Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms

Part 1

by

Mary Jane Angelo

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

*Mary Jane Angelo**

> "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."[1]

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1. Philip Johansson, *Crucibles of Evolution,* EARTHWATCH INST. J., Aug. 2001, at 5, 13.

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.[2] In essence, the commercialization of genetic engineering[3] 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."[4] Not only has genetic engineering dramatically accelerated evolution, but it

2. Genetically modified plant crops have been planted commercially in the United States since 1994. By 2002, more than 88 million acres of genetic engineering-derived crops were being planted annually in the United States. Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants, 67 Fed. Reg. 50,578, 50,578 (Aug. 2, 2002).

3. Throughout this Article, the term "genetic engineering" and "genetic modification" will be used interchangeably and will be used consistently with the U.S. Department of Agriculture ("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." USDA, ANIMAL AND PLANT HEALTH INSPECTION SERV., APHIS BIOTECHNOLOGY: PERMITTING PROGRESS INTO TOMORROW 1 (2006), http://aphis.usda.gov/publications/biotechnology/content/printable_version/BRS_FS_permitprogress_02-06.pdf [hereinafter APHIS BIOTECHNOLOGY].

4. Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation*, 20 REV. LITIG. 589, 590 (2001).

also has accomplished things that probably never would 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, plants, and animals). This dramatic jumping of biological barriers does not occur in nature or through conventional breeding practices.[5]

Many products have been modified by genetic engineering 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")[6] 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 United States, more than 130 million acres worldwide,[7] and new and different genetically modified ("GM") crops

5. 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 cross-breeding between varieties or breeds of the same species, and rarely, between species in the same genus. *Id.*

6. 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 3. Throughout this Article, "GM" will refer to "genetically modified."

7. Proposed Federal Action to Update Field Test Requirements for

continually being developed, the time has come for a serious reevaluation of the 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. However, the truth, as with most truths, 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 the risks typically addressed by environmental regulatory programs. Although legal scholars, such as Thomas O. McGarity,[8] 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 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 GMOs. While most environmental laws have been adopted as a reaction to a particular environmental catastrophe or crisis,[9] this Article asserts

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Biotechnology Derived Plants, 67 Fed. Reg. at 50,578. The Office of Science and Technology Policy states that while the increases in GM crops are most dramatic in the United States, 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, *supra* note 3, at 1. 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 Website, http://usbiotechreg.nbii.gov (follow "Database" hyperlink; then follow "All Products" hyperlink) (last visited Nov. 28, 2006).

8. *See infra* notes 241-42 and accompanying text.

9. *See* Michael Allan Wolf, Essay, *Environmental Law Slogans for the New Millennium*, 35 U. RICH. L. REV. 91, 99 (2001) ("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 without the Donora, Pennsylvania disaster and Los Angeles's poisonous smog; the Coastal Zone Management Act without the Santa Barbara oil spill; the Oil Pollution Act of 1990 without the *Exxon Valdez* debacle; or the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) without Love Canal.") (footnotes omitted); *see also* Bradley C.

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 Edward O. Wilson[10] and Richard Dawkins,[11] and the work of legal scholars, such as William H. Rodgers,[12] Owen Jones,[13] and E. Donald Elliot,[14] 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 living organisms, such as non-indigenous organisms and new types of artificially cultivated organisms like farmed fish and endangered species bred to repopulate or increase populations in existing environments. Part II of this Article sets forth a fact pattern that illustrates the state of GMOs 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 ("EPA"), the Food and Drug Administration ("FDA"), and the U.S. Department of Agriculture ("USDA"). 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.[15] Part VI

Karkkainen, *Panarchy and Adaptive Change: Around the Loop and Back Again*, 7 MINN. J. L. SCI. & TECH. 59, 66-67 (2005).

10. Edward O. Wilson's works on evolutionary biology include EDWARD O. WILSON, SOCIOBIOLOGY: THE NEW SYNTHESIS (1975) [hereinafter WILSON, SOCIOBIOLOGY] and EDWARD O. WILSON, THE DIVERSITY OF LIFE (1992).

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

12. *See infra* note 249 and accompanying text.

13. *See infra* notes 247, 252, 263-66 and accompanying text.

14. *See infra* notes 259-61, 267 and accompanying text.

15. 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); Lakshman D. Guruswamy, *Sustainable Agriculture: Do GMOs Imperil Biosafety?*, 9 IND. J. GLOBAL LEGAL STUD. 461 (2002); Katherine Ives, *The Benefits of Biotechnology, the Intersection of GAT/WTO and Other Trade Issues*, 10 MICH. ST. U. DETROIT C.L. J. INT'L L. 13 (2001); Kevin C. Kennedy, *International Trade in Agriculture: Where We've Been, Where We Are, and Where We're Headed*, 10 MICH. ST. U.

describes evolutionary biology theory and explores how it has been employed to help shape many areas of the law. This Part VI 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 AND THE CASE OF THE "POPCORN SHRIMP"

Consider the following scenario. A genetic engineering company produces GM corn that contains the gene from a particular type of shrimp, which enables the corn plant itself to produce a toxin normally produced by the shrimp.[16] 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"),[17] EPA conducts a cost-benefit analysis and concludes that the benefits of the GM corn 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 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

DETROIT C.L. J. INT'L L. 1 (2001); Gerry Kiely, *WTO and Market Access: Subsidies, Tarification and Barriers to Freer Trade,* 10 MICH. ST. U. DETROIT C.L. J. INT'L L. 7 (2001); Darren Smits & Sean Zaboroski, *GMOs: Chumps or Champs of International Trade?*, 1 ASPER REV. INT'L BUS. & TRADE L. 111 (2001); Sabrina Safrin, Comment, *Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements*, 96 AM. J. INT'L L. 606 (2002); Holly Saigo, Note, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol,* 12 GEO. INT'L ENVTL. L. REV. 779 (2000).

16. The author would like to recognize Professor Patricia Dilley for suggesting to the author that this scenario gives new meaning to the term "popcorn shrimp."

17. 7 U.S.C. §§ 136-136y (2000).

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 than 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."[18] 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, so the birds are now exposed to the toxin and suffer ill effects. 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 warnings. 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

18. *See* 7 C.F.R. §§ 205.202, 205.105, 205.2 (2006).

has a similar 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 introducing 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 were not 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, 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 the 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.[19] Farmers throughout the United States were forced to destroy their crops. The farmers filed a class action lawsuit.[20] In addition, consumers alleging fraud, negligence, and

19. *StarLink Corn: How it Reached the Food Supply*, A.P., Dec. 4, 2002, http://archive.showmenews.com/2000/dec/20001204busi011.asp; *see also* 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 et al., U.S. Dept. of Agric., Econ. Research Serv., *StarLink: Impacts on the U.S. Corn Market and World Trade* (2001), http://www.ers.usda.gov/briefing/biotechnology/starlinkarticle.pdf.

