical limits. Similarly, other use restrictions (e.g., "Do not use within 100 feet of a stream, river, or lake") may not be particularly useful if seeds from plants that produce the pesticide are saved and planted during subsequent growing seasons. Such seeds would not be labeled, and it is at least possible that farmers using these seeds would not even be aware that the seeds were from plants that had been engineered to produce a pesticide.

To date, EPA's regulation of GMOs has focused on three categories: 1) the regulation under FIFRA and FFDCA of genetically modified microbial organisms that have pesticidal characteristics; 2) the regulation under FIFRA and FFDCA of genetically modified plants that have pesticidal characteristics; and 3) the regulation under TSCA of genetically modified microorganisms that do not have pesticidal characteristics. EPA does not yet have any rules governing GM animals.

Currently, EPA regulates pesticidal GMOs under FIFRA in much the same way as it does traditional chemical pesticides. [81] Thus, for pesticidal GMOs, EPA uses its authority under FIFRA to regulate the "pesticide," rather than targeting regulation at the process by which the pesticide is created.[82] 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."[83] This definition is very broad and can include living organisms and substances produced by living organisms as well as traditional chemical pesticides. EPA has interpreted this definition to include pesticidal GMOs. Thus, pesticidal GMOs must be registered under FIFRA prior to sale or distribution in the United States. The standard for registration is the same for pesticidal GMOs as for traditional chemicals.

During the 1990s, EPA attempted to develop a comprehensive regulatory program for GMOs. Unfortunately, these efforts met with controversy, political pressure, scientific uncertainty, and bureaucratic delay, which together resulted in regulations for GMOs with very modest effect. The first EPA GMO final rule was the 1994 final rule on the regulation of GM microorganisms under FIFRA.[84] The other significant final regulation was the July 19, 2001 rule for the regulation of GM pesticidal plants, which EPA currently calls "plant-incorporated protectants," under FIFRA.[85] Each of these rules took approximately 10 years to develop. Countless public hearings, scientific advisory council meetings, Congressional hearings and interagency negotiations were held. Despite all of these efforts, however, the resultant rules are quite modest and do not really

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before suspension takes place. 7 U.S.C. §136d(c) (2006). FIFRA also authorizes EPA to order a recall of unused pesticide as part of a cancellation. 7 U.S.C. §136k (2006).

[81] *See* Angelo, *supra* note 41 at 174.

[82] *See* Angelo, *supra* note 41 at n. 328.

[83] 7 U.S.C. §136(u) (2006).

[84] 59 Fed. Reg. 45611 (Sept. 1, 1994).

[85] 66 Fed. Reg. 37814 (July 19, 2001).

tackle the complex and novel risks of GMOs. The thrust of the rules is to define the scope of regulation – i.e., to outline what types of pesticidal GMOs EPA believes warrant regulation based on risk/benefit considerations. Under the rules many pesticidal GMOs are not subject to regulation at all because EPA believes they pose a low potential for risk to humans and/or the environment. The rules do not, however, impose any new approaches to regulating pesticidal GMOs. Instead, at least for the foreseeable future, EPA has chosen to rely on the old standby of FIFRA regulation, with the cost/benefit analysis leading to the label restriction.

1. Microbial GM Pesticides Under FIFRA

The first category of pesticidal GMOs regulated by EPA under FIFRA was microbial GMOs. EPA had regulated naturally occurring microbial pesticides, such as *B.t.*, for many years.[86] In the early 1980s, when the pesticide industry began to develop microorganisms that had been genetically modified to impart or enhance a pesticidal characteristic, EPA began to regulate these organisms. Microbial pesticides are regulated in much the same way as traditional pesticides at the large-scale testing and registration stages. However, with regard to small-scale testing of microbials, EPA expressed concerns regarding the potential for adverse effects. Small-scale testing of most traditional pesticides is generally considered to pose very limited risks and thus, is typically not regulated by EPA. Because microbial pesticides are living organisms that have the potential to reproduce and spread in the environment, even small-scale testing can present unreasonable adverse effects on the environment.[87] Thus, EPA promulgated a rule that requires notification prior to any small-scale testing of certain microbial pesticides, including microbial GMOs.[88] Section 5 of FIFRA [89] authorizes EPA to issue experimental use permits (EUP's) for the testing of new pesticides or new uses of existing pesticides. Under EPA's existing regulations at 40 CFR Part 172, EUP's are generally issued for large-scale testing of pesticides.[90] A large-scale test under Part 172 includes any terrestrial application on a cumulative acreage of more than 10 acres of land or any aquatic application on more that 1 acre of surface water.[91] For traditional pesticides, EPA presumes that tests conducted on 10 acres or less of land or 1 acre or less of water

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86. Although *B.t.* was first registered by EPA for use as a pesticide in 1959, it was not the first microbe to be used as a pesticide. Between 1939 and 1951, another bacterium, *Bacillus popilliae*, an obligate bacterial pathogen that causes a milky disease in the larvae of the Japanese beetle and other scarab beetles, was used in 14 eastern states and the District of Columbia. *See* R.E. PFADT, FUNDAMENTALS OF APPLIED ENTOMOLOGY 239 (3rd Ed. 1978).

87 *See* 59 Fed. Reg. 45,600 (1994) (codified at 40 C.F.R. § 172).

88 40 C.F.R. §172.45 (2006).

89. 7 U.S.C. § 136(c) provides that the Administrator may issue an EUP only if she determines that the applicant needs such a permit to accumulate information necessary to register a pesticide under section 3 of FIFRA.

90 40 C.F.R. §172.3 (2006).

91 *Id.*

("small-scale tests") would not require EUP's. For certain GM microorganisms, however, EPA determined that even scale tests warrant an evaluation.[92]

After almost ten years of deliberation and a series of EPA and federal government-wide policy statements that were made available to EPA's Scientific Advisory Panel (SAP) [93] and the Biotechnology Science Advisory Committee (BSAC), [94] on September 1, 1994, EPA promulgated the final rule on experimental use permits and notifications for genetically modified pesticidal microorganisms.[95] The rule codifies the early screening procedure first set forth in the Coordinated Framework by requiring notification before the initiation of small-scale field testing of certain microbial pesticides in order to determine whether an EUP is necessary.[96]

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[92] In October 1984, EPA published a policy statement entitled "Microbial Pesticides: Interim Policy on Small Scale Field Testing. 49 Fed. Reg. 40,659 (Oct. 17, 1984). In June 1986, EPA reiterated the provisions of the Interim Policy Statement as part of the Office of Science and Technology Policy's Coordinated Framework for Regulation of Biotechnology. 51 Fed. Reg. 23,313 (June 26, 1986). These policy statements described EPA's concern about the potential for adverse effects associated with small-scale environmental testing of certain microbial pesticides. To address the situation, these statements specified that EPA be notified prior to initiation of small-scale testing of all non-indigenous and genetically modified microbial pesticides. The purpose of the notification was to allow EPA to conduct an assessment of these small-scale tests in order to make a determination as to whether or not the test should be carried out under an EUP that allows EPA oversight. In addition, the 1986 Policy stated EPA's plan for future rulemaking to codify the interpretation set out in the policy. Subsequent to the issuance of the 1986 Policy, a number of documents were issued by EPA or other parts of the federal government having relevance to this final rule, including: a Federal Register notice issued by EPA in February 1989 (54 Fed. Reg. 7026), requesting comment on issues related to this final rule; Federal Register notices issued by the Office of Science and Technology Policy (OSTP) in July 1990 (55 Fed. Reg. 31118) and February 1992 (57 Fed. Reg. 6753) that addressed issues relating to the appropriate scope of federal oversight of introduction into the environment of modified organisms; and a "Report on National Biotechnology Policy" issued in February 1991 by the Council on Competitiveness. In addition, EPA made available to the public and to its FIFRA Scientific Advisory Panel (SAP) and Biotechnology Science Advisory Committee (BSAC) several draft proposals addressing the notification scheme for small-scale testing of certain genetically modified microbial pesticides.

[93] FIFRA section 25(d) requires EPA to submit draft proposed and final rules to an advisory panel, the SAP, for comment as to the impact on health and the environment of the rules. 7 U.S.C. § 136w(d). The comments, evaluations, and recommendations of the SAP, and the response of the EPA Administrator, must be published in the Federal Register. *Id.* Section 25(d) permits the chairperson of the panel, after consultation with the Administrator, to create temporary subpanels on specific projects to assist the full panel. *Id.* Because of the unique issues associated with the regulation of biotechnology, specialized SAP subpanels have been convened from time to time to address biotechnology matters.

[94] In the 1986 Coordinated Framework, EPA announced that it was establishing a Science Advisory Committee for biotechnology to provide peer review of specific product submissions under FIFRA, TSCA, and other EPA statutes and scientific oversight of the Agency's biotechnology programs. *See* Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. at 23,318.

[95] Microbial Pesticides, Experimental Use Permits and Notifications, 59 Fed. Reg. 45600 (September 1, 1994) (hereinafter Microbial Pesticides Rule). The proposed rule, Microbial Pesticides; Experimental Use Permits and Notifications, can be found at 58 Fed. Reg. 5878 (Jan. 22, 1993) (hereinafter Microbial Pesticides Proposed Rule).

[96] Microbial Pesticides Rule, *supra* note 95. Under the rule, testing conducted in facilities designed and

The most controversial issue that arose during the lengthy development of this rule was the appropriate scope of regulation. EPA decided to require notification for "microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified."[97] In other words, EPA rejected a "product" based scope of regulation in favor of a "process" based one.[98] By defining the regulated organisms as those whose genetic material had been "deliberately modified," EPA was drawing a regulatory line between microorganisms that had not been genetically modified and those that had, regardless of the resulting product.

One other issue that was somewhat controversial was whether EPA should require notification for "non-indigenous" microbial pesticides. Under the 1984 Policy Statement and the 1986 Coordinated Framework, EPA had been requiring notifications to be

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operated to adequately contain the microbial pesticide would not be subject to the notification requirements. *Id.* Records describing containment, however, would be required to be developed and maintained. *Id.*

[97] 58 Fed. Reg. 5882 (1993). In the proposed rule, EPA had identified three options for defining the scope of genetically modified microbial pesticides subject to notification requirements. Microbial Pesticides Rule, *supra* note 95. EPA's preferred option provided the most clear-cut scope of regulation. This is the definition of scope EPA developed based on comments from the public in response to earlier Federal Register announcements, the SAP subpanel, the BSAC, and other agencies including USDA. The Agency preferred this option because it believes this option covers the appropriate microbial pesticides and has a high degree of regulatory utility. Microbial Pesticides Proposed Rule, *supra* note 95. Option two was similar to option one because in both approaches EPA made the initial assessment of the potential risks presented by certain categories of microbial pesticides. Option two was based on the 1990 Office of Science and Technology (OSTP) policy statement, and read as follows: "Microbial pesticides that have been deliberately modified in hereditary traits with the exception of: 1) Microorganisms modified solely: a) Through chemical or physical mutagenesis; b) By the movement of nucleic acids using physiological processes including, but not limited to, transduction, transformation, or conjugation; or c) By plasmid loss or spontaneous deletion. 2) Organisms that have been modified by the introduction of noncoding, nonexpressed nucleotide sequences that cause no phenotypic or physiological changes in the parental organism. 3) Organisms resulting from a deletion, rearrangement, or amplification, within a single genome, including its extrachromosomal elements." 58 Fed. Reg. 5882 (1993).

In both Options one and two EPA directly indicated the pesticides that are included in the scope rather than leaving the risk determination up to the researcher. Option two is different than Option one in that it casts a somewhat different net of coverage. Option two was included in the proposal for illustrative purposes only; comment was not solicited on this option. Option three defined the scope of regulation as "Indigenous microbial pesticides for which specific pesticidal activities have been created or increased by deliberative processes or techniques." 58 Fed. Reg. 5883(1993). Option three is significantly different than Options one and two in that, although the initial scope of option three is much broader than the other options, it provides greater latitude on the part of the researcher to assess whether the Agency must be notified prior to small-scale environmental testing. Notification would not required for microbial pesticides whose pesticidal activities have been increased, but which are unlikely to pose a greater risk in the test site environment, or for microorganisms whose phenotype has been changed only by the microorganisms introduction into a new environment, but which are unlikely to pose a greater risk in the test site environment. 58 Fed. Reg. 5883 (1993).

[98] 58 Fed. Reg. 5878 (codified at 40 CFR Part 172).

submitted for all small-scale testing of non-indigenous organisms.[99] In the final rule, EPA opted to require small scale notification only for those non-indigenous microbial pesticides that have not been acted upon by the U.S. Department of Agriculture either by issuing or denying a permit or determining that a permit is unnecessary.[100] EPA based this decision on its belief that to do otherwise and continue the imposition of the notification requirement on all non-indigenous microbial pesticides would constitute duplicative oversight because the USDA/APHIS already regulates small-scale testing of the vast majority of these organisms.

The final rule also includes provisions that enable EPA to address situations where small-scale testing results in unanticipated and untoward effects. Section 172.57 requires persons using microbial pesticides in small-scale tests to submit any information they obtain concerning the potential for unreasonable adverse effects from the microbial pesticide,[101] and section 172.59 enables EPA to take immediate actions to prevent use of a microbial pesticide if such use would create an imminent threat of substantial harm to health or the environment.[102] Although EPA has developed some data requirements geared to address potential risks from microbial pesticides, in general,[103] EPA has not yet developed any data requirements targeted specifically to microbial GMOs.