20. *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 preempted by FIFRA and that the economic loss rule barred recovery. *Id.* at 833. The trial court held that FIFRA did not preempt the farmers' claims, that the contamination of crops by neighboring GM crops provided a claim to which

breach of warranty for recklessly exposing millions of consumers to these unapproved and potentially dangerous products filed class action lawsuits.[21] 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]

Another documented instance of the risks illustrated by the popcorn shrimp hypothetical is a case where the British government ordered the destruction of experimental fields of herbicide-tolerant oilseed rape plants because the GM 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

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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.

21. Jill Carroll, *Judge Will Approve Settlement on Use of StarLink Corn*, WALL ST. J., Mar. 7, 2002, at A4.

22. *See* Rebecca M. Bratspies, *Consuming (F)ears of Corn: Public Health and Biopharming*, 30 AM. J.L. & MED. 371, 387 (2004); Bratspies, *supra* note 19, at 594-95; Lin et al., *supra* note 19, at 46.

23. *Farmers Advised to Destroy GM Crops*, BBC NEWS ONLINE, May 27, 2000, http://news.bbc.co.uk/2/hi/uk_news/politics/766539.stm.

24. Thomas Hayden, *Bad Seeds in Court: When Genetically Modified Plants Contaminate Their Crops, Organic Farmers Fight Big Biotech*, U.S. NEWS & WORLD REP., Jan. 28-Feb. 4, 2002, at 34. For an interesting twist on the economic consequences of genetic contamination, see *Monsanto Canada Inc. v. Schmeiser*, [2004] S.C.R. 902. Schmeiser, a farmer in Saskatchewan, was sued by Monsanto for patent infringement when Schmeiser's canola crop was found to contain the company's patented modified genes that made the crops herbicide-resistant. Schmeiser did not have a license for use and did not purchase the company's crop, yet ninety-five to ninety-eight percent of his 1998 crop consisted of the GM 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. *Id.* Schmeiser countersued Monsanto for the contamination of his non-GM crops with the herbicide-resistant canola. *Id.*

25. Wendy Thai, Recent Developments, *Transgenic Crops: The Good, the Bad, and the Laws*, 6 MINN. J. L. SCI. & TECH. 877, 880 (2005); John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999). However, 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; Rick Weiss, *Gene-Spliced Corn No Big Threat to Butterflies, Studies Say*, WASH. POST, Nov. 3, 1999, at A3. EPA has prepared a document evaluating risks to Lepidoptera in general from *Bt* plant-incorporated protectant. AGRIC. BIOTECH. STEWARDSHIP TECHNICAL

number of insect pests have demonstrated resistance to *Bacillus thuringiensis* ("*Bt*"), an important low-risk nonengineered 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.[27]

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 superweeds or pest resistance. In addition, pathways for exposure to hazards may be much greater and more widespread because GMOs are living organisms 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 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

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COMM.—NON-TARGET ORGANISM SUBCOMM. AND NOVIGEN SCIENCES, INC., AMENDED REVISED RESPONSE TO EPA'S DATA CALL-IN NOTICE CONCERNING THE POTENTIAL FOR ADVERSE EFFECTS OF BT CORN ON NON-TARGET LEPIDOPTERANS (2001), *available at* http://www.epa.gov/pesticides/biopesticides/pips/executive_summary_and_preface.pdf.

26. Researchers at Texas A&M University 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, Texas A&M University, *Science Hopes to Keep One Step Ahead of Adaptive Bugs*, Sept. 6, 1996, http://agnews.tamu.edu/stories/ENTO/adbugs.htm (last visited Dec. 19, 2006).

27. Jörg Romeis et al., *Transgenic Crops Expressing* Bacillus thuringiensis *Toxins and Biological Control*, 24 NATURE BIOTECH. 63, 63 (2006).

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 that 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 risks 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 organisms, humans, and the environment. Such hazard is determined by the chemical and toxicological properties of the substance.[28] Although the risk of direct harm posed by exposure to

28. 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

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 the exposure component of risk 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.[29]

One of the major 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 GM foods to pose a risk of human allergenicity.[30] The primary concern appears to be that if a gene is

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of crop growth when they will be the most effective in killing weeds. However, if GM 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. L.G. FIRBANK ET AL., THE IMPLICATIONS OF SPRING-SOWN GENETICALLY MODIFIED HERBICIDE TOLERANT CROPS FOR FARMLAND BIODIVERSITY: A COMMENTARY ON THE FARM SCALE EVALUATIONS OF SPRING SOWN CROPS 1, 19-20 (2003), *available at* http://www.defra.gov.uk/environment/gm/fse/results/fse-commentary.pdf.

29. For a description of EPA's process for determining risks posed by pesticides, see generally http://www.epa.gov/pesticides/factsheets/riskassessment.htm (last visited Feb. 5, 2007).

30. 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 MICH. ST. U. DETROIT C.L. J. INT'L L.. 39 (2001); Jack Laurie, *Biotechnology and Agriculture,* 10 MICH. ST. U. DETROIT C.L. J. INT'L L. 29 (2001); Ellen Messer, *Food Systems and Dietary Perspective: Are Genetically Modified Organisms the Best Way to Ensure Nutritionally Adequate Food?*, 9 IND. J. GLOBAL LEGAL STUD. 65 (2001); Katharine Van Tassel, *The Introduction of Biotech Food to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645 (2004); 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). In fact, in 2001, *The New York 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 Lewontin, *Genes in the Food!*, N.Y. REV. OF BOOKS, June 21, 2001, at 81, 83 (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* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on*

moved from one organism, to which a certain segment of the population has an allergy, to another food organism that 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 that 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.[31] Eliminating this risk would require mechanisms to segregate the GM corn and to warn consumers that the GM corn may be allergenic to people with shrimp allergies. Without such protections, consumers will not be aware that by eating corn products they may be exposed to substances normally produced by

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Genetically Modified Food and Agriculture, 44 B.C. L. REV. 733, 759-63 (2003); Frank J. Miskiel, *Voluntary Labeling of Bioengineered Food: Cognitive Dissonance in the Law, Science, and Public Policy*, 38 CAL. W. L. REV. 223 (2001); Lauren Zeichner, *Product vs. Process: Two Labeling Regimes for Genetically Engineered Foods and How They Relate to Consumer Preference*, 27 ENVIRONS ENVTL. L. & POL'Y J. 467 (2004); Sarah L. Kirby, Note, *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 GMO 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. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839-42 (Jan. 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.*

31. *See generally* Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181, 186-87 (1998) (discussing FDA labeling regulations for allergens in GM foods). 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. D. DOUGLAS HOPKINS ET AL., ENVTL. DEF. FUND, A MUTABLE FEAST: ASSURING FOOD SAFETY IN THE ERA OF GENETIC ENGINEERING 10 (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, NAT'L WILDLIFE FED'N, BIOTECHNOLOGY AND THE ENVIRONMENT: A PRIMER ON THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 32 (1988).

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 GMOs. 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) produce 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 and 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 United States. 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.[32]

B. Novel Risks: GMOs as "Darwin in Hyperspeed"[33]

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

32. 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, 288 (1996).

33. Deacon & Paterson, *supra* note 4, at 590.

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.[34]

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 GM products parallels the risk of the introduction of any non-native species into a new environment.[35] Even very small genetic manipulations can significantly change an organism's ability to survive and flourish in a particular ecosystem.[36] Examples abound regarding the disastrous and unpredicted effects of introducing non-native species into the environment, displacing native species.[37]

Introducing GMOs into the environment could have similar impacts.[38] 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.[39] Once released into the environment, the spread of a GMO may be extremely difficult, if not impossible, to control.[40] 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 GM plant to transfer its genes to related existing weed species, wild

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34. 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).

35. David J. Earp, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1653-55 (1994); *see also* L. L. Wolfenbarger & P. R. Phifer, *The Ecological Risks and Benefits of Genetically Engineered Plants*, 290 SCIENCE 2088, 2088 (2000).

36. Earp, *supra* note 35, at 1653; Wolfenbarger & Phifer, *supra* note 35, at 2088.

37. *See* Judy J. Kim, Note, *Out of the Lab and into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms,* 16 FORDHAM INT'L L.J. 1160, 1166-67 (1993).

38. *See* Earp, *supra* note 35, at 1653.

39. *Id.* at 1654.

40. *Id.* at 1653-54.

relatives of the GM plant must grow in the geographic areas where the GM plant is introduced.[41] Most major crops grown in the United States are of foreign origin.[42] Thus, hybridization between GM 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.[43] Thus, these crop plants are unlikely to become weeds themselves when genetically altered.[44] However, many U.S. minor crops do have wild relatives in the United States.[45] Further, once the GM 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 risk posed by the potential for GM plants to cross-pollinate other plants is an economic risk. One economic cost that has arisen due to GMOs' ability to out-cross 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."[46] Organic farmers

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41. *Id.* at 1666-69.

42. *See* JANE RISSLER & MARGARET MELLON, THE ECOLOGICAL RISKS OF ENGINEERED CROPS 113 (1996) (showing the geographic origin of rice (southwest Asia), soybeans (northeast Asia), wheat (Middle East), and corn (Central America)).

43. Mary Jane Angelo, *Embracing Uncertainty, Complexity and Change: An Eco-Pragmatic Reinvention of a First Generation Environmental Law*, 33 ECOLOGY L.Q. 105, 153 n.235 (2006).

44. *See* Earp, *supra* note 35, at 1654.

45. Meeting Minutes: FIFRA Scientific Advisory Panel Meeting, Plant-Incorporated Protectants Based on Virus Coat Protein Genes: Science Issues Associated with the Proposed Rule (Dec. 6-8, 2005), *in* SAP REPORT NO. 2006-01 [hereinafter SAP REPORT].

46. *See generally* 7 C.F.R. §§ 205.300-.301 (2006). The regulation requires product labels to differentiate between 100% organic, organic, and 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 any nonorganic constituents must be either nonorganic agricultural products that are not commercially available in an organic form, or are products that are permitted under 7 C.F.R. § 205.605 (2006). *See* USDA, AGRIC. MKTG. SERV., LABELING PACKAGED PRODUCTS UNDER THE NATIONAL ORGANIC STANDARDS, http://www.ams.usda.gov/nop/ProdHandlers/

who 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 nonorganic 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 of major organic soybean and corn growers found that thirteen percent of their product purchasers request crops to be tested for the presence of GMOs.[47] The costs of such tests are approximately $300 per test.[48] 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 United States. These European organic crops are lower-priced because organic growers in Europe do not have to pay for genetic testing, as GM crops are not widely grown in European Union countries.[49]

In addition, serious concerns have arisen regarding the risk that plants producing pesticidal substances such as the *Bt* toxin[50] on a continual basis may hasten the development of pest resistance to these beneficial pesticides.[51] Many non-GM biological pesticides, such as the naturally occurring *Bt* microbe, are relied on by organic and nonorganic growers alike. These microbial pesticides are very effective pesticides and are a relatively low risk to non-target organisms.[52] They are applied to crops on an as-needed basis. When a crop plant is genetically engineered to produce a pesticide, such as the *Bt* 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

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labelTable.pdf (last visited Nov. 10, 2006).

47. ERICA WALZ, ORGANIC FARMING RES. FOUND., FOURTH NATIONAL ORGANIC FARMER'S SURVEY 88 (2004), *available at* http://www.organicaginfo.org/record.cfm?pk_doc_id=3233&doc_num=1.

48. Rick Gush, *Organic Farming vs. Genetic Engineering,* HOBBY FARMS, Jan./Feb. 2006, at 28.

49. *Id.*

50. *Bacillus thuringiensis,* ("*Bt*") 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* FUNDAMENTALS OF APPLIED ENTOMOLOGY 239 (Robert E. Pfadt, ed., 1978).

51. *See* Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297, 306-10 (2002) (analyzing the problem of pest resistance with regard to *Bt* corn).

52. 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, 259, 285 (1996).

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.[53] Evidence already exists that GM crops producing the *Bt* toxin may be responsible for the development of *Bt* resistance in certain pest species, such as the diamondback moth.[54] If such resistance continues to develop in other pest species, growers will lose an important tool in their pest management arsenal. This is of particular concern to organic growers, for whom naturally occurring microbial pesticides such as *Bt* are among the few pesticides available to them that allow them to sell their crops as "organic."[55]

D. Uncertain Risks: New Technology and Lack of Experience

Perhaps the greatest concern with GM 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 GM crops for approximately ten years,[56] the GMOs that are in widespread use are primarily a few limited types, such as *Bt*, viral coat proteins, and herbicide tolerance, in a few very well-understood crops, such as corn and soy.[57] The fact that there have not been widespread environmental or human health problems resulting from the use of GMOs is not surprising. This limited

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53. Matthew Rich, Note, *The Debate over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 893, 895 (2004). This is a similar phenomenon to the bacterial resistance that is occurring with regard to the overuse of antibiotics. *See generally* Michael Misocky, Comment, *The Epidemic of Antibiotic Resistance: A Legal Remedy to Eradicate the "Bugs" in the Treatment of Infectious Diseases*, 30 AKRON L. REV. 733 (1997).

54. *See* Bruce E. Tabashnik et al., *One Gene in Diamondback Moth Confers Resistance to Four* Bacillus thuringiensis *Toxins*, 94 PROC. NAT'L ACAD. SCI. 1640 (1997).

55. *See* 7 C.F.R. § 205 (2006) (non-GMO *Bt* is not contained in the list of prohibited substances in 7 C.F.R. §§ 205.602-603).