2. GM Plant-Incorporated Protectants under FIFRA

Another category of pesticidal GMOs regulated by EPA under FIFRA are genetically modified pesticidal plants, or "plant-incorporated protectants" (PIPs)[104] In July 2001, EPA published its long-awaited rule for the regulation of PIPs under

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[99] Notice of Coordinated Framework, 49 Fed. Reg. 50, 856 (1984); Coordinated Framework, 51 Fed. Reg. 23,302 (June 26, 1986).

[100] 40 CFR § 172.45. The final rule also contains several provisions that were not very controversial and were not changed significantly from what was proposed. In the final rule, testing conducted in facilities designed and operated to adequately contain the microbial pesticide would not be subject to the notification requirements. *Id.* Records describing containment, however, would be required to be developed and maintained. *Id.*

[101] 40 CFR § 172.57

[102] 40 CFR § 172.59. The final rule also amends 40 CFR § 172.3 to clarify EPA's rationale for presuming that an EUP is not required prior to small-scale testing with most pesticides. The language of section 172.3 is modified to clarify that the determination of whether an EUP is required would be based on risk considerations, rather than on a definitional presumption about whether a substance is a pesticide. This clarification has general applicability to all pesticides and is not limited to microbial pesticides. 40 C.F.R. § 172 (2006).

[103] The data requirement for microbial pesticides can be found at 40 C.F.R. § 158.740 (2005). These data requirements parallel the requirements for traditional chemical pesticides and do not specifically address potential risks caused by living organisms reproducing and spreading in the environment. *Id.*

[104] A plant-incorporated protectant (PIP) 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. As is described infra, EPA also regulates PIPs in food pursuant to the FFDCA. *See infra* notes 125-128 & accompanying text.

FIFRA.[105] EPA initially proposed a version of what is now the PIP rule in 1994.[106] In the 1994 proposal, EPA identified several categories that it believed should be exempt from FIFRA regulation because they are low risk. The most significant proposed exemption was for PIPs that closely resemble plants that could be created naturally or through traditional plant breeding. EPA based this proposed exemption on the premise that new exposures would be unlikely if the genetic material leading to the production of the PIP is derived from a plant closely related to the recipient plant.[107] An example of this is using GM technology to insert a gene that is normally found in one variety of corn into another variety of corn. EPA posited that this type of GM plant would be exempt because it does not pose any new risks that would not have evolved naturally or through traditional breeding.[108] EPA presented three options for the exemption. All three options focused on the relationship between the source organisms and the recipient organisms. In other words, all three proposed options were based on the "product" rather than the "process" by which the product was created. Accordingly, in the proposed rule, no distinction was drawn between PIPs created through conventional plants breeding versus those created through genetic engineering.[109]

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[105] 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. EPA's first attempt to describe its plans to regulate PIPs 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," 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 PIPs, referred to as "plant-pesticides" in the 1994 proposal and later renamed plant-incorporated protectants, under FIFRA and FFDCA and, outline what types of PIPs EPA believed warranted regulation based on risk/benefit considerations. The final plant-incorporated protectant rule, promulgated in 2001, adopted some, but not all of the exemptions proposed in 1994. *See* 40 CFR Part 174. For an historical discussion of the Plant-Incorporated Protectant Rule, *see generally* Angelo, *supra* note 30.

[106] 59 Fed. Reg. 60,496 (November 23, 1994).

[107] 59 Fed. Reg. 60,496 (November 23, 1994).

[108] 40 C.F.R. § 174.25.

[109] EPA proposed three categories of exemptions based on EPA's proposed findings that plant pesticides in these categories did not warrant regulation either because they so closely resemble the types of plants that could be created through traditional plant breeding or that they had been found to be low risk. 59 Fed. Reg. 60496 (November 23, 1994). One category of pesticidal GMOs that EPA believed did not warrant regulation were plant that have been genetically modified to contain genes that are derived from closely related plants and thus will not cause new exposures to non-target organisms. Under this proposal, the *B.t.* delta-endotoxin would not be exempt when it is produced in corn, for example, because the delta-endotoxin is derived from a bacterium rather than from a plant that is closely related to corn. *Id.* A pesticidal substance that is naturally produced by a certain variety of corn and is introduced into another variety of corn, however, would be exempt. Another category that EPA proposed to exempt were those plant-pesticides that would not be expected to adversely affect non-target organisms because they are less likely to be directly toxic because of their mechanism of action. *Id* This category consists of plant-pesticides that

Between 1994 and 2001, when it published the final PIP rule, EPA held Countless public hearings, scientific advisory council meetings, congressional hearings, and interagency negotiations.[110] 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 merely defines the scope of what types of pesticidal GMOs EPA believes warrant regulation.[111] The final rule exempts PIPs from all FIFRA regulatory requirements, except for the requirement of reporting adverse effects information,[112] PIPs derived through conventional plant breeding if the genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible[113] with the recipient plant and if the genetic material has never been derived from a source that is not sexually compatible with the recipient plant. Because EPA has defined sexual compatibility as occurring only through conventional breeding, only conventionally bred crops are exempted from regulation.[114] In other words, in the 2001 final rule, EPA reject the "product-based" approach set forth in the 1994 proposed rule in favor of the "process-based" approach, which exempts PIPs based on the process by which they were created. If a PIP is developed through conventional plant breeding, it is exempt, whereas if the same PIP is developed through genetic engineering, it is subject to regulation. Thus, in the final rule, EPA departed from the

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act primarily by affecting the plant so that pests are inhibited from attaching to the plant, penetrating the plant's surface, or invading the plant's tissue. Under this proposed exemption, a substance that acts by causing a structural barrier to pest penetration in the plant would be exempt. The third category that EPA proposed to exempt were plants that have been GM to contain the genes for coat proteins from a plant virus. *Id* This type of GM acts essentially as a vaccine protecting the plant from viruses. EPA proposed these GMOs for exemption based on the fact that plant viruses are ubiquitous in the human food supply and are not known to cause any adverse affects to humans or the environment. *Id*

[110] 66 Fed. Reg. 37772 (2001).

[111] 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 PIPs within EPA's jurisdiction warrant regulation under FIFRA. EPA believes that many PIPs 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.

[112] The final rule requires any person who produces, for sale or distribution, a PIP exempt under the rule, who obtains information regarding adverse effects on human health or the environment alleged to have been caused by the PIP, to submit such information to EPA. 40 C.F.R. § 174.71.

[113] EPA defines the term "sexually compatible" "as a viable zygoteis formed only through the union of two gametes through conventional breeding." 40 C.F.R. § 174.3.

[114] EPA's rationale for exempting the products of conventional plant breeding from FIFRA requirements is that conventionally bred plant varieties have been used by humans for thousands of years without ill effects. Because conventional breeding can only take place between plants that are sexually comparable, it is likely that such plants already share, or have shared in the past, genetic material, and therefore, exposure to the new plant variety whether by humans or non-target organisms will not likely be novel. 66 Fed. Reg. 37794-95 (July 19, 2001).

"product-based" approach articulated in the Coordinated Framework in favor of the "process-based" approach that the U.S. government had steadfastly avoided in the 1980s and 1990s.[115] The scaling-back of the exemption was in response to public comments received on the proposal, as well as to a joint FIFRA SAP and BSAC meeting held in January, 1994, in which the joint panel considered the and supported the use of an exemption criteria based on the technology (i.e., process) used to produce the PIP.[116] The joint panel based its support on a combination of the uncertainties about how genes would function in the new genetic background and building public confidence in the products of genetic engineering.

On the same day as the final PIP rule was published, EPA published a request for additional comment on the exemptions it proposed in 1994.[117] Specifically, EPA solicited comment on the two alternative approaches to PIPs derived from plants sexually compatible with the recipient plant: 1) whether all PIPs derived should be exempt regardless of the technique used to introduce the PIP into the plant; and 2) whether EPA should establish a notification process that would implement a screening procedure to determine whether a PIP derived through genetic engineering from a plant sexually compatible with the recipient qualifies for exemption.[118] To date, EPA has not taken any action on either of the two alternative approaches for which it sought additional comment in 2001.[119]

Accordingly, EPA's final PIP rule merely draws a line between PIPs subject to regulation and those not subject to regulation under FIFRA.[120] The rule does not provide any provisions detailing how a PIP will be evaluated and regulated under FIFRA. Once it is determined that a substance is a pesticidal GMO subject to FIFRA regulation, the regulatory process is similar to, with only very minor modifications, the regulatory process for all pesticides – i.e., registration based on a cost/benefit analysis, labeling restrictions on use, and cancellation or suspension for registered GMOs found to pose unreasonable adverse affects. As described above, many of the risks posed by GMOs are of a different character than those posed by traditional chemical pesticides. Accordingly, existing FIFRA data requirements, labeling requirements, and regulatory approaches are not adequate to address these risks. [121] E PA has not yet developed any data requirements whatsoever for GM pesticidal plants, nor has it adopted any regulations addressing information requirements to support registration,[122] product labeling requirement,[123] or experimental use permitting for PIPs.[124] In the absence of any such new requirements,

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[115] 40 CFR § 152.20.
[116] 66 Fed. Reg. 37855, 37857-58 (July 19, 2001).
[117] 66 Fed. Reg. 37855 (July 19, 2001).
[118] 66 Fed. Reg. 37858-60 (July 19, 2001).
[119] Personal correspondence with Laurel Celeste, EPA Attorney, on May 23, 2006.
[120] 66 Fed. Reg. 37772 (2001).
[121] *See generally,* 66 Fed. Reg. 37772 (2001).
[122] 40 C.F.R. § 174 Subpart H (reserving a subpart for future data requirements).
[123] 40 C.F.R. § 174 Subpart G (reserving a subpart for future labeling requirements).
[124] 40 C.F.R. § 174 Subpart U (reserving a subpart for future experiment use permit requirements).

EPA relies on existing requirements that were crafted for traditional chemical pesticides to GM plants, regardless of the poor fit with GMOs.

3. GM Pesticides in Food Under the FFDCA

In addition to regulating pesticides under FIFRA, EPA is responsible for regulating pesticide residues in human food or animal feed under the Federal Food, Drug, and Cosmetic Act (FFDCA).[125] Pursuant to section 408(a) of the FFDCA, a pesticide chemical residue in or on food is not considered to be safe unless EPA has issued a tolerance for such residue and the residue is within the tolerance limits.[126] EPA may issue an exemption from the requirements of a tolerance if EPA determines that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.[127] In the 2001 final PIP rule, EPA adopted an exemption under this standard. As with the FIFRA PIP exemptions, EPA's FFDCA exemption for PIPs focuses on sexual compatibility through conventional breeding. [128]

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[125] 21 U.S.C. § 346. The Reorganization Plan No. 3 of 1970, which created EPA, granted EPA authority to establish tolerances for residues of pesticide chemicals in foods and animal feeds. Reorganization Plan No. 3 of 1970, 3 C.F.R. at 199 (1970 Comp.), *reprinted in* 5 U.S.C. app. 1 Reorg. Plan 3 1970 and in 84 Stat. 2086. Regulatory authority over other non-pesticidal substances in foods and animal feeds was left within the jurisdiction of the Food and Drug Administration.

[126] 21 U.S.C. § 346a(a)(1).

[127] 21 U.S.C., § 346a(c)(2)(A).

[128] 40 C.F.R. § 174.479. This exemption provides: "Residues of a pesticidal substance that is part of a plant-incorporated protestant from a sexually compatible plant are exempt from the requirement of a tolerance if all the following conditions are met: (a) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient food plant. (b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant. (c) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health." In addition, EPA has exempted from the tolerance requirement nucleic acids that are part of PIPs. In addition, EPA exempted inert ingredients from sexually compatible plants. 40 C.F.R. §174.485. This exemption provides: "An inert ingredient, and residues of the inert ingredient, are exempt if all of the following conditions are met: (a) The genetic material that encodes the inert ingredient or leads to the production of the inert ingredient is derived from a plant sexually compatible with the recipient food plant. (b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant. (c) The resides of the inert ingredient are not present in food form the plant at levels that are injurious or deleterious to human health." "Inert ingredient" is defined as "any substance, such as a selectable marker, other than the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient, and includes the genetic material necessary for the production of the substance, provided that genetic material is intentionally introduced into a living plant in addition to the active ingredient." 40 C.F.R. § 174.3. EPA has also exempted from the tolerance requirement. And has o exempted from the requirements the residues of certain *B.t.* in specified crop foods. 40 C.F.R. §§ 174.455 & 174.456 (exempting from the requirement for a tolerance *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production in cotton and *Bacillus thuringiensis* modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn, respectively).

4. Non-Pesticidal GMOs Under TSCA

In addition to regulating biotechnology products that act as pesticides under FIFRA and FFDCA, EPA also has authority to regulate GMOs under the Toxic Substances Control Act (TSCA).[129] The regulatory jurisdiction under TSCA extends to all chemical substances, which are defined as "organic or inorganic substances of a particular molecular identity, including . . . any combination of such substances occurring in whole or part as a result of a chemical reaction or occurring in nature," but excluding pesticides.[130] EPA has interpreted this broad definition of chemical substances to include living organisms.[131] Under section 5 of TSCA, all new chemical substances are automatically covered and subject to a 90 day screening mechanism, known as a Pre-Manufacture Notification (PMN).[132] Upon receiving a PMN for a new chemical substance, EPA has 90 days to perform screening to determine whether it is necessary to impose controls to prevent unreasonable risk or substantial exposure to the chemical.[133] If EPA fails to take action within the 90-day period, the new chemical substance may be manufactured, processed, distributed, sold, used, or disposed.[134]

In 1997, EPA adopted a final rule governing pre-manufacture review under TSCA section 5 of certain genetically modified microorganisms. The rule defines a "new" microorganism to be one formed by the deliberate combination of genetic material from source organisms classified in different taxonomic genera, that is not on the TSCA inventory.[135] EPA's interpretation is that any genetic modification of a microorganism where genetic material from an organism in one genus is inserted into an organism from a different genus is a "new" microorganism subject to the TSCA section 5 requirements.[136] The rationale behind this interpretation is that intergeneric microorganisms have significant potential for exhibiting new traits or combinations of traits.[137] Thus, these

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[129] 15 U.S.C. §2601, et al. (2006).

[130] 15 U.S.C. §2602(2)(A) (2006). Certain substances are by statute explicitly excluded from TSCA jurisdiction. These are substances that are covered by other regulatory authorities, such as food, drugs, cosmetics, firearms, and pesticides. 15 U.S.C. §2602(2)(B).

[131] 40 C.F.R Part 710. EPA's interpretation is that living organisms whether natural occurring or genetically modified are made up of a combination of substances of particular identities that occur in nature or occur in whole or part as a result of a chemical reaction. Accordingly EPA has treated living organisms as chemical substances under TSCA.

[132] 15 U.S.C. §2604(a) (2006).

[133] 15 U.S.C. §2604(a).

[134] 15 U.S.C. §2604(a).

[135] 40 C.F.R. § 725.3 (2006).

[136] As with the microbial pesticides under FIFRA, one of the most significant issues surrounding the regulation of biotechnology products under TSCA is the issue of the appropriate scope of regulation. EPA first announced its interpretation that a "new" microorganism is an intergeneric microorganism in the 1986 Coordinated Framework. *See* Coordinated Framework, *supra* note 57.

[137]. By using "intergeneric" as the definition of a new microorganism, EPA was abiding by the principles articulated in the Coordinated Framework to focus regulations on product rather than the process by which the

organisms have the potential to result in new types of risks in the environment. Such "new" microorganisms could include microorganism used commercially for such purposes as: production of industrial enzymes and other specialty chemicals; non-pesticidal agricultural practices (e.g. biofertilizers); and break-down of chemical pollutants in the environment. The rule creates a reporting vehicle designed specifically for new microorganisms called the Microbial Commercial Activity Notice (MCAN).[138] An MCAN must be submitted at least 90 days prior to the use of intergeneric microorganisms for commercial purposes in the United States, providing EPA with a 90-day opportunity to review the new genetically modified organism to determine whether additional regulations is necessary to prevent unreasonable risks or substantial exposure.[139]

Although EPA has established the MCAN notification processes for intergeneric microorganism, it has not promulgated any rules addressing how to evaluate or reduce risks from such organisms. Neither has EPA promulgated any rules addressing genetically modified plants or animals under TSCA. Nevertheless, EPA has repeatedly stated that it intends to address TSCA oversight of transgenic[140] plants and other organisms.[141] EPA has not provided a specific timetable for developing such

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product was created. Announcement of Policy, 51 Fed. Reg. 23,302 (June 26, 1986). In other words, all intergeneric microorganisms are subject to the regulation regardless of whether they were created by genetic engineering or some other process.

[138] 40 C.F.R. § 725.30 (2006).

[139] 40 C.F.R. § 725.50 (2006). The rules also addresses intergeneric microorganisms used in research and development for commercial purposes and creates a requirement for reporting on testing new microorganisms in the environment. 40 C.F.R. § 725.1 (2006). This requirement is referred to as the TSCA Experimental Release Application (TERA). *Id.* A TERA must be submitted at least 60 days prior to initiating such field trial. 40 C.F.R. §725.250 (2006). The TERA provides a shorter review period than the MCAN to provide more flexibility to researchers conducting limited field testing. *Id.* TSCA section 5(h) provides certain exemptions from the Premaufacture Notice (PMN) screening process. The sections most applicable to intergeneric microorganisms are sections 5(h)(3) and (5)(h)(4). 15 U.S.C. §2604(h)(3); 15 U.S.C. §2604(h)(4). Section 5(h)(3) exempts substances manufactured or processed only in "small quantities" for research and development (R&D) from PMN requirements. 15 U.S.C. §2604(h)(3). TSCA section 5(h)(4) authorizes EPA to exempt by rule the manufacture of any new chemical substance if EPA determines that use of such substance will not present an unreasonable risk of injury to health or the environment. 15 U.S.C. §2604(h)(4). TSCA §5(h) provides exemptions from PMN screening. In addition, the rule exempts from MCAN requirements intergeneric microorganism used in research and development in contained structures provided adequate containment requirements are met and researcher maintain records. 40 C.F.R. § 725.428 (2006).

[140] The term "transgenic" refers to an organism created through genetic engineering by moving a gene from one organism to another.

[141] TSCA Policy Statement on Oversight of Transgenic Organisms (Including Plants), 70 Fed. Reg. 27625, 27629 (May 16, 2005). EPA stated that recent information suggests that transgenic plants and other organisms are being developed for uses which appear to be subject to TSCA jurisdiction. *Id.* EPA provided examples such as plants that are being genetically modified to produce industrial grade oils. *Id.* EPA noted that while many of these plants are subject to oversight by the USDA's Animal and Plant Health Inspection Service (APHIS), while being tested in the environment following APHIS approval of a

regulation.[142]

B. Food and Drug Administration Authority

FDA's primary authority governing the regulation of genetically modified foods is found in section 402(a) (2) C of the FFDCA.[143] This section provides that a food shall be deemed adulterated if it contains any food additives that is unsafe within the meaning of section 409.[144] Section 409 provides that a food additive is deemed unsafe unless the additive and its use or intended use complies with a properly promulgated food additive regulation.[145] The statute defines the term food additive to mean any substance that is intended for use in or which may be reasonably expected to become a component of or otherwise affect the characteristics of any food, provided the substance "is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1st, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use . . . ."[146] Accordingly, commonly used natural substances that are added to foods, such as spices, in addition to certain chemical additives, are not considered food additives because they are considered to be generally recognized as safe (GRAS).[147]

In 1992 FDA published a policy statement on "foods derived from new plant varieties."[148] This policy provided guidance on how FDA would treat genetically modified foods in the regulatory process. The policy included within the definition of "genetic modification" alterations of the genotype that occurred using any technique, whether conventional plant breeding or new biotechnology techniques.[149] Thus, under this definition virtually all cultivated food crops were considered to be genetically modified.[150] This approach of treating all cultivated food crops as genetically modified regardless of the process used to modify them is consistent with the coordinated

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petition for non-regulated status these plants cease to be subject to regulation by USDA. *Id.* Moreover, EPA notes that transgenic animals that are not under the jurisdiction of the Food and Drug Administration appear to be subject to TSCA. *Id.* The policy statement would address whether EPA should exercise jurisdiction under TSCA over such transgenic organisms prior to their commercial use. 70 Fed. Reg. 27625, 27629 (May 16, 2005).

[142] *Id.*

[143] 21 U.S.C. §301, et seq. Pursuant to the Reorganization Plan No. 3 of 1970, FDA is responsible for the regulation of residues in food other than pesticide residues, which are regulated by EPA. *See supra* note 125-128 and accompanying text.

[144] 21 U.S.C. §342(a)(2)(C).

[145] 21 U.S.C. §348

[146] 21 U.S.C. §321(S)

[147] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (May 1992).

[148] *Id.*

[149] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,984.

[150] *Id.* at 22,984.

framework stated policy choice of regulating products rather than process.[151] However, the 1992 policy went further, establishing what is in essence a presumptive GRAS status to genetically modified foods as well as conventionally bred foods.[152] This presumption was based on FDA's conviction that, based on its experience, the likelihood of a significant risk from a genetically modified food is very low.[153] FDA believes that the traditional approach used by conventional crop breeders to insure food safety has been successful in the past in identifying and eliminating food crops that exhibited unexpected, adverse traits prior to commercial use and that such processes would sufficiently screen out potentially risky genetically modified foods.[154] The 1992 policy statement explained that FDA believed that "in most cases, the substances expected to become components of food as a result of genetic modification will be the same as or substantially similar to substances commonly found in food, such as proteins, fats and oils, and carbohydrates . . . " and would thus qualify as generally recognized as safe.[155] FDA did acknowledge that some GM foods would not qualify as GRAS, including those that involve the transfer of genes coding for substances that can cause allergenic responses in humans, those that are known to be toxic, or those that are likely to become a macroconstituent in the human or animal diet, thereby affecting the nutritional value of GM foods.[156] FDA's position is, in essence, that if the GM food is "substantially equivalent" to a food product already in the human food supply with a history of safe use, the GM food will, in the vast majority of cases, be safe, and therefore, no premarket evaluation of the safety of the GM food is necessary.[157] Nevertheless, FDA leaves it up to the producer of the new plant variety to determine the GRAS status of its product.[158] Thus, FDA's approach to regulating GM foods is to establish a presumption of safety and to leave it to the food producer, on a voluntary basis, to determine whether it is necessary to seek out FDA review of the safety of their product prior to introducing the product into the market. This decision has been controversial, and, in light of such controversy, in 2001 FDA published proposed regulations which would require manufacturers and importers of genetically modified food to provide FDA with pre-market notification of their intent to market genetically modified foods.[159] To date, FDA has not taken final action on this proposal.

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[151] *See* Coordinated Framework, *supra* note 57 and accompanying text.
[152] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22990.
[153] *Id.* at 22,989.
[154] Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22991.
[155] *Id.* at 22985.
[156] *Id.* at 23000.
[157] For a full discussion of the substantial equivalency doctrine, *see generally* Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 UNIV. OF MICH. J.L. REFORM 403 (2002).
[158] Statement of Policy: Foods Derived From New Plants Varieties, 57 Fed. Reg. at 22985.
[159] Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,706-01 (Jan, 2001). In the January 2001 Federal Register, FDA proposed to require the submission of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals at least 120 days prior to the commercial distribution of such foods. *Id.* FDA stated that it was proposing this action to "ensure that it has the appropriate amount of information" and to "permit the agency to assess on an ongoing basis

Currently, FDA stands alone as the only federal agency following the policy of the Coordinated Framework to regulate based on product rather than process. FDA's 1992 policy does not distinguish based on the techniques used to produce the new plant variety. Instead, it relies on the standard of substantial equivalency, which applies equally to conventionally bred plant varieties and genetically engineered plant varieties. As described above, the lack of even pre-market notification had been widely criticized by those who believe that human health cannot be adequately protected without at least some level of evaluation of risk presented by new GM foods.

C. U.S. Department of Agriculture Authority

1. GMOs Under the Plant Protection Act

The USDA's Animal and Plant Health Inspection Service (APHIS) has authority to regulate GMOs pursuant to the Plant Protection Act (PPA).[160] APHIS' mandate under the PPA is to prevent the release and spread in the environment of "plant pests," which are defined broadly as organisms which can directly or indirectly injure or cause disease or damage in or to any plants or plant parts.[161] In 1993 APHIS published a final rule amendment to the regulations pertaining to the introduction of certain genetically engineered organisms and products to provide for a notification process prior to the introduction of certain GMOs.[162] APHIS also amended the regulation to provide for a petition process allowing for determination that certain GMOs are no longer considered "regulated articles,"[163] APHIS' term for GMOs that pose potential plant pest risk. In the

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whether plant-derived bioengineered foods comply with the standards of the Federal Food, Drug, and Cosmetic Act." *Id.* In the Federal Register notice, FDA stated that the scientific community generally supports the regulatory approach articulated in FDA's 1992 policy but that the proposal is a response to the many consumers, public interest groups and some state officials that have expressed concern regarding the lack of a requirement for pre-market review. *Id.* at 4707. However, to date, FDA has not published a final rule addressing pre-market review.

[160] 7 U.S.C. 7701-7772. The 2000 Plant Protection Act consolidated the authorities of two previously existing statutes under which APHIS asserted its regulatory jurisdiction over GMOs, the Plant Pest Act, 7 U.S.C. 150aa-150jj (1994) and the Plant Quarantine Act, 7 U.S.C. 151-164, 166-167 (1994).

[161] 40 C.F.R. § 340.1.

[162] 58 Fed. Reg. 17044 (March 31, 1993). The final rule was the outgrowth of a 1992 proposed rule. 57 Fed. Reg. 53,036 (Nov. 6, 1992). The final rule followed the basic design of the proposed rule, with some modifications based on comments received.