56. Bratspies, *supra* note 51, at 303-04.

57. MARGARET MELLON & JANE RISSLER, UNION OF CONCERNED SCIENTISTS, ENVIRONMENTAL EFFECTS OF GENETICALLY MODIFIED FOOD CROPS: RECENT EXPERIENCES (2003), http://www.ucsusa.org/food_and_environment/genetic_engineering/environmental-effects-of-genetically-modified-food-crops-recent-experiences.html (last visited Jan. 6, 2006).

universe of GMOs is generally considered to be fairly innocuous.[58] 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 into the environment. What is perhaps of greater concern than the GMOs in current widespread use, however, are the many GM products in the research and development stage that may pose much more significant risks. For example, research is being conducted on a variety of GM crops that have been engineered to produce new types of pesticides and pharmaceutical and industrial products.[59] If these GMOs are not properly contained and are allowed to spread into the environment, humans and wildlife alike could be unwittingly exposed to hazardous pharmaceutical or industrial substances.[60]

This discussion of the risks of GMOs is not intended to suggest that GMOs have no benefits. For instance, many scientists believe that GM pesticides may provide a less risky alternative to chemical pesticides because many GMOs are less toxic than chemical pesticides, more narrowly targeted towards the intended pest, and released into the environment in smaller quantities.[61] This

58. 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 GM 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 id.*

59. *See* Thai, *supra* note 25, at 879, 887 (2005); APHIS BIOTECHNOLOGY, *supra* note 3, at 1.

60. *See generally* Thai, *supra* note 25, at 878-85.

61. 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 *Bt* 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

discussion on the unique ecological risks posed by GM 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 Regulation of Biotechnology*.[62] The stated purpose of the document was

> to provide a concise index of U.S. laws related to biotechnology, to clarify the policies of the major regulatory agencies that will

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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, the rDNA technique may be used to create plants with improved photosynthetic and nitrogen fixation capabilities, thereby reducing the need to apply fertilizers. Angelo, *supra* note 32, at 284-86; Proposed Policy, Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,496 (Nov. 23, 1994). Despite the potential benefits of GM crops, recent studies suggest that the benefits may be short-lived or may be offset by unexpected consequences. For example, a recent study conducted by scientists at Cornell University demonstrates that growing secondary pest populations have slowly eroded the benefits of *Bt* technology in China. Shenghui Wang et al., *Tarnishing Silver Bullets:* Bt *Technology Adoption, Bounded Rationality and the Outbreak of Secondary Pest Infestations in China* (paper prepared for presentation at the American Agricultural Economic Association Annual Meeting, July 22-26, 2006), *available at* http://www.grain.org/ research_files/SWang_tarnished.pdf.

62. 49 Fed. Reg. 50,856 (Dec. 31, 1984). Although commonly used interrelatedly with genetic engineering, the U.S. government has defined the term "biotechnology" as: "the use of various biological processes, both traditional and newly devised, to make products and perform services from living organisms or their components." Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753, 6754 (Feb. 27, 1992).

> 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.[63]

In 1986, OSTP published the final announcement of policy and notice for public comment in *Coordinated Framework for Regulation of Biotechnology* (the "*Coordinated Framework*").[64]

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.[65] 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.[66] Specifically, the *Coordinated Framework* stated that "techniques of biotechnology are not inherently risky and that biotechnology should not be regulated as a process, but rather that the products of biotechnology should be regulated in the same way as products of other technologies."[67] In other words, the *Coordinated*

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63. Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. at 50,856.

64. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

65. *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.

66. *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 Regulation of Consumer Choice,* 118 HARV. L. REV. 525 (2004).

67. Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J. L. REFORM 403, 431 (2002) (quoting COMM. ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, NAT'L RES. COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 25 (2000)). During the 1980s and early 1990s, the executive branch was focused on promoting biotechnology as the United States' hope for a strong economic future. The feeling at the time was that the United States 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

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 depended only 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 biotechnology. These agencies include EPA, USDA, FDA, the National Institutes of Health ("NIH"), and the Occupational Safety and Health Administration ("OSHA").[68] The two federal agencies identified in the *Coordinated Framework* as having the primary authority to regulate environmental risks posed by GMOs are EPA and USDA.[69] The primary agency identified as having the authority to address risks from GM food is FDA.[70]

B. Environmental Protection Agency Authority

EPA is the primary federal agency charged with the regulation of environmental risk-producing activity in the United States.[71] 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 FIFRA and Federal Food, Drug, and Cosmetic Act ("FFDCA").[72] FIFRA governs the manufacture, sale, and distribution of pesticides in the United States, and addresses both environmental and human health risks associated with such pesticides.[73] The reach of EPA's authority under FFDCA, on the other hand, extends only to pesticides in food, and addresses only the human health risks associated with such pesticides.[74] EPA's third authority for regulating GMOs is found in Toxic Substances Control Act ("TSCA"), which is EPA's "catch-all"

President Dan 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* THE PRESIDENT'S COUNCIL ON COMPETITIVENESS, VICE PRESIDENT DAN QUAYLE, CHAIRMAN, REPORT ON NATIONAL BIOTECHNOLOGY POLICY (Feb. 1991); *see generally* Marden, *supra* note 30.

68. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303.

69. *Id.* at 23,304-05.

70. *Id.*

71. 42 U.S.C. § 4321 (2000).

72. *Id.*

73. 7 U.S.C. §§ 136-136y (2000).

74. 21 U.S.C. § 342 (2000).

authority for regulating substances that do not fall within the jurisdictional bounds of its other authorities.[75] Although none of these 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 modified to exhibit pesticidal characteristics, is FIFRA.[76] The origins of FIFRA are in the 1910 Federal Insecticide Act (the "Act"), which was a classic consumer protection statute.[77] It was designed to address grievances from consumers, primarily farmers, that pesticides sold to them were either too weak and therefore did not kill the pests, or too strong, thereby harming the crops themselves.[78] The Insecticide 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.[79] The Act 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*,[80] attempts were made to bring environmental concerns into the Act.[81] 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

75. 15 U.S.C. §§ 2601-2629 (2000).

76. 7 U.S.C. §§ 136-136y (2000).

77. CHRISTOPHER J. BOSSO, PESTICIDES AND POLITICS 53-60 (1987).

78. *Id.*

79. *Id.* at 11.

80. RACHEL CARSON, SILENT SPRING (1962).

81. 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* Angelo, *supra* note 43, at 109.

of pesticide law in the United States.

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.[82] 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.[83] 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."[84] FIFRA defines "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."[85] 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.[86]

EPA generally relies on labeling requirements to impose risk-reduction measures on the use of traditional pesticide products. For example, EPA regulations at 40 C.F.R. § 156.10 contain extensive labeling requirements addressing, among other things, warnings, precautionary statements, and directions for use.[87] 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.[88] These labeling restrictions are translated into use

82. 7 U.S.C. § 136a(a), (c)(9) (2000).

83. *Id.* § 136a(a).

84. *Id.* § 136a(c)(5)(D).

85. *Id.* § 136(bb).