[163] *Id.* The term "regulated article" is defined as "[a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organisms, or vector or vector agent belongs to any genera or taxa designated in s 340.2 and meets the definition or plant pest, or is an unclassified organism and/or organisms whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Director, BBEP, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from, a donor organisms where the material is well characterized and contains only non-coding regulatory regions." 7 C.F.R. § 340.1.

final rule, APHIS stated that it believed these actions would relieve unnecessary restrictions on the introduction of regulated articles based on experience.[164] The notification procedure is allowed for the introduction of most genetically modified plants that are considered regulated articles, provided that the introduction is conducted in accordance with specified eligibility requirements and performance standards.[165] This would alleviate the need to obtain a permit prior to the introduction of those regulated articles. The stated rationale for replacing permitting for most regulated articles with notification is that APHIS believes that the notification process is sufficient for many regulated articles, based on the considerable experience APHIS gained in permitting genetically modified plants since it established its permitting process for regulated articles in 1987.[166] APHIS stated that it had issued over 300 permits for field tests and over 1000 permits for the movement of regulated articles.[167] Based on this experience, APHIS stated that it has determined that introduction of many regulated articles can be conducted with little or no plant pest or environmental risk.[168]

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[164] *Id.*

[165] Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status 57 Fed. Reg. 53,036-53,037 (Nov. 6, 1992).

[166] *Id.* at 53,036

[167] Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. at 53,036. By 2001, USDA had issued 1117 field test authorizations for more than 57,0000 acres of GM crop field testing. 67 Fed. Reg. 50578.

[168] Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. at 53,036. To qualify for the notification process, six eligibility requirements must be met. The regulated article must be: 1) one of a list of plants species which includes corn, cotton, potato, soy bean, tobacco, tomato or any additional plant species that APHIS has determined may be safely introduced in accordance with the performance standards; 2) the introduced genetic material is "stably integrated" in the plant genome; 3) the introduced genetic material is well characterized and does not contain genes whose expressions in the regulated article result in plant disease; 4) the introduced genetic material does not cause the production of an infectious entity or result in constituents that are new to the plant and are toxic to non target organisms; 5) the introduced genetic material does not pose a significant risk of the creation of any new plant virus; and 6) the plant has not been modified to contain functionally intact genes derived from human or animal pathogens. 7 C.F.R. § 340.3(b) (2006). The performance standards for introductions under the notification procedure include a number of requirements designed to prevent unintentional spread of the regulated article's genetic material in the environment. 7 C.F.R. § 340.3(c). These requirements are geared toward containing the spread of the organisms during field testing, but are not applicable to commercial release of the organism into the environment. The performance standard requirements include: 1) requirements that plants or plant materials be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit; 2) that when released into the environment the regulated article plant must be planted in such a way that it is not inadvertently mixed with non-regulated plant materials which are not part of the environmental release; 3) that the plant and plant parts must be maintained in such way that the identity of all material is known while it is in use; and 4) that the plants parts must be contained or devitalized when no longer in use, that there must be no viable vector agent associated with the regulated article, that when there is a significant probability that gene movement of the regulated article via pollen will result in viable progeny persisting in the environment such movement must be minimized, and upon

For releases into the environment beyond controlled field testing, APHIS adopted a final rule which established a process for petitioning to determine non-regulated status.[169] For any organism for which such a petition is granted, that organism is no longer considered a "regulated article," and therefore, is exempt for all APHIS regulation.[170] The petitioner must supply certain data regarding the organisms, including field test data.[171] APHIS then reviews the data for potential "plant pest" risk.[172] Plant pest risk is direct or indirect injury, damage to, or disease in any plant or plant product.[173] If APHIS determines the organism poses no plant pest risk, it will grant the petition and the organism will be exempt form APHIS regulation.[174]

As with EPA's GMO regulation to date, APHIS' regulations focus on which GMOs require submission of notification prior to field testing and which GMOs are completely exempt from APHIS regulatory oversight. APHIS' regulations do not address how to regulate GMOs that are released into the environment to minimize environmental risk. Moreover, APHIS' focus on plant pest risk does not adequately address the other types of unique risks that may be posed by GMOs.

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termination of the field tests, no viable material shall remain which is likely to volunteer in subsequent seasons, or volunteers shall be managed to prevent persistence in the environment. 7 C.F.R. § 340.3(c).

[169] 7 C.F.R. § 340.6 (2006).

[170] *Id.*

[171] *Id.*

[172] A process for publication in the federal register and public comment is provided. 7 C.F.R. § 340.6(2)(d).

[173] The term "plant pest" means: "any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:

(A) A protozoan.

(B) A nonhuman animal.

(C) A parasitic plant.

(D) A bacterium.

(E) A fungus.

(F) A virus or viroid.

(G) An infectious agent or other pathogen.

(H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs."

7 U.S.C. 7702(14). Although the term "plant pest" is not defined to include organisms that cause harm to human health or environmental health in general, the 2000 PPA extended the authority of USDA to consider human health and broad environmental harm. The PPA gives USA the authority to prohibit or restrict the importation, exportation and interstate movement of plants, plant products, certain biological control agents, *noxious weeds* and plant pests. The term "noxious weed" means: "any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the *public health, or the environment*." 7 U.S.C. 7702(10). (emphasis provided).

[174] APHIS retains the authority to "reregulate" the organisms if it becomes a plant pest in the future. Organisms exempt from APHIS regulation may still be subject to EPA or FDA regulation.

2. Non-Indigenous Organisms Under the PPA

In addition to its regulations addressing GMOs, in1995, under the authority of the PPA, APHIS published a proposed rule in the federal register relating to the introduction of non-indigenous organisms into the environment.[175] The proposal would establish comprehensive regulations on the importation, interstate movement and release into the environment of certain non-indigenous organisms.[176] APHIS stated that it believed this action was necessary because the plant pest regulations under which the movement of certain non-indigenous organisms were regulated at the time did not adequately address the introduction of the non-indigenous organisms that may potentially be plant pests.[177]

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[175] Introduction of Non-Indigenous Species, 60 Fed. Reg. 5,288 (Jan. 26, 1995) (to be codified at C.F.R. part. 305).

[176] *Id.*

[177] *Id.* at 5,288. Exotic species are frequently called non-indigenous species. A common definition for exotic species are those "plants and animals found outsider their usual habitats." David J. Bederman, *International Control of Marine 'Pollution' by Exotic Species*, 18 ECOLOGY L.Q. 677, 678 (1991). Historically, U.S. regulation of non-indigenous species has been limited to a few federal acts which are limited in scope and effectiveness. See Eric Biber, Note, *Exploring Regulatory Options for Controlling the Introduction of Non-Indigenous Species to the United States*, 18 VA. ENVTL. L.J. 375, 396-405 (1999) (hereinafter *Regulatory Options for Control*); *see also* Daniel P. Larson, *Combating the Exotic Species Invasion: The Role of Tort Liability*, 5 DUKE ENVTL. L. & POL'Y F. 21, 34-36 (1995) (hereinafter *Invasion*). In addition to the PPA, the Lacey Act, prohibits the importation into the United States of any animal species that are designated as "injurious to human beings, to the interests of agriculture, horticulture, forestry, or to wildlife" by the Secretary of the Interior. 16 U.S.C. §3371-78 (2005); 18 U.S.C. §42(a)(1) (2005). Similarly, the previous iterations of the PPA, 7 U.S.C. § 147A, 149, 150AA-150JJ, the Federal Noxious Weed Act of 1974, 7 U.S.C. §2801-2814 (2005), and the Federal Seed Act, 7 U.S.C. §1551-1610 (2005) regulated the importation of exotic plant species. The current statutory system is inherently reactive. For example, the Lacey Act requires the Secretary of the Interior to classify exotic species as injurious once they have already been introduced to the particular ecological environment. *See* Steven A. Wade, *Stemming the Tide: A Plea for New Exotic Species Legislation*, 10 J. LAND USE & ENVTL. L. 343, 345-353 (1995). *See also* Biber, *Regulatory Options for Control* at 396-405. As such, attempts to limit or eliminate the risks posed by exotic species face a daunting task as the invasive species has already established itself as a prevalent nuisance in the particular ecosystem. *See* Larsen, *Invasion*, at 28-31. This approach, frequently labeled as the "dirty list" method, places the burden on the Secretary to show that the particular species is harmful before importation may be banned, thereby ensuring that the species in question can establish itself before a coordinated federal response can prevent the resulting damage in the species' new ecosystem. *Id.* at 28. Furthermore the Lacey Act only regulates *intentional* introductions of exotic species, which would not include the accidental introduction of species such the zebra mollusk, which has caused some of the most significant ecological damage. *Id.* at 29. While currently the Lacey Act only addresses intentionally introduced exotic species, authors proposing legislative reform have argued for including high-risk activities likely to lead to the introduction of exotic species. *See* Biber, *Regulatory Options for Control,* at 440. Legislative reform predicated on a "clean list approach" would place the burden on the introducer of the exotic species to show that the new species would not negatively affect the ecosystem. *Id.* at 465. In conjunction with the burden-shifting, further legislative reforms could include imposition of a strict liability standard for the release of any exotic species akin to CERCLA. *Id.* at 427-28 (noting however that such a strict liability standard should retain more flexibility than the CERCLA model so that insurance plans may be utilized to avoid the litigiousness inherent in CERCLA matters). *See* Larsen, *Invasion*, at 29.

The proposed regulations would provide a means of screening current non-indigenous organisms prior to their introduction to determine the potential plant pest risk associated with the particular introduction.[178] The pre-1995 regulations for non-indigenous organisms were limited to the movement of known plant pests and did not address the movement of non-indigenous organisms not previously known to present a plant pests risk or the release of such organisms into the environment.[179] A 1993 U.S. Congress Office of Technology Assessment (OTA) report cited the loss of billions of dollars due to the negative affects of certain non-indigenous organisms and suggested that APHIS should revise its regulation to more adequately address such risk.[180] Accordingly, under the 1995 proposed regulations, persons wishing to import or move interstate a regulated non-indigenous organisms would be required to obtain a permit from APHIS.[181] Under the proposal a regulated organism of concern would fall into one of the following categories: 1) an organism of foreign origin that is not present in the United States; 2) an organism of foreign origin that is present in the United States but is capable of further expansion beyond its present established range; and 3) an organism of foreign origin that has reached its full range of potential establishment in the United States but is sufficiently biologically different from the organism that is present in the United States to warrant concern.[182]

The new regulation also proposes data requirements to assess the plant pest and environmental risks involved in a proposed introduction. Information required to be provided as part of the permitting process would include a description of the life cycle, biology, and ecology of the regulated organism.[183] In addition, information must be provided on whether the regulated organism has been genetically modified, and if so, a description of the genetic modification must be provided.[184] If the regulated organism has been genetically modified through sexual recombination and selection for traits not typical of the organism in nature, through induced mutation and selection for special traits, or other classical techniques, APHIS would require a description of the modification in order to assess the biology of the modified regulated organism insofar as it differs from that of an unmodified organism of the same species.[185] If, on the other hand, recombinant DNA techniques have been used to affect the modification the permit application would be handled under the regulations for the genetically modified organisms.[186] Other information that must be provided includes information on the

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[178] Introduction of Non-Indigenous Species, 60 Fed. Reg. at 5,288.
[179] *Id.*
[180] *Id.*
[181] Introduction of Non-Indigenous Species, 60 Fed. Reg. at 5,290. As part of its permit review process APHIS would be required to seek input of appropriate state agencies as well as other federal agencies such as the US Fish and Wildlife Service and Environmental Protection Agency. *Id.* at 5,291.
[182] Introduction of Non-Indigenous Species, 60 Fed. Reg. at 5,291.
[183] Introduction of Non-Indigenous Species, 60 Fed. Reg. at 5,292.
[184] *Id.*
[185] *Id.*
[186] *Id.*

geographic location where the regulated organism was originally collected and information on the established range of the regulated organism in the United States.[187]

Permits for the release of a regulated organism into the environment would require more information to support a permit than the permits involving importation or interstate movement with no intended release into the environment.[188] For release permits, information must be provided regarding all testing and reviews that have been conducted to assess the effects of the regulated organism and the environment, the effect of the regulated organism on the environment in its established range, and the host specificity of the regulated organism under both artificial and natural conditions.[189] If APHIS issues a permit, the permit would specify the applicable conditions for the introduction of the regulated organism.[190] The proposal also provides a process for obtaining an exemption from regulation. In determining whether to exempt a particular regulated organism a physical to determine whether such organism would not present a significant plant pest risk would be required.[191] To date, APHIS has not issued a final rule.

V. THE NEED FOR A REEVALUATION

In the 1980s and 1990s when the U.S. regulatory agencies were first tasked with developing regulatory approaches to GMOs, they were working in a vacuum attempting to determine where GMOs fit into existing regulatory programs, what agencies had existing relevant jurisdiction and what aspects of GMOs were subject to regulation under existing statutory schemes. The clear direction, dating back to the 1986 Coordinated Framework, was that no new or additional statutory authority was required, and that GMOs would be regulated under the existing patchwork of statutes under which GMOs could be shoehorned. Moreover, early attempts to regulate GMOs sought to follow the constraints of what now appears to be the misguided U.S. policy that regulation should be based on the characteristics of the product rather than the process by which the product was produced.

With the experiences gleaned over the past 20 years, we now know that some of the problems caused by GMOs differ not just in extent, but also in type, from those posed by traditional chemicals. Well known examples include the potential allergens in Starlink corn that have been distributed throughout the world, the dramatic acceleration of pest resistance to the natural insecticide *B.t.*, potential risks to monarch butterflies

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[187] *Id.* In addition, the permit applicant must submit detailed information on the procedures, processes, and safeguards that will be used at the destination facility to prevent the escape and dissemination of the regulated organism and any material accompanying the regulated organism for a permit involving either the importation or interstate movement of a regulated organism. *Id.*

[188] *Id.* at 5,294.

[189] *Id.*

[190] *Id.*

[191] *Id.* at 5,295.

caused by exposure to *B.t.* pollen, cross-fertilization of neighboring farms resulting in loss of organic certification, and the prospect of superweeds that cannot be easily eliminated. As can be seen from the above description of current U.S. regulation of GMOs, the decision to rely on three agencies operating under at least three different statutes with overlapping jurisdiction, none designed with GMOs as a primary focus, has resulted in haphazard and incomplete regulatory policy with no clearly identifiable overriding guiding principle for regulating the risks of GMOs. Although the three agencies do consider many of the types of risks described in this Article, they do not adequately address the unique degree of exposure potential and the unique evolutionary impacts GMOs may have. Moreover, the agencies regulate in a piecemeal fashion with no clear standards to guide their decisions on whether a GMO should be permitted to be released into the environment. For example, EPA regulates GMOs under the cost/benefit standards of FIFRA and TSCA. Thus, under such an analysis, a GMO that is believed to have significant economic benefits may be permitted to be released without a full understanding of the potential novel risks it may pose. As discussed above, EPA does not have data requirements specific to GMOs and is severely constrained by having labeling restrictions as the primary risk reduction tool available under FIFRA.

Currently, EPA's approach to microbial GMO pesticides is to require notification and submission of data prior to small-scale testing of microbials whose genetic material has been deliberately modified. However, EPA does not have clear standards for deciding whether to register GM microbial pesticides or how to regulate them to adequately address their unique attributes. With regard to PIPs, EPA's approach is to regulate GM PIPs on a case-by-case ad hoc basis without any established data requirements, labeling requirements or other regulations. As to non-pesticidal GM microbes, EPA has drawn the regulatory threshold at intergeneric organisms and requires pre-manufacture notification and data submission for such organisms. Again, however, EPA has not established a comprehensive regulatory approach for determining which organisms to allow to be commercialized or how to reduce such risks from the commercialization of such products. Under USDA/APHIS regulations, the focus is on plant pest risk, which does not address the full range of risks of GMOs. Moreover, USDA's approach is focused on deregulating GMOs.

The evaluation of pesticidal GM foods appears to be the one area with an appropriately clear standard governing when a GM food should be permitted. Under the 1996 Food Quality Protection Act,[192] the FFDCA was amended to include a "safety" standard for pesticide residues in food, which requires reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.[193] Thus, as to pesticidal GM foods, EPA at least has a clear risk-based standard to guide its decision-making.

For non-pesticidal GM foods, on the other hand, FDA has not required any pre-

[192] P.L 104-170, 110 Stat. 1489 (Aug. 3, 1996).
[193] 21 U.S.C., 346a(c)(2)(A).

market notification or data submission, and instead presumes that most GM foods are substantially similar to foods already consumed by humans and animals and leaves it to the producer to determine whether testing or further evaluation are indicated. Accordingly, the vast majority of GM foods do not undergo formal agency review prior to becoming part of the human food supply. Consequently, a rethinking of U.S. GMO policy is warranted. Because GMOs reflect human tinkering with the evolutionary process, evolutionary biology theory may assist in crafting a new approach to regulating GMOS.

Two recent scientific studies highlight the shortcomings of U.S. GMO policy and regulation. In 2002 the National Academy of Sciences, National Research Council (NRC) published a report (NRC report) evaluating the regulation of transgenic plants.[194] The report reaches some unanticipated conclusions regarding the risks of transgenic plants. The conventional wisdom prior to the issuance of the report was that the impact of the deliberate release of biological novelty whether through conventional breeding or genetic modification could be measured in two ways: 1) the number of genetic changes; and 2) the taxonomic or phylogenetic distance between the source and the recipient.[195] Historically there was an assumption that the greater the novelty of the introduced species the greater the potential environmental risk associated with such novelty. The report shows that this is not necessarily the case. Specifically, the report concludes that changes at any level of genetic information can have profound environmental consequences, that the consequence of biological novelty depends strongly on the specific environment into which the organism is released, that the significance of the consequences of the introduction of novelty depends on societal values, that the introduction of any type of biological novelty can have unintended and unpredicted effects on recipient communities and ecosystems, and that it is not possible to quantitatively differentiate the genetic environmental risk associated with the release of conventionally breed crop cultivars and the introduction of new GM species.[196]

Perhaps most significantly, the NRC Report in essence rejects the Coordinated Framework approach of regulating the characteristics of the product rather the process by which the product is created. Specifically, the NRC concluded that genetic engineering can "introduce specific traits or combination of traits that pose unique risks." [197] Moreover, in evaluating the APHIS regulatory program for GMOs, the NRC Report concludes that with regard to the APHIS petitioning process, it is imperative that once a

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[194] National Research Council, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* (2002) (hereinafter NRC Report). The NRC Report was in response to a 2000 request from the United States Department of Agriculture requesting that the National Academy of Sciences examine the scientific basis for an operation of the APHIS regulatory oversight of transgenic plants. Previous NRC committees have examined other issues related to the safety of genetically modified organisms, but none of the previous reports specifically address APHIS oversights or how commercial use of genetically modified crops with non-pesticidal traits could affect agricultural and non-agricultural environments.

[195] *Id.* at 49-51.

[196] *See generally* NRC Report.

[197] NRC Report at 48.

petition is granted there be further monitoring and oversight.[198] Further the report identifies the treatment of non-target affects and pesticides resistance as superficial and accordingly recommends that APHIS should increase rigors of its environmental assessments or completely defer to EPA on these issues.[199] The report strongly recommends improvements in post commercialization testing and monitoring of transgenic plants.[200] Specifically two different types of ecological monitoring to assess in final anticipated or long-term incremental environmental impacts are suggested.[201] The first would include a network of trained observers to detect unusual changes in agricultural on unmanaged eco-systems.[202] The second recommendation is for the establishment of long term monitoring program that examines planting patterns and uses a subset of species and abiotic parameters as indicators of long-term shifts in an ecosystem.[203]

Although the NRC Report is focused primarily on APHIS regulation, EPA's proposal to exempt from FIFRA regulation all pesticidal PIPs which receive genetic material from a sexually compatible plant regardless of whether the PIP was produced by genetic engineering or conventional breeding is not consistent with the scientific findings of the NRC Report. The report rejects the idea that the ecological risks are higher when a gene is moved between organisms that are not closely related as opposed to movement of the gene between closely related or sexually compatible organisms.[204] EPA's focus on sexual compatibility may have some validity from the standpoint of protecting human beings from dietary risks associated with GMO foods. For example, moving a gene between closely related or sexually compatible organisms may insure the types of substances that human beings are exposed to in their diet does not significantly change. If a gene is moved from one variety of corn to another related variety of corn, the chance of the genetic modification resulting in significant new exposures to humans is relatively low. However, in evaluating ecological risks the NRC has found that the same analysis does not hold true, and in fact, the movement of genes between closely related organisms can result in the same type and magnitude of ecological risks as moving genes between unrelated organisms.[205] The primary factor in determining the ecological risks associated with the release of the GMO into the environment is the specific environment into which the GMO is released and how such environment is able to handle the new organism.

The second significant recent scientific analysis is the 2005 EPA SAP

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[198] *Id.* at 120. Moreover the report recommends more opportunities for public participation and enhanced peer review in the petitioning process. *Id.* at 165

[199] *Id.* at 167-91.

[200] NRC Report, 192-219.

[201] *Id.*

[202] *Id.* at 205-07.

[203] *Id.* at 207-13. Moreover the report notes that the ability of APHIS to monitor is hampered by the lack of baseline data and comparative data on environmental impacts of previous agricultural practices. NRC Report at 194-95.

[204] *Id.* at 36-43.

[205] *Id.*

consideration of the risks of PIPs based on virus coat protein genes.[206] This meeting was held to enable the SAP to consider the scientific issues associated with EPA's proposed exemption of certain PIPs that had been genetically modified to be resistant to viral infection.[207] The SAP evaluated a number of potential risks associated with these PIPs, including the risk of out-crossing with wild relatives and the risk of the PIP itself becoming weedy.[208] The SAP recommended a set of criteria to evaluate species to help determine the likelihood of such events occurring and evaluated biological containment and/or mitigation methods as a potential means for ensuring the PIP does not outcross with wild relatives.[209] The SAP report contains the type of science-based criteria that could form the basis of a new comprehensive approach to regulating certain non-traditional risks from GMOs.[210]

In addition to these recent scientific evaluations, a number of legal scholars have evaluated various aspects of U.S. regulation of GMOs and have concluded that there are significant shortcomings. Many of these scholars have concluded that the U.S. should abandon its policy of relying on existing legal authorities in favor of a new overriding genetic engineering statute that would eliminate many of the regulatory gaps, overlaps and inconsistencies that currently exist.[211] However, these scholars have not articulated a

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[206] Meeting Minutes: FIFRA Scientific Advisory Panel Meeting, December 6-8 2005, *A Set of Scientific Issues being Considered by the Environmental Protection Agency Regarding: Plant-Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the proposed Rule,* SAP Report No. 2006-01 (on file with author) (hereinafter SAP Report).

[207] EPA first proposed exempting certain PIPs that had been genetically engineered to be resistant to viral infection in its 1994 proposed rule.

[208] SAP Report at 11.

[209] *Id.*

[210] *See generally* SAP Report.

[211] Legal scholars have also evaluated a number of non-regulatory approaches for addressing GMOs. Some commentators have expressed the view that federal regulation of GMOs is not needed at all. The basis for this argument is the belief that the private sector can adequately police itself and ensure that GMOs that are likely to cause human health or environmental problems are not commercially available. However, as can be seen from recent events such as with Starlink corn, the biotech industry has not demonstrated its ability to adequately screen for or control GMOs. In addition, some scholars have evaluated the effectiveness of a variety of common law remedies for addressing potential harms from GMOs. However, none of these theories appear to be adequate. For example, the basis of the theory of strict liability is that the product has a defect that renders it unreasonably dangerous, thereby creating a duty to warn consumers of the danger. However, in order to warn, a manufacturer of a GMO must be able to predict what potential future problems may be. Also, warning a consumer is not a sufficient guard against harm. Although the consumer may be able to heed a warning, once the GMO is released in to the environment where it can reproduce and spread, a warning to a consumer will have no effect. Similarly, under negligence theory it must be established that the manufacturer or supplier breached its duty to a foreseeable plaintiff by failing to act in a reasonable manner. However, damages for negligence are not an adequate remedy because once the GMOs are reproducing and spreading in the environment, there may be no way to control them. Pursuant to a theory of breach of warranty, Plaintiffs need to establish that when the defendant sold the product, the defendant made express or implied warranties and the product did not conform to these warranties. The product does not need to be unreasonably dangerous. Breach of warranty is unlikely to be used with regard to GMOs because due to the inherent unpredictability of GMOs, manufacturers will be

clear overriding regulatory standard or decision-making approach that could be incorporated in to such a statute and could apply to the regulation of all GMOs.[212]

Perhaps two of the most significant recent works addressing legal responses to the risks of GMOs are Professors Thomas O. McGarity and Gregory N. Mandel. Professor McGarity's article focuses on the human risks associated with the consumption of GMO foods.[213] He analyzes the use of "substantial equivalency" in the law and shows how it has proven to be ineffective.[214] Professor Mandel's article, on the other hand, looks at the adequacy of existing laws in addressing the environmental risks of GMOs released into the environment in the context of the 2002 NRC Report.[215] Mandel, drawing on the regulatory gaps and shortcomings identified in the NRC Report, suggests ways to improve the law to better address risks.[216] While both of these pieces are important

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reluctant to offer or imply warranties. Finally, common law nuisance law may not by adequate. Once a GMO is released payment of damages may not be adequate because damages will continue to occur as the organism reproduces and moves through the environment. There may be no way to ever "recall" the GMO as you could with a traditional chemical product. *See* Kunich, *supra* note 6 at 835-40.

[212] For example, one legal scholar has proposed an alternative new statute, "Transgenic Release Act" (TRA), to be administered by EPA and to be the only federal statute regulating the environmental effects of genetically engineered organisms. Under TRA, there would be an EPA maintained resister of transgenic organisms and a center for transgenic research and testing. The TRA would not require prerelease testing or certification. Administrative penalties would be available to cover clean-up costs. Kunich, *supra* note 6 at 859-63.

[213] Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 UNIV.MICH. J.L. REFORM 403 (2002).

[214] A full discussion of the potential human health risks associated with genetically modified foods and FDA's regulation of such risks is beyond the scope of this Article. For an excellent discussion of these matters *see* McGarity, *Seeds of Distrust*, *supra* note 213. In this article Professor McGarity evaluates FDA's approach to genetically modified foods and focuses on the role that the substantial equivalence doctrine has played in such regulation. Professor McGarity concludes that the substantial equivalence doctrine is not adequate to insure food safety and instead suggests a more precautionary approach be taken in regulating genetically modified foods. Most significantly he proposes that pre-release notification should be required to provide FDA with an opportunity to review GM foods prior to commercialization. He also proposes requiring additional data collection, data evaluation and risk assessment and monitoring and enforcement. *Id.*

[215] Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. AND MARY L. REV. 2167 (2004).