86. The plain language of FIFRA does not mandate a strict cost-benefit balancing. The statute merely requires that EPA "tak[e] into account" economic and social as well as environmental considerations. *Id.* Nevertheless, EPA has consistently interpreted and implemented this standard as a strict cost-benefit balancing, and this interpretation has been upheld in a number of administrative and judicial decisions. *See, e.g.*, Envtl. Def. Fund, Inc. v. EPA, 548 F.2d 998, 1005 (D.C. Cir. 1976); *In re* Chapman Chem. Co., 1 E.A.D. 199, 203 (EPA 1976); *In re* Protexall Prods., Inc., 2 E.A.D. 854 (EPA 1989).

87. 40 C.F.R. § 156.10 (2006).

88. *Id.*

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."[89]

EPA has stated that it recognizes that many types of restrictive labeling it relies on to regulate traditional chemical pesticides may not be appropriate for pesticidal GMOs.[90] For example, geographical limitations on the use of the GMO may not be 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

89. 7 U.S.C. § 136j(a)(2)(G) (2000). 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(i)(2)(ii).

90. Proposed Policy; Plant Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,496, 60,507 (Nov. 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) (2000). 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. *Id.* 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" suspensions. *Id.* § 136d(c). Ordinary suspension is issued where such action is necessary to prevent an imminent hazard during the time required for cancellation proceeding. *Id.* § 136d(c)(1). "Imminent hazard" is defined as a likelihood of serious harm during the duration of cancellation proceedings. *Id.* § 136(*l*). 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 before suspension takes place. *Id.* § 136d(c)(3). FIFRA also authorizes EPA to order a recall of unused pesticide as part of a cancellation. *Id.* § 136k(a).

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.[91] 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.[92] 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, defoliant, or desiccant . . . ."[93] 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.[94]

During the 1990s, EPA attempted to develop a comprehensive regulatory program for GMOs. Unfortunately, these efforts were 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.[95] 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.[96] Each of these

91. *See* Angelo, *supra* note 43, at 174.

92. *Id.* at 171-72 n.328.

93. 7 U.S.C. § 136(u).

94. *See* Angelo, *supra* note 43, at 172.

95. Microbial Pesticides; Experimental Use Permits and Notifications, Final Rule, 59 Fed. Reg. 45,611-12 (Sept. 1, 1994) (codified at 40 C.F.R. pt. 172).

96. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants, 66 Fed. Reg. 37,772, 37,814 (July 19, 2001) (codified at 40 C.F.R. pt. 152).

rules took approximately ten 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 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 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.[97]

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 *Bt*, for years.[98] 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.[99] Thus, EPA promulgated a rule that requires notification prior to any small-scale testing of certain microbial pesticides, including microbial GMOs.[100] Section 5 of FIFRA authorizes EPA to issue experimental use permits ("EUPs")

97. *See* Angelo, *supra* note 43, at 174.

98. Although *Bt* 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 fourteen eastern states and the District of Columbia. *See* FUNDAMENTALS OF APPLIED ENTOMOLOGY 239 (Robert E. Pfadt ed., 1978).

99. *See* Microbial Pesticides; Experimental Use Permits and Notifications, Final Rule, 59 Fed. Reg. 45,600 (Sept. 1, 1994) (codified at 40 C.F.R. pt. 172).

100. 40 C.F.R. § 172.45 (2006).

for the testing of new pesticides or new uses of existing pesticides.[101] Under EPA's existing regulations, EUPs are generally issued for large-scale testing of pesticides.[102] A large-scale test includes any terrestrial application on a cumulative acreage of more than ten acres of land or any aquatic application on more that one acre of surface water.[103] For traditional pesticides, EPA presumes that tests conducted on ten acres or less of land or one acre or less of water ("small-scale tests") would not require EUPs.[104] For certain GM microorganisms, however, EPA determined that even small-scale tests warrant an evaluation.[105]

After almost ten years of deliberation and a series of EPA and federal government-wide policy statements that were made

101. 7 U.S.C. § 136c(a) (2000) 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.

102. 40 C.F.R. § 172.3 (2006).

103. *Id.* § 172.3(a), (c)(1)-(2).

104. *Id.*

105. 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. 23,302 (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. *See, e.g.*, EPA: Microbial Pesticides; Request for Comment on Regulatory Approach, 54 Fed. Reg. 7026 (Feb. 15, 1989) (requesting comment on issues related to this final rule); Office of Science and Technology Policy: Principles for Federal Oversight of Biotechnology, 55 Fed. Reg. 31,118 (July 31, 1990) (addressing the appropriate scope of federal oversight of GMO introduction and requesting comment); Office of Science and Technology: Exercise of Federal Oversight Within Scope of Statutory Authority, 57 Fed. Reg. 6753 (Feb. 27, 1992); (addressing the appropriate scope of federal oversight of GMO introduction); THE PRESIDENT'S COUNCIL ON COMPETITIVENESS, *supra* note 67. 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.

available to EPA's Scientific Advisory Panel ("SAP")[106] and the Biotechnology Science Advisory Committee ("BSAC"),[107] on September 1, 1994, EPA promulgated the final rule on experimental use permits and notifications for GM pesticidal microorganisms.[108] 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.[109]

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."[110] In other words, EPA rejected a "product-based" scope of

106. 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 of the rules on health and the environment. 7 U.S.C. § 136w(d) (2000). 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.

107. 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. 23,313, 23,318 (June 26, 1986).

108. Microbial Pesticides; Experimental Use Permits and Notifications, 59 Fed. Reg. 45,600 (Sept. 1, 1994) (codified at 40 C.F.R. pt. 172) [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].

109. Microbial Pesticides Rule, 59 Fed. Reg. at 45,600. Under the rule, testing conducted in facilities designed and operated to adequately contain the microbial pesticide would not be subject to the notification requirements. *Id.* at 45,602. Records describing containment, however, would be required to be developed and maintained. *Id.*

110. *Id.* at 45,601. In the proposed rule, EPA had identified three options for defining the scope of GM microbial pesticides subject to notification requirements. Microbial Pesticides Proposed Rule, 58 Fed. Reg. at 5882. 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

regulation in favor of a "process-based" one.[111] By defining the regulated organisms as those whose genetic material had been "deliberately modified,"[112] 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 submitted for all small-scale testing of non-indigenous organisms.[113]

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because it believed this option covered the appropriate microbial pesticides and had a high degree of regulatory utility. *Id.* at 5882-85. 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.

Id. at 5882 (citation omitted). 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 "[i]ndigenous microbial pesticides for which specific pesticidal activities have been created or increased by deliberate processes or techniques." *Id.* at 5883. 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 be 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. *Id.*

111. Microbial Pesticides Rule, 59 Fed. Reg. at 45,600 (codified at 40 C.F.R. pt. 172).

112. Microbial Pesticides Proposed Rule, 58 Fed. Reg. at 5882.

113. Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,885-86 (Dec. 31, 1984); Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic

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 USDA either by issuing or denying a permit or determining that a permit is unnecessary.[114] 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 USDA (through the Animal and Plant Health Inspection Service ("APHIS") already regulates small-scale testing of the vast majority of these organisms.[115]

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,[116] 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.[117] Although EPA has developed some data requirements geared to address potential risks from microbial pesticides in general,[118] 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

Substances Control Act, 51 Fed. Reg. 23,313, 23,321 (June 26, 1986).