[216] Some of the regulatory gaps that Mandel identifies include: 1) EPA does not yet regulate transgenic animals, such as salmon; 2) EPA has not yet began to evaluate transgenic plants that produce pharmaceuticals or industrial products, or transgenic plants that are drought tolerant, salinity tolerant or virus resistant; 3) APHIS does not conduct an environmental assessment of transgenic plants submitted through the notification process; 4) APHIS environmental risk assessment has been criticized by the NRC for lacking scientific rigor, balance and transparency and for relying too heavily on existing scientific literature rather than requiring the development of new experimental data: 5) Once APHIS grants a petition for nonregulated status, it no longer has any authority over the GMO or its progeny; 6) FDA does not require pre-market notification; and 7) APHIS requirements pertaining to preventing environmental release so not cover release or movement of pollen. Mandel, *supra* note 215 at 2231-34. Mandel argues that many of the existing shortcomings can be attributed to the reliance on statutes that predate the advent of GM technology. To address these concerns, Mandel proposes that statutory and regulatory structures should be

contributions to the legal discourse on regulating GMOs, this Article suggests a broader lens through which reform of GM regulation can benefit. By using evolutionary biology, this Article builds on the work of previous scholars and demonstrates that the regulation of living organisms must go beyond traditional approaches to regulating human behavior by considering the behavior of the organisms themselves.

VI. EVOLUTIONARY BIOLOGY

In 1982, William Rodgers called upon his colleagues to bring people back into the legal analysis of environmental law.[217] It is now time for a call to bring biology back into the analysis.[218] The conventional wisdom is that "[l]aw deals in human behavior." [219] While this may be true in the vast majority of legal contexts, in certain areas, law may need to look beyond human behavior and extend its reach to address the behavior of other living organisms. Nowhere is this more true than where the law attempts to address disruptions to ecological systems by living organisms, whether genetically modified or non-indigenous. A regulatory regime that stops at considering human behavior may make sense, for example, in addressing risks from the release of a particular chemical substance into the environment as a result of human behavior. In this context, the social value of the human behavior that results in the release can be considered along with the risks posed by the chemical. Once it is determined that the release of a certain amount of the chemical is acceptable, the only concern is how to restrict the human behavior to achieve that goal. Regulatory restrictions that change or limit the human behavior that ultimately presents the risk can be imposed and the risk will be reduced to the desired level.

With living organisms, however, the law must not limit itself to considering

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revised to overhaul the division of regulatory responsibility. *Id.* at 2246-51.

[217] Rodgers, *Bringing People Back: Toward a Biological Theory of Taking in Natural Resources Law*, 10 ECOL. L. Q. 205 (1982).

[218] As a general matter, the relationship between law and science has been an uneasy one. Although science intersects with virtually all areas of law, practitioners of the two disciplines do not seem to relate well. Many areas of law, including medical malpractice, patent law, and environmental law, rely heavily on scientific evidence to prove up individual cases, however, it seems that scientific knowledge has not been used as effectively to inform policy choices in these areas of the law. Robert J. Condlin, "*What's Really Going on?": A Study of Lawyer and Scientist Interdisciplinary Discourse,* 25 RUTGERS COMPUTER & TECH. L.J. 181 (1999). For additional discussion of the relationship between law and science, particularly in the environmental arena, *see generally,* Susan Haack, *Trial and Error: The Supreme Court's Philosophy of Science*, AMERICAN JOURNAL OF PUBLIC HEALTH; 2005 Supplement 1, Vol. 95, pp66-73 (2005); SHEILA JASANOFF, SCIENCE AT THE BAR (Harvard University Press,1995); and Wendy E. Wagner, *The "Bad Science" Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66-Fall LAW & CONTEMP. PROBS. 63 (2003). Wendy E. Wagner, *The Science Charade In Toxic Risk Regulation* 95 COLUM. L. REV. 1613 (1995).

[219] Owen D. Jones, Evolutionary *Analysis in Law: An Introduction and Application to Child Abuse,* 75 N.C. L. REV. 1117 (1997) (stating that every legal regime "inescapably reflects some behavioral model purporting to draw causal arrows between supposed influences and law-relevant behavior.")

human behavior. By their very nature, living organisms can spread and reproduce in the environment. Moreover, living organisms may be able to out-compete other species and/or cause disruptions to ecological systems. Simply controlling human behavior, short of outright banning of the release of such organism, will not permit an effective response to many of the potential risks posed by such organisms. Accordingly, when designing a system to address the risks posed by living organisms, the law should not limit its inquiry to considering how human beings handle the living organisms. Instead, the law must look further and ask how the organism themselves are likely to behave once they are released into the environment. Evolutionary biology theory may be useful not only in predicting the behavior of living organisms, but also in designing regulatory systems to address the risks posed by the organisms.[220] With a reasonable understanding of the organism's likely behavior, the law can be tailored to address potential risks resulting from such behaviors. Just as human behavior in the environmental arena is not solely motivated by economics, environmental harms cannot solely be prevented by a legal system that strives only to control human behavior.

Ironically, evolutionary biology theory has not been used widely in environmental law.[221] It may seem obvious that if the principles of evolutionary biology and ecology belong anywhere in the legal world it should be in the world of environmental law, but until recently, environmental law has been somewhat divorced from such considerations. Environmental law has concerned itself with regulating the behaviors of people and business entities and minimizing releases of hazardous substances and wastes to the air, water and land. This approach may work with regard to toxic chemical or pollution control, but with the ever increasing development of new technologies involving living organisms and the increased risks of environmental harms caused by these new living organisms themselves, it is now evident that even the corners of settled environmental law largely have bypassed the mission of protecting natural systems from the novel risks associated with these genetically manipulated organisms

A. *Evolutionary Biology Theory*

Although frequently used in popular parlance to suggest some type of predetermined path from simple to complex or sophisticated, the concept of evolution from a biological standpoint is quite simply the process by which change occurs as traits are passed from one generation to the next. Of course, in the early 21st century, virtually

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[220] One of the few attempts to apply evolutionary biology theory to the regulation of non-human living organisms was a 2000 student Note applying the theory to biotechnology patent law. Through an evolutionary biology analysis, the author proposes that patents be granted only on those non-naturally occurring organisms "whose prospects for continued existence are predicated not upon their selection by nature, but upon their selection by people." Ryan M.T. Iwasaka, *Chakrabaty to Chimera; The Growing Need for Evolutionary Biology in Patent Law,* 109 YALE L.J. 1505 (2000).

[221] S*ee* William H. Rodgers, Jr., *Where Environmental Law and Biology Meet: Of Panda's Thumbs, Statutory Sleepers, and Effective Law,* 65 COLO. L. REV. 25 (1993).

every schoolchild is aware that such traits are passed from parent to offspring via the transmission of genetic information contained in the DNA.[222] In nature, periodic random mutations of DNA result in variation occurring among the members of a species. Some variations are more advantageous to survival than others in a particular environment. Individuals that possess the advantageous traits are more likely to survive to pass their genes on to the next generation.[223] For evolution to occur, three factors must be present: 1) variation (caused by mutations in DNA) in the physical and behavioral traits possessed by individuals within a species; 2) heredity – that is, the ability to pass genetic information, including mutated genetic information, necessary for physical or behavioral traits from parent to offspring; and 3) differential reproduction – the tendency of some inherited traits to survive in the gene pool more than others.[224] Differential reproduction is the result of selective pressures that favor some mutations over others, thereby enabling certain organisms to reproduce and limiting the ability of other organisms to reproduce. Because evolution results from the combined effect of these three factors, only the genetic mutations that are favored under the selective pressures of the environment survive in the long term.

The theory of natural selection, first described by Charles Darwin[225] in 1859 holds that individuals that have certain traits that confer an advantage to their survival in a particular environment will be more likely to survive (i.e., more "fit" from an evolutionary standpoint) and pass the genetic information that leads to such advantageous traits onto their offspring. Individuals who do not possess such advantageous traits will be less likely to survive and/or reproduce and accordingly, their genetic material will be less likely to be passed on to future generations. In this way, over many generations, the traits that are more advantageous become more dominant in the populations.

A related but very different theory is that of "sexual selection." This theory, rather than focusing on an individual's general ability to survive, focuses on an

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[222] Long before the discovery of DNA by Watson and Crick in the 1950s, for which they were awarded the 1962 Nobel Prize. Scientists understood that traits were passed from one generation to the next without understanding the precise biological mechanism for the transmission of such traits.

[223] Of course, simply because an organism is more likely to survive than its peers, does not necessarily mean that it will be more likely to pass on its genetic material to its offspring. This depends on that organism's ability to mate and reproduce. The ability to mate and reproduce is the subject of a theory related to the theory of "natural selection," which is referred to as 'sexual selection." For a description of sexual selection, *see infra* note 226 & accompanying text.

[224] For a more thorough description of evolutionary biology, *see* Owen D. Jones, *Evolutionary Analysis in Law: An Introduction and Application to Child Abuse,* 75 N.C. L. REV. 1117 (1997).

[225] Although the phrase "the survival of the fittest" is often cited in association with reference to Charles Darwin, in fact, Darwin never uttered those words. The phrase was coined by Herbert Spencer in 1867. Unfortunately, the term is probably responsible for the general misunderstanding of evolutionary biology that permeates modern culture. Suggesting that some organisms are more "fit" for survival implies that there is some absolute notion of a specific combination of traits conferring the most "fitness." In reality, in all likelihood there are unlimited combinations of traits that may confer fitness to a particular environment. Moreover, "fitness" is not static. As environmental pressures change, the traits that will confer fitness also change.

individual's ability to attract mates and successfully mate, and therefore reproduce. If an individual posses traits that make him or her more likely to be able to obtain a suitable mate, that individual's genetic material will more likely be passed on than will that of an individual who does not possess such a trait. In the natural world, traits that make an individual more attractive to potential mates may include traits such as large size, robustness and health – obvious traits that would increase the odds of survival of offspring who inherit such traits from their parents. What is more fascinating to human observers, however, is the spectacular array of "attractiveness" traits that have evolved in nature the function of which appears to be solely to lure mates. Such traits include vivid coloration, flashy plumage and elaborate dances and rituals.[226]

In recent years, evolutionary biology theory has undergone its own evolution. The conventional wisdom that evolutionary processes follow a steady, stable pathway has been rejected in favor of a notion of life on earth "in jittery motion…ready to dart off in an instant."[227] In other words, evolution is now believed to occur in fits and spurts rather than in a slow steady progression. Such evolutionary spurts occur in response to environmental pressure and may be more pronounced in response to environmental pressures novel, or atypical, to a geographic locale, such as the quick onset of a severe drought to flood in an area that typically does not experience such extremes.[228] The new understanding of evolutionary biology suggests significant potential implications in the area of the release of GMOs into the environment. If introducing novel environmental pressure can result in spurts of evolution, perhaps, introducing novel organisms into the existing environment could have similar dramatic effects.

B. *Law and Biology*

One area of legal scholarship that has incorporated evolutionary biology theory is the field of "Law and Biology."[229] The field of Law and Biology, largely developed by Margaret Gruter and her colleagues at the Gruter Institute, has been described as an attempt to "use the insights of modern biology, particularly the features about the distribution and proliferation of characteristic within populations, and insights into behavioral factors like the evolution of cooperation, in studying law."[230] Law and biology theory states that any system that exhibits the three features of reproduction, variation and selection by the environment will evolve in the direction of greater fitness

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[226] Of course, sexual attractiveness in humans is not without its own set of peculiar traits such as wealth, expensive cars, fashionable clothing, and fashion magazine worthy body type.

[227] JONATHAN WEINER, THE BEAK OF THE FINCH (Vintage 1994).

[228] This new understanding of evolution in nature is related to the "new ecology" which rejects the balance of nature in favor of a more dynamic view of ecological processes. *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).

[229] The movement was called "Law and Biology" to emphasize its relation to the "Law and Economics" movement. E. Donald Elliott, *Law and Biology: The New Synthesis?,* 41 ST. LOUIS U.L.J. 595 (1997).

[230] *Id.* at 599.

with the environment. The "environment" for law is the larger community, the political culture and values of the community in which the law takes place. [231] Legal precedent is the "reproduction" of law -- both in terms of precedent in the case law and the perpetuation of similar statutory schemes through copying and basing one statute on previous statues.

With regard to GMOs, the law must evolve to address this newly evolved set of risks. In evolutionary terms, the "selective pressure" that will drive this change is the intense public concern, both in the U.S. and abroad, regarding the risks of GMOs. The only element missing to complete the trio of evolutionary prerequisites to dramatic legal evolution is the variation or the mutations. In the law, this can only come into being as a new idea. Just as in biological evolution most new changes turn out to be bad or neutral, for the law to evolve, there must be a variety of new ideas from which the selective pressures of public concern can hit on the right one. To date, the vast majority of attempts to regulate GMOs has merely been a proliferation of old models. These old models do not work for GMOs. There is a natural evolution of biology and law. Biological organisms evolve in accordance with principles of evolutionary biology -- essentially Darwinian natural selection.

This Article proposes that there is a way to use evolutionary biology theory, which has been largely ignored by the legal community: using biological models to design legal systems aimed at environmental protection more effectively by incorporating consideration of the evolutionary impacts of biological organisms – or the raw materials that we are working with in an environmental legal system – to more effectively design a system that addresses the novel risks posed by human intervention in these biological processes.

In recent years, a number of legal scholars have begun to look to evolutionary biology theory for insights into human social behavior in the hopes that such insights may provide direction for legal reforms.[232] This area of scholarship is based on the scientific recognition that natural selection affects both genetically determined physical and behavioral traits.[233] Accordingly, evolutionary biology may play a predictive role in

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[231] E. Donald Elliot describes three ways in which biological models and insights have been used in the Law and Biology movement. The first is the use of biological models to describe the dynamics of legal systems – i.e., how law works by analogy to other complex systems. The second is to help develop a natural law basis for law through a better understanding of how and why humans are the way they are, particularly in comparison to other animals and particularly in terms of operation or aggressive behavior in groups. The third is to provide insight into how we can design legal systems more effectively. If we have a better understanding of human nature – of the raw materials that we are working with in a legal system – then perhaps we can design laws to work more effectively. Elliot, *supra* note 229.

[233] In 1975, biologist E.O. Wilson's book, *Sociobiology*, first introduced the idea that selective forces act on genetic behavioral traits, including in humans, in addition to physical traits. *See* EDWARD O. WILSON, SOCIOBIOLOGY: THE NEW SYNTHESIS (1975). From 1975 until the late 1980's and early 1990s, scholars and the public alike expressed extreme discomfort with applying this theory to human behavior. In the ensuing years, scholars have refined the theory and in its current iteration, it is more socially acceptable. Owen D. Jones, *Law and Evolutionary Biology: Obstacles and Opportunities,* 10 J. CONTEMP. HEALTH L.

evaluating what types of human behavior are likely to occur in given circumstances.[234]

Recently, evolutionary biology theory has been studied as a way to understand human behavior, including socially abhorrent behavior, such as rape[235] and child abuse.[236] Although some scholars such as E. Donald Elliott and William Rodgers have studied evolutionary biology in the context of environmental law, their work, unlike what is being proposed in this Article, uses the theory to predict human behavior and use such predictions to aid in the design of environmental regulation. [237]

In recent years, scholars have increasingly applied evolutionary biology theory to

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& POL'Y 265 (1993). Scholars are now careful to point out that evolutionary biology theory should not be used to argue that simply because a behavior is evolutionarily adaptive, such behavior must be allowed or encouraged. Instead, scholars now make clear that evolutionary biology theory's major limitation is its lack of incorporation of normative values. Thus, while the theory can help us understand why a certain behavior exists, it cannot tell us whether such behavior should be tolerated or encouraged by society or the law. Jones at 273. Moreover, the theory should not be used to suggest that human being have no ability to control their behaviors. *Id.* at 274-75.

[234] Jones at 277-78. For example, as Jones described, evolutionary biology might predict that step-parents are more likely to kill step-children than are biological parents. Such a prediction could influence child welfare policy. *Id.*

[235] *See* Own D. Jones, *Law and the Biology of Rape: Reflections on Transitions,* 11 HASTINGS WOMEN'S L.J. 151 (2000) (opining that because the law's ability to prevent rape is a function of its behavioral model of rape, evolutionary biology theory may be an effective model of the behavior, thereby aiding the law in attempting to deter rape.). *See also* Brian Kennan, *Evolutionary Biology and Strict Liability for Rape,* 22 Law & Psychol. Rev. 131 (1998) (proposing a new approach to rape based on evolutionary biology, which would replace the mental element of rape).

[236] *See* Own D. Jones, *Evolutionary Analysis in Law: An Introduction and Application to Child Abuse,* 75 N.C.L. Rev. 1117(1997) (setting forth a comprehensive application of evolutionary biology theory to child abuse).

[237] *See e.g.,* E. Donald Elliott, *The Tragi-Comedy of the Commons: Evolutionary Biology, Economic and Environmental Law,*20 Va. ENVTL. L.J. 17 (2001) (opining that in the past two decades legal scholars have increasingly looked at human nature from an evolutionary biology perspective to explain legal phenomenon). In this article, Elliott uses evolutionary biology theory to explain the evolution of environmental law. For example, Elliott analogizes the human/environmental relationship to a host/parasite relationship, wherein it is to the advantage of the parasite to preserve its host and maintain a mutually advantageous relationship. *Id.* Some environmental law scholars have used evolutionary biology theory in a variety of other creative ways. For example, Professor William Rodgers has used the theory to analyze the human behavior of deception as it occurred in a particular Atomic Energy Act case. William H. Rodgers, *Deception, Self-Deception, and Mythology: The Law of Salmon in the Pacific Northwest,* 26 PAC. L. J. 821 (1995). *See also* William H. Rodgers, Jr., *Where Environmental Law and Biology Meet: Of Panda's Thumbs, Statutory Sleepers, and Effective Law,* 65 COLO. L. REV. 25 (1993). In this article, Rodgers cites various evolutionary quirks as a comparison to human legal framework. The author notes how certain species' current traits, such as a housecat's tail, which at one point served a useful function, are a poor adaptations for an environment full of closing doors; similarly, certain laws continue to "time-lag" in problematic fashion, and remain on the books despite no longer serving society's needs. *Id.* at 52-53. The author argues for a better understanding of the inevitable influences that evolutionary biology plays in the law-making norms of society, as laws, like evolutionary biology, influence both history and human behavior. *Id.* at 56. The author concludes with a plea for a better understanding by those drafting laws to not assume that "their decrees alone can suffice to bring about … altruistic behavior" and that like evolution, lawmaking can result in both adaptation and maladaptation. *Id.* at 74-75.

a variety of "non-biological" entities. Richard Dawkin's concept of the selfish gene led to the idea that entities other than genes may also be able to evolve in accordance with natural selection.[238] Dawkins coined the term "memes" to describe entities other than DNA that may be subject to natural selection.[239] The concept of evolutionary biology applying to non-biological memes has led legal scholars to attempt to apply evolutionary biology theory to legal concepts such as copyright law. For example, Professor Thomas Cotter has argued that principles of evolutionary biology may help to illuminate important issues of copyright law and policy. He describes how copyright affects the way in which ideas and fragments of expression come into existence, compete and evolve.[240]

VII. AN EVOLUTIONARY BIOLOGY MODEL FOR REGULATING GMOS

A. General Considerations

Although the existing legal approaches to regulating GMOs, as well as the refinements suggested by other scholars, adequately address some of the risks associated with GMOs, to fully address these complex issues, a more dramatic and transformative approach is warranted. The law must undergo a more dramatic and ongoing evolution to keep pace with the dramatic changes that genetic engineering has made and has the potential to make to the evolution of life. This Article proposes that a completely new legal approach drawing on principles of evolutionary biology is needed to address the risk of novel environmental and economic harms caused by human intervention in and manipulation of evolution. The new approach would go well beyond traditional common law theory or conventional regulatory approaches, both of which focus solely on regulating human behavior and largely ignore the behavior of other organisms. Regulating human behavior cannot adequately address environmental and economic risks created by human manipulation of evolution. For example, traditional environmental standards may limit the quantity of a substance that can be safely released in to the environment. However, quantity of GMOs produced or released into the environment may be irrelevant to GMOs, because they are able to reproduce and proliferate in the environment on their own. Traditional environmental law focuses on imposing limitation on where or how a substance can be used. For example, a regulation may prohibit the use of a substance toxic to aquatic organisms within X number of feet of a water body, may limit the time of year a substance may be used to avoid wildlife migration events, or may

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[238] RICHARD DAWKINS, THE SELFISH GENE (1976). The idea is that any entity that can copy itself is subject to natural selection, provided that the copies possess sufficient fidelity to the original, that random mutation occasionally occurs, creating variability and that some of the random mutations confer a selective advantage in the environment. *Id.* Dawkins posits that whenever these conditions, which he calls "Universal Darwinism," exist in the appropriate proportion, the process of natural selection necessarily will occur. *Id.*

[239] *Id.*

[240] Thomas F. Cotter, *Memes and Copyright,* 80 TUL. L. REV. 331 (2005).

limit the geographic areas in which a substance may be used to avoid exposure to protected species or sensitive ecosystems. Moreover, under FIFRA, in particular, use restrictions are accomplished through language contained in the pesticide product label. The assumptions embedded in the labeling approach are that the only relevant conduct to be controlled is that of the human user of the pesticide. Reliance on labeling instructions is misplaced when addressing risks posed by living organisms capable of reproducing and moving in the environment. When the behavior of the regulated living organisms themselves is taken into account, the shortcomings of such an approach, and the need for a new approach, become apparent.

The new approach should reject regulating on the basis of the product in favor of regulation based on the process used to create the product. Scientific understanding gleaned since the 1986 Coordinated Framework, in conjunction with public concern have demonstrated that ignoring the process by which the organism is created is fraught with problems. Consistent with proposals of other legal scholars, this Article proposes the adoption of a new federal statute to comprehensively address all human health and environmental risks potentially arising out of the introduction of GMOs into the environment and human food supply. [241] The most logical existing agency to have primary regulatory authority under the new statute is the EPA, which is the federal agency with the most expertise in evaluating environmental risks and human health risks associated with the release into the environment of potentially harmful substance.[242] Due to the considerable scientific uncertainty surrounding GMOs, such a statute should adopt a precautionary approach, requiring premarket agency review with the burden on the entity seeking authorization to provide reasonable assurances that the requisite human health and environmental criteria have been met. To provide such reasonable assurance, submission of specified data should be required to enable the reviewing agency to make an informed decision based on scientific data whether the GMO should be permitted to be released into the environment.[243] The type and amount of data required will vary with the extent of the release and whether adequate physical or biological containment can be

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[241] *See* Kunich, *supra* note 6 , Mandel, *supra* note 215 and McGarity, *supra* note 213.

[242] In addition, the EPA already has the SAP and the BSAC, which have significant expertise in and experience evaluating environmental and human health risks associated with GMOs.

[243] The term "reasonable assurances' is used in a some of state environmental permitting statutes. Under such a statute, permit applicants that seek certain authorizations have the burden of providing reasonable assurances that the proposed activity will not have adverse effects on the environment. Under Florida law, for example, reasonable assurances are not synonymous with absolute guarantees. Hoffert v. St. Joe Paper Co., 12 F.A.L.R. 4972, 4987 (Dept. Envtl. Regulation, Dec. 6, 1990). The level of evidence the applicant must provide to demonstrate reasonable assurance is case specific depending upon the nature of the issues involved. Dept. of Transp. v. J.W.C., Co., Inc., 396 So.2d 778, 789 (Fla. 1st DCA 1981). Moreover, the reasonable assurance standard does not require the Applicant to perform every known test concerning an issue in order to establish entitlement to a permit. Booker Creek Preservation, Inc. v. Mobil Chemical Co., 481 So.2d 10, 13 (Fla. 1st DCA 1986). Rather, reasonable assurance means a "substantial likelihood" that the project will be successfully implemented. Metropolitan Dade Co. v. Coscan Florida, Inc., 609 So.2d 644, 648 (Fla. 3rd DCA 1992).

ensured. For example, for limited field testing, data demonstrating adequate containment may obviate the need for the type and level of data necessary for full-scale commercial release. The data requirements should reflect the best scientific understanding of the types of risks identified in this Article -- i.e., traditional risks, novel risks and economic risks.

In evaluating data to determine whether to authorize release, the reviewing agency should, cognizant of the uncertainties of releasing living organisms into the environment and the lack of ability to retrieve such organisms once they have reproduced and spread in the environment, employ a binary approach whereby it is recognized that once released, traditional risk minimization mechanisms, such as labeling instructions may not be meaningful in this context. Once a decision is made to authorize release into the environment, the reviewing agency should not abandon jurisdiction, as APHIS does with its determination of non-regulated status, but instead should retain regulatory jurisdiction over the GMO, require continued monitoring, and submission of adverse effects information as EPA does under 40 CFR 174.71. A new statutory provision should authorize the relevant agency to bring enforcement actions seeking administrative, civil and criminal penalties, and should authorize the destruction of crops and other GMO products if necessary to prevent unacceptable human health or environmental risks.

This Article sets forth a proposed decision-making framework that should be used to guide the reviewing agency decision-making on whether to authorize the release of a GMO. Under the decision-making framework, EPA would ask specific questions to evaluate each of the types of risks discussed in this Article. Most significantly, with regard to all risk categories, other than traditional risks, the decision-making framework questions are based at least in part on an evolutionary biology evaluation of the GMO. In other words, the questions focus on the "mutation" and its effect on the organism (e.g., whether the intentional mutation imparts some selective advantage on the organism), the ability of the organism to reproduce and pass this trait on to its progeny (i.e., whether the GMO can reproduce, whether it has a reproductive advantage or disadvantage, whether terminator genes or sterility mechanisms are imparted), and the environmental pressures to be asserted on the GMO (e.g., will the GMO be released into an environment where it will have a selective advantage).[244] Consequently, any new federal statute on GMOs should mandate an *ex ante* analysis that must be conducted prior to the release of a pesticidal GMO into the environment.

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[244] It should be noted that while none of the existing regulatory programs provide for a comprehensive step by step analysis of the various types of GMO risk identified in this article, the agencies do evaluate many of these risk, albeit in a case-by-case piecemeal fashion. For an example of the risk analysis that EPA conducts in evaluating PIPs, *see Bacillus thuringiensis* CRY3Bb1 Protein and the Genetic Material Necessary for its Production (Vector ZMIR13L) in Event MON863 Corn (006484) Fact Sheet , EPA Publication Number 730-F-05-002 (May 2005) *available* at http://www.epa.gov/pesticides/biopesticides/ingrdients/factsheets/factsheet_006484.htm (last visited June 2, 2006).