114. 40 C.F.R. § 172.45(a), (c) (2006). 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. § 172.45(a)(2), (d)(2). Records describing containment, however, would be required to be developed and maintained. § 172.45(e)(4).

115. Microbial Pesticides Rule, 59 Fed. Reg. at 45,602.

116. 40 C.F.R. § 172.57.

117. *Id.* § 172.59. The final rule also amends 40 C.F.R. § 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 § 172.3 was 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. *Id.* § 172.3.

118. The data requirements for microbial pesticides can be found at 40 C.F.R. § 158.740 (2006). 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.*

FIFRA are GM pesticidal plants, or "plant-incorporated protectants" ("PIPs").[119] In July 2001, EPA published its long-awaited rule for the regulation of PIPs under FIFRA.[120] EPA initially proposed a version of what is now the PIP rule in 1994.[121] In the 1994 proposal, EPA identified several categories that it believed should be exempt from FIFRA regulation because they were low-risk.[122] 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.[123] An example of this is using genetic modification 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 could not have evolved naturally or through traditional breeding.[124]

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119. 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 Federal Food, Drug, and Cosmetics Act. *See infra* notes 142-45 and accompanying text.

120. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants, 66 Fed. Reg. 37,772 (July 19, 2001) (codified at 40 C.F.R. pts. 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 SAP and the BSAC 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. 60,496, 60,519, 60,535, 60,542, 60,545 (Nov. 23, 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 PIP rule, promulgated in 2001, adopted some, but not all, of the exemptions proposed in 1994. *See* 40 C.F.R. § 174. For an historical discussion of the PIP rule, see generally Angelo, *supra* note 32, at 290-98.

121. Proposed Policy; Plant Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetics Act, 59 Fed. Reg. 60,496 (Nov. 23, 1994).

122. *Id.* at 60,500-01.

123. *Id.*

124. *Id.* at 60,502-03.

EPA presented three options for the exemption.[125] 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 plant breeding versus those created through genetic engineering.[126]

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.[127] 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.[128] The

125. *Id.* at 60,501.

126. *Id.* One category of pesticidal GMOs that EPA believed did not warrant regulation were plants 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 *Bt* 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.* at 60,502-03. 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.* at 60,503. This category consists of plant-pesticides that 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 genetically modified to contain the genes for coat proteins from a plant virus. *Id.* at 60,503-04. This type of GMO 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.*

127. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants, 66 Fed. Reg. 37,772, 37,775 (July 19, 2001).

128. Under EPA's definition of PIPs, 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 a low probability of risk and will not cause unreasonable adverse effects on the environment. For

final rule exempts certain PIPs from all FIFRA regulatory requirements, except for the requirement of reporting adverse effects information.[129] The exempt PIPs are those 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[130] 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 exempt from regulation.[131] In other words, in the 2001 final rule, EPA rejected 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 "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.[132] The scaling-back of the exemption was in response to public comments received on the proposal, as well as to a joint EPA, SAP, and BSAC meeting held in January 1994, in which the joint panel considered the matter and supported the use of an exemption criteria based on

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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(a) (2006). This exemption was promulgated because EPA found that microorganisms used as biological control agents were adequately regulated by other federal agencies, such as USDA.

129. The final rule requires any person who produces, for sale or distribution, a PIP exempt under the rule, or 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 (2006).

130. EPA defines the term "sexually compatible" in plants as when "a viable zygote is formed only through the union of two gametes through conventional breeding." 40 C.F.R. § 174.3.

131. 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 compatible, 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. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants, 66 Fed. Reg. at 37,794-95.

132. 40 C.F.R. § 152.20.

the technology (i.e., process) used to produce the PIP.[133] The joint panel based its support on a combination of the uncertainties about how genes would function in the new genetic background and the importance of 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 comments on the exemptions it proposed in 1994.[134] 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.[135] To date, EPA has not taken any action on either of the two alternative approaches for which it sought additional comment in 2001.[136]

Accordingly, EPA's final PIP rule merely draws a line between PIPs subject to regulation and those not subject to regulation under FIFRA.[137] 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 effects. 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[138] are not adequate to address these risks. EPA has not yet developed any data requirements whatsoever for GM pesticidal plants, nor has it adopted any regulations addressing information

133. Plant-Incorporated Protectants (Formerly Plant-Pesticides) Supplemental Proposal, 66 Fed. Reg. 37,855, 37,857-58.

134. *Id.*, at 37,855.

135. *Id.* at 37,858-61.

136. Interview by Mary Jane Angelo with Laurel Celeste, EPA Attorney (May 23, 2006).

137. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772 (July 19, 2001).

138. *See generally id.*

requirements to support registration,[139] product labeling requirements,[140] or experimental use permitting for PIPs.[141] In the absence of any such new requirements, EPA relies on existing requirements that were crafted for traditional chemical pesticides to regulate 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 FFDCA.[142] Pursuant to section 408(a) of 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.[143] 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."[144] In the 2001 final PIP rule, EPA adopted an exemption under this standard. As with FIFRA PIP exemptions, EPA's FFDCA exemption for PIPs focuses on sexual compatibility through conventional breeding.[145]

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139. 40 C.F.R. § 174 pt. H (2006) (reserving a subpart for future data requirements).

140. *Id.* § 174 pt. G (reserving a subpart for future labeling requirements).

141. *Id.* § 174 pt. U (reserving a subpart for future experimental use permit requirements).

142. 21 U.S.C. § 346 (2000). 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. 199 (1970 Comp.), *reprinted in* 5 U.S.C. app. 184, *and in* 84 Stat. 2086 (1970-71). Regulatory authority over other non-pesticidal substances in foods and animal feeds was left within the jurisdiction of the FDA.

143. 21 U.S.C. § 346a(a)(1).

144. *Id.* § 346a(c)(2)(A).

145. 40 C.F.R. § 174.479 (2006). This exemption provides:

> Residues of a pesticidal substance that is part of a plant-incorporated protectant 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.

Id. In addition, EPA has exempted from the tolerance requirement nucleic acids that are part of PIPs. In addition, EPA exempted inert ingredients from

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 TSCA.[146] The regulatory jurisdiction under TSCA extends to all chemical substances, which are defined as "organic or inorganic substance[s] of a particular molecular identity, including . . . any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature," but excluding pesticides.[147] EPA has interpreted this broad definition of chemical substances to include living organisms.[148] Under section 5 of TSCA, all new chemical substances are automatically covered and subject to a ninety-day screening mechanism, known as a Pre-Manufacture Notification ("PMN").[149] Upon receiving a PMN for a new chemical substance, EPA has

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sexually compatible plants. *Id.* § 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 residues of the inert ingredient are not present in food from the plant at levels that are injurious or deleterious to human health.

Id. "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.

Id. § 174.3. EPA has also exempted from the tolerance requirement nucleic acids that are part of PIPs and the residues of certain *Bt* in specified crop foods. *Id.* §§ 174.455-.456 (exempting from the requirement for a tolerance *Bt* Cry1F protein and the genetic material necessary for its production in cotton and *Bt* modified Cry3A protein (mCry3A) and the genetic material necessary for its production in corn, respectively).

146. 15 U.S.C. §§ 2601-2629 (2000).

147. *Id.* § 2602(2)(A)-(B). 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. *Id.* § 2602(2)(B).

148. 40 C.F.R § 710.26(c). EPA's interpretation is that living organisms, whether naturally 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.

149. 15 U.S.C. § 2604(a) (2000).

ninety days to perform screening to determine whether it is necessary to impose controls to prevent unreasonable risk or substantial exposure to the chemical.[150] If EPA fails to take action within the ninety-day period, the new chemical substance may be manufactured, processed, distributed, sold, used, or disposed.[151]

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 TSCA inventory.[152] 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 TSCA section 5 requirements.[153] The rationale behind this interpretation is that intergeneric microorganisms have significant potential for exhibiting new traits or combinations of traits.[154] Thus, these organisms have the potential to result in new types of risks in the environment. Such "new" microorganisms could include microorganisms 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").[155] An MCAN must be submitted at least ninety days prior to the use of intergeneric microorganisms for commercial purposes in the United States, providing EPA with a ninety-day opportunity to review the new GMO to determine whether additional regulations are necessary to prevent unreasonable risks

150. *Id.*

151. *Id.* § 2604(g).

152. 40 C.F.R. § 725.3 (2006).

153. 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 for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,307 (June 26, 1986).

154. 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 product was created. *Id.* at 23,302. In other words, all intergeneric microorganisms are subject to the regulation regardless of whether they were created by genetic engineering or some other process.

155. 40 C.F.R. § 725.3 (2006).

or substantial exposure.[156]

Although EPA has established the MCAN notification processes for intergeneric microorganisms, it has not promulgated any rules addressing how to evaluate or reduce risks from such organisms. Neither has EPA promulgated any rules addressing GM plants or animals under TSCA. Nevertheless, EPA has repeatedly stated that it intends to address TSCA oversight of transgenic[157] plants and other organisms.[158] EPA has not provided a specific timetable for developing such regulation.[159]

C. *FDA Authority*

FDA's primary authority governing the regulation of GM foods

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156. *Id.* § 725.50. The rule 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. *Id.* § 725.1. This requirement is referred to as the TSCA Experimental Release Application ("TERA"). *Id.* A TERA must be submitted at least sixty days prior to initiating such a field trial. *Id.* § 725.250(a). TERA provides a shorter review period than MCAN to provide more flexibility to researchers conducting limited field testing. TSCA section 5(h) provides certain exemptions from the Premanufacture 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)-(4) (2000). Section 5(h)(3) exempts substances manufactured or processed only in "small quantities" for research and development (R&D) from PMN requirements. *Id.* § 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. *Id.* § 2604(h)(4) (2000). In addition, the rule exempts from MCAN requirements intergeneric microorganisms used in R&D in contained structures, provided adequate containment requirements are met and researchers maintain records. 40 C.F.R. §§ 725.428, 725.450(d).

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

158. TSCA Policy Statement on Oversight of Transgenic Organisms (Including Plants), 70 Fed. Reg. 27,625, 27,631 (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 APHIS, these plants cease to be subject to regulation by USDA while being tested in the environment following APHIS approval of a petition for nonregulated status. *Id.* Moreover, EPA notes that transgenic animals that are not under the jurisdiction of FDA 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. *Id.*

159. *Id.*

is found in section 402(a)(2)(C) of FFDCA.[160] This section provides that a food shall be deemed adulterated if it contains any food additives that are unsafe within the meaning of section 409.[161]

Section 409 provides that a food additive is deemed unsafe unless the additive and its use or intended use comply with a properly promulgated food additive regulation.[162] 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 as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use . . . .[163]

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").[164]

In 1992, FDA published a policy statement on "foods derived from new plant varieties."[165] This policy provided guidance on how FDA would treat GM 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.[166] Thus, under this definition, virtually all cultivated food crops were considered to be genetically modified.[167] This approach of treating all cultivated food crops as genetically modified regardless of the process used to modify them is consistent with the *Coordinated Framework* stated policy choice of regulating products rather than

160. 21 U.S.C. §§ 301-97 (2000). 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* notes 140-43 and accompanying text.

161. 21 U.S.C. § 342(a)(2)(C).

162. *Id.* § 348.

163. *Id.* § 321(s).

164. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,989 (May 29, 1992).

165. *Id.* at 22,984.

166. *Id.* at 22,984 n.3.

167. *Id.*

process.[168] However, the 1992 policy went further, establishing what is in essence a presumptive GRAS status to GM foods as well as conventionally bred foods.[169] This presumption was based on FDA's conviction that, based on its experience, the likelihood of a significant risk from a GM food is very low.[170] FDA believed 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 GM foods.[171] The 1992 policy statement explained that FDA believed that "[i]n most cases, the substances expected to become components of food as a result of genetic modification of a plant 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 GRAS.[172] FDA did acknowledge that some GM foods would not qualify as GRAS, including those that involve the transfer of gene 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.[173] 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 pre-market evaluation of the safety of the GM food is necessary.[174] Nevertheless, FDA leaves it up to the producer of the new plant variety to determine the GRAS status of its product.[175] 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 that would

168. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

169. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990.

170. *Id.* at 22,986-87.

171. *Id.* at 22,987.

172. *Id.* at 22,985.

173. *Id.* at 23,000.

174. For a full discussion of the substantial equivalency doctrine, see generally McGarity, *supra* note 67.

175. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,985.

require manufacturers and importers of GM food to provide FDA with pre-market notification of their intent to market GM foods.[176] To date, FDA has not taken final action on this proposal.

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.[177] As described *supra*, 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.

D. USDA Authority

1. GMOs Under the Plant Protection Act

USDA's APHIS has authority to regulate GMOs pursuant to the Plant Protection Act ("PPA").[178] The APHIS mandate under PPA is to prevent the release and spread in the environment of "plant pests," which are defined broadly as organisms that can directly or indirectly injure or cause disease or damage in or to any plants or plant parts.[179] In 1993, APHIS published a final rule amendment to

176. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 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 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.

177. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,992.