B. Looking Before You Leap and the Precautionary Principle

Due to the ability of GMOs to spread and reproduce in the environment, rather than attempting to "regulate" the GMOs, some GMOs simply should not be permitted to be released into the environment. In other areas of environmental law, a binary approach, or an "on/off" approach, to regulating environmental risks may not be appropriate. A binary approach results in a high risk of error of either over-regulating low environmental risks when the switch is off or under-regulating high environmental risks when the switch is on. These risks are referred to as type 1 and type 2 scientific errors, respectively. A more appropriate approach to regulating many environmental risks, for example releases of chemicals pollutant into the environment, may be through the use of a "rheostat switch" rather than an on/off switch. Under the rheostat switch approach, the level of regulation is adjusted depending on the level of risk presented. For GMOs however, the rheostat approach may not be appropriate. GMOs are living organisms that can spread and reproduce in the environment. Once a GMO is released in the environment there is no guarantee that regulators will ever be able to gain control over the organism. Accordingly if an evolutionary biology advantage has been imposed on a GMO enabling it to provide and reproduce readily in the environment, a binary approach may be more appropriate. Under this approach the off switch would be employed to prevent the release of such organisms into the environment whenever the risks have the potential to be high. Such an approach would, by its nature, result in more type 2 errors by erring on the side of preventing the release of organisms into the environment unless the risks are well understood and determined to be acceptable. Thus, a binary approach as employed in this way would be a precautionary approach and would be similar to the approach asserted by proponents of the precautionary principle.

The Precautionary Principle evolved in the context of international efforts to protect biodiversity.[245] The premise of the principle is that where risks could be catastrophic or irreversible, we should proceed cautiously. The Precautionary Principle, a principle ratified in a number of international environmental agreements, holds that where risks are potentially irreversible or catastrophic, a lack of full scientific understanding should not stand in the way of efforts to reduce such risks**.** [246] It is not

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[245] Convention on Biological Diversity (Rio de Janeiro), Dec. 29 1993, 1760 U.N.T.S. 79.

[246] *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 Cartegena Protocol on Biosafety provides that it is "reaffirming the precautionary approach . . . contained in . . . the Rio Declaration on Environment and Development . . .." Final Draft of Biosafety Protocol Approved at Montreal Meeting on Biological Diversity Convention, vol. 23, Intrl. Envtl. Rep. (BNA), No. 3, 125 (Jan. 29, 2000). Article 10(6) of the Protocol provides that "[l]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." *Id.*

prudent to rush into potentially risky behavior simply because you do not have 100% scientific certainty that the behavior will not result in the feared harm. Some have described this approach as the "look before you leap" approach to environmental decision-making.[247]

Perhaps the most serious concern with pesticidal GMOs stems from the uncertainty of the risks of GMOs. Nowhere does the Precautionary Principle appear to make more sense that with GMOS, for which harms, were they to occur, may truly be irreversible due to fact that once released into the environmental, GMOs can spread and reproduce. Moreover, although the risk of GMO release creating a new superweed or disrupting the balance of natural ecosystems may be small, the consequences could be disastrous and irreversible.[248] The precise nature and magnitude of the risk is difficult to predict because of the almost infinite variety of potential GMOs, the ability of GMOs to reproduce and spread, the complexity inherent in natural ecosystems, and the dearth of long-term data on the effects of GMOs.[249]

C. Addressing Traditional Risks, Novel Risks, Economic Risks, and Uncertain Risks: A Decision-Making Framework

For traditional risk considerations that GMOs share with conventional chemical substances such as toxicity or other harm to humans and non-target organisms, the current approaches to determining type and extent of toxicity or other harm to humans and other non-target organism can be employed. Data requirements similar to those for conventional pesticides under FIFRA could be utilized to determine toxicity. However, due to ability of GMOs to spread in the environment, exposure assessments will have to be tailored to the GMOs biology. If a crop plant is genetically engineered to produce a substance that is not toxic or allergenic when ingested by humans, but is allergenic when inhaled, the reviewing agency will have to consider inhalation routes of exposure. For example, if the GM plant produces the allergenic substance in its pollen, EPA will have to consider likely exposure of humans to such pollen through inhalation. In addition, it the GM is able to outcross with wild relatives which will produce pollen containing the allergen, even greater exposure could occur.

In evaluating whether a GMO passes the first step in the framework related to traditional risk, the threshold question should be whether the applicant has provided reasonable assurances that the GMO is "safe" for humans. The statute should adopt the human safety standard of the FFDCA. As to fish and wildlife, a similar safety standard could also apply, but with an "out" for GMOs that provide overriding benefits to public health. For example, a GMO that provides an overriding medical benefit may be allowed

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[247] National Research Council, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* (2002).

[248] *See* John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L.R. 807, 819 (2000-2001).

[249] *See* Steen, *supra* note 29 at 764.

even if it is not completely safe for some fish and wildlife.[250]

To obtain authorization to release the GMO into the environment, the applicant must provide reasonable assurances that the release will not pose adverse novel risks (i.e., their ability to outcross to wild relatives and potentially cause superweeds). EPA should evaluate the probability that the GMO will be able to outcross to wild relatives and whether the wild relatives will be given a selective advantage from the genetic modification. This involves a consideration of a number of factors including, whether sexually compatible relatives[251] of the GMO exist in the area in which it is to be released,[252] the ability of the GMO to form viable hybrids with wild or weedy relatives, whether the genetic modification imparts a traits that increases the fitness of the wild plant, and whether GMO out-crossed wild plants will be likely to out-compete other plants in the environment, thereby becoming weedy or invasive. For example, if a plant is genetically engineered to be resistant to certain viral infection that normally kills a large percentage of a sexually compatible weed's seedlings, when the weed gains the ability to resist the viral infection, significantly larger numbers of its seedlings may flourish, thereby creating a superweed that can out-compete other plants and whose population is no longer held in check by the virus. If, on the other hand, the weed seedling population is not ecologically limited by the virus, but instead is ecologically limited by some other factor such as safe site for germination, the weed may not have a selective advantage imparted from its viral resistance.[253]

Similarly, to obtain authorization for release, the applicant should be required to provide reasonable assurances that the release of the GMO will not cause adverse risks from the GMO itself becoming more evolutionarily fit– i.e., the risks associated with the GMO itself gaining a selective advantage that results it is become akin to an invasive no indigenous species. For this type of risk, however, the presence or absence of wild relatives is irrelevant. The risk assessment instead will focus on whether the GMO, by virtue of the genetic engineering, and/or its introduction into a new environment, has become more "fit." For example, a crop plant that has been bred to rely on the application of chemical insecticides to limit insect pest damage may not be able to survive on its own outside of cultivation with such chemical intervention. If, however,

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[250] This approach is analogous to, but more protective than, the approach taken in FIFRA under which the standard for registering a pesticide is based on a cost/benefit analysis, except in the case of public health pesticide, in which the risks of the pesticide are weighed against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide. *See* 7 U.S.C. § 136(bb) (defining the term "unreasonable adverse effects on the environment").

[251] Some examples of crop plants with sexually compatible wild relatives in the U.S. are barley, plants in the plum family, and watermelons. *See* SAP Report, *supra* note 43, at 16.

[252] SAP seems to believe that relevant geographic area is the continental U.S., however, unless physical barriers exist to prevent the spread to Canada and Mexico, the appropriate consideration may be entire continents. Moreover, as can be seen from the StarLink debacle, once a GMO is commercialized, it may be virtually impossible to prevent it from entering other countries or continents, whether intentionally or inadvertently.

[253] SAP Report *supra* note 43, at 21.

the crop is genetically engineered to make it resistant to the insect pest, it may be able to flourish on its own. Thus, EPA would have to consider the likelihood that the crop itself could become invasive due to the selective advantage imparted on it and the likelihood, if the GMO escapes from cultivation, that it will be fit to compete in nature.

To obtain authorization to release the GMO into the environment, the applicant must provide reasonable assurances that the release will not cause adverse economic risks. The economic risks posed by GMOs include risk of loss of ability to sell a product as organic due to contamination with GMOs, the economic costs to testing organic crops to determine whether such contamination has taken place, and the risk of a GMO causing a pest species to develop resistance to a particular biological pesticide. The economic risks to organic farmers share many of the same considerations as novel risks – i.e., the ability of the GMO to outcross. In the case of economic risk, however, the concern is not with out-crossing to wild relatives, but is out-crossing to organically grown crops. For example, if pollen from GMO corn fertilizes nearby organic corn crops, the organic grower will not be able to sell her product as organic. Moreover, with regard to this type of economic cost, the concern is not with out-crossing to a species that will be more fit in the environment. Any contamination of organic crops, whether resulting in viable progeny or not, may be sufficient to cause economic harms. Accordingly, careful evaluation of the GMO must be done to ensure it does not have the ability to genetically contaminate other crops.

With regard to the development of resistance to economically important biological pesticides due to transgenic plants, the risk considerations are somewhat different. Here, the concern is not with the selective advantage imparted to the transgenic plant, but rather is with the evolution of the pest species that feeds on, or is otherwise exposed to, the transgenic plant. To protect against such an outcome, EPA typically requires applications for registration to develop and implement an insect resistance management plan (IRM).[254] These plans typically rely on the planting of refuges surrounding transgenic crops that provide a location and food source for insects that do not expose the insects to the transgenic plant, and therefore, the pesticide, thereby allowing non-resistant insects to survive and reproduce. To date, EPA's practice has been to approve interim IRM plan or allow time for registrants to develop better data and long-term IRM plans.[255] Nevertheless, even with the best IRM plan, if a GMO is able to reproduce and spread in the environment to the extent that it is no longer contained in controlled crop fields that implement the IRM, such plans are meaningless. Accordingly, applicants seeking approval for GMOs that produce existing pesticidal substance should be require to conduct an *ex ante* analysis of the likelihood of the development or acceleration of resistance based on the biology of the relevant pest species and the likely

[254]Examples of EPA's guidance for IRM plans for PIPs can be viewed at http://www.epa.gov/pesticides/biopesticides/pips/bt_cotton_refuge_2001.htm (last visited August 8, 2206) and http://www.epa.gov/pesticides/biopesticides/pips/bt_brad2/4-irm.pdf (last visited August 8, 2006).
[255] *Id.*

quantity and distribution of the pesticide in the environment.

If the manufacturer cannot provide reasonable assurances that any particular non-traditional risk (novel or economic) will not occur, in order to obtain authorization to release the organism, the manufacturer would have to demonstrate that it would genetically manipulate the GMO, not only to have the desired pesticidal trait, but also to prevent the non-traditional risk from occurring. In other words, any evolutionary selective advantage that had been imparted as a result of genetic engineering must be eliminated. This could be achieved in a number of ways. For example, to prevent out-crossing with weedy relative or genetically contaminating other crops, the GMO can be "biologically contained" by genetically engineering it to have pollen of a shape or size that is physically incapable of cross pollinating other plants. To prevent the GMO from spreading through reproduction, the plant could be engineered to contain a "terminator" gene, which turns off the genetic modification after one generation or the GMO could be manipulated so that it is sterile and can exist only for one generation. In addition, to address concerns with the development of pest resistance, the manufacturer of the GMO could develop resistance management plans that require refugia to be established to enable "non-resistant" pests to flourish. To address concerns with a lack of control over a GMO once it is out in the environment, the GMO could be genetically engineered to make it susceptible to a specific herbicide, so that some level of control could be established were a problem to occur. Just as there are any number of ways to genetically engineer organisms to make them more evolutionarily "fit" for certain financial and societal purposes, there is no limit to ways to genetically engineer organisms to make them less evolutionarily "fit" to prevent human health, environmental and economic harms. Finally, it should be noted that, although this Article proposes a decision-making framework that ideally would be adopted in a new federal statue designed to address all types of GMOs, in the absence of Congress adopting such a comprehensive statute, the proposed framework could be incorporated into the regulatory processes of the EPA, FDA and USDA. However, such a change would most likely require amendments to the agencies' organic statutes to incorporate the regulatory standards proposed in this Article.

VIII. CONCLUSION

Genetic engineering has accelerated and dramatically changed the course of evolution to not only have potential economic and societal benefits, but also to create completely novel and unpredictable risks. Novel approaches that rely on principles of evolutionary biology are needed to address these novel risks. In the past, the U.S has relied upon the existing patchwork of statutes and regulations spread among several regulatory agencies to regulate GMOs. Not only has this approach has resulted in regulatory inconsistencies and interagency turf battles, but it is inherently skewed in that it does not take into consideration the different types and degree of risk posed by GMOs. Evolutionary biology theory can provide a framework for a new comprehensive regulatory program to address the entire range of risks posed by GMOs. The approach proposed in this Article

addressed the full array of risks and sets forth a clear regulatory standard ad decision-making framework to guide regulators in determining whether or under what conditions to allow GMOS to be released into the environment. Such an approach is necessary to ensure the potential risks of GMOs are adequately considered prior to allowing the spread of such organisms in the environment. Now that humans have added the Wright Brothers to the equation of biological evolution through genetic engineering, it is time to put the Wright Brothers into the equation of legal evolution.