178. 7 U.S.C. §§ 7701-7772 (2000). The 2000 Plant Protection Act consolidated the authorities of two previously existing statutes under which APHIS asserted its regulatory jurisdiction over GMOs, the Federal Plant Pest Act, 7 U.S.C. §§ 150aa-150jj (1994), and the Plant Quarantine Act, 7 U.S.C. §§ 151-164, 166-167 (1994).

179. 7 C.F.R. § 340.1 (2006).

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.[180] APHIS also amended the regulation to provide for a petition process allowing for determination that certain GMOs are no longer considered "regulated articles,"[181] the term APHIS uses for GMOs that pose potential plant pest risk. In the final rule, APHIS stated that it believed, based on experience, these actions would relieve unnecessary restrictions on the introduction of regulated articles.[182]

The notification procedure is allowed for the introduction of most GM plants that are considered regulated articles, provided that the introduction is conducted in accordance with specified eligibility requirements and performance standards.[183] This would alleviate the need to obtain a permit prior to the introduction of those regulated articles. The stated rationale for replacing the permitting process 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 GM plants since it established its permitting process for regulated articles in 1987.[184] APHIS stated that it had issued over three hundred permits for field tests and

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180. Genetically Engineered Organisms and Products, Final Rule, 58 Fed. Reg. 17,044 (Mar. 31, 1993). The final rule was the outgrowth of a 1992 proposed rule. Genetically Engineered Organisms and Products, 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.

181. Genetically Engineered Organisms and Products, Final Rule, 58 Fed. Reg. at 17,044. The term "regulated article" is defined as

> [a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism 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 Administrator 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 organism where the material is well characterized and contains only non-coding regulatory regions.

7 C.F.R. § 340.1.

182. Genetically Engineered Organisms and Products, Final Rule, 58 Fed. Reg. at 17,044-45.

183. Genetically Engineered Organisms and Products, Proposed Rule, 57 Fed. Reg. at 53,036-37.

184. *Id.* at 53,037.

over one thousand permits for the movement of regulated articles.[185] Based on this experience, APHIS stated that it had determined that introduction of many regulated articles can be conducted with little or no plant pest or environmental risk.[186]

For releases into the environment beyond controlled field testing, APHIS adopted a final rule which established a process for petitioning to determine nonregulated status.[187] For any organism for which such a petition is granted, that organism is no longer considered a "regulated article," and therefore is exempt from all

185. *Id.* By 2001, USDA had issued 1117 field test authorizations for more than 57,000 acres of GM crop field testing. *See* Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants, 67 Fed. Reg. 50,578 (Aug. 2, 2002).

186. Genetically Engineered Organisms and Products, Proposed Rule, 57 Fed. Reg. at 53,037. To qualify for the notification process, six eligibility requirements must be met: (1) the regulated article is one of a list of plants species, which includes corn, cotton, potato, soybean, tobacco, and 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. *Id.* § 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 specify: (1) 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 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 that the plants parts must be contained or devitalized when no longer in use; (4) that there must be no viable vector agent associated with the regulated article; (5) 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 (6) that upon 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. *Id.*

187. *Id.*

APHIS regulation.[188] The petitioner must supply certain data regarding the organism, including field test data.[189] APHIS then reviews the data for potential "plant pest" risk.[190] Plant pest risk is direct or indirect injury, damage to, or disease in any plant or plant product.[191] If APHIS determines the organism poses no plant pest risk, it will grant the petition and the organism will be exempt from APHIS regulation.[192]

As with EPA's GMO regulation to date, APHIS's regulations focus on which GMOs require submission of notification prior to field testing and which GMOs are completely exempt from APHIS regulatory oversight. APHIS's regulations do not address how to regulate GMOs that are released into the environment to minimize environmental risk. Moreover, APHIS's 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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188. *Id.*

189. *Id.* § 340.6(c)(5).

190. A process for publication in the Federal Register and public comment is provided. *Id.* § 340.6(d)(2).

191. 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) (2000). 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. PPA gives USDA 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*." *Id.* § 7702(10) (emphasis added).

192. 7 C.F.R. § 340.6(d) (2006). 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, in 1995, under the authority of PPA, APHIS published a proposed rule relating to the introduction of non-indigenous organisms into the environment.[193] The proposal would establish comprehensive regulations on the importation, interstate movement, and release into the environment of certain non-indigenous organisms.[194] APHIS believed this action was necessary because the plant pest regulations under which the movement of certain non-indigenous organisms was regulated at the time did not adequately address the introduction of the non-indigenous organisms that may potentially be plant pests.[195] The proposed regulations would "provide a means

193. Introduction of NonIndigenous Organisms, 60 Fed. Reg. 5288 (Jan. 26, 1995) (to be codified at 7 C.F.R. pt. 335).

194. *Id.*

195. *Id.* Exotic species are frequently called non-indigenous species. A common definition for exotic species are those "plants and animals found outside 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); *see also* Daniel P. Larsen, *Combating the Exotic Species Invasion: The Role of Tort Liability*, 5 DUKE ENVTL. L. & POL'Y F. 21, 34-36 (1995). In addition to PPA, the Lacey Act prohibits the importation into the United States of any animal species that are designated by the Secretary of the Interior as injurious to human beings, to the interests of agriculture, horticulture, forestry, or to wildlife. 16 U.S.C. §§ 3371-78 (2000); 18 U.S.C. § 42(a)(1) (2000). Similarly, the previous iterations of the PPA, 7 U.S.C. §§ 147a, 149, 150aa-150jj (2000), the Federal Noxious Weed Act of 1974, 7 U.S.C. §§ 2801-14 (2000), and the Federal Seed Act, 7 U.S.C. §§ 1551-1610 (2000), 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, 345-53 (1995); *See also* Biber, *supra*, at 398. 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, *supra*, at 28. 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.* Furthermore, the Lacey Act only regulates *intentional* introductions of exotic species, which would not include the accidental introduction of species such the zebra mussel, which has caused some of the most significant ecological damage. *Id.* at 24-25,

of screening certain non-indigenous organisms prior to their introduction to determine the potential plant pest risk associated with the particular introduction."[196]

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 pest risk or the release of such organisms into the environment.[197] 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.[198] 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.[199] 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.[200]

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

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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, *supra,* 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.* 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 the Comprehensive, Environmental Response, Compensation, and Liability Act ("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 also* Larsen, *supra*, at 36-38.

196. Introduction of NonIndigenous Organisms, 60 Fed. Reg. at 5288.

197. *Id.*

198. *Id.* at 5288-89.

199. *Id.* at 5290. 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 U.S. Fish and Wildlife Service and EPA. *Id.* at 5291.

200. *Id.* at 5291-92.

permitting process would include a description of the life cycle, biology, and ecology of the regulated organism.[201] 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.[202] 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."[203] 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 GMOs.[204] Other information that must be provided includes information on the geographic location where the regulated organism was originally collected and information on the established range of the regulated organism in the United States.[205]

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.[206] For release permits, information must be provided regarding all testing and reviews that have been conducted to assess the effects 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.[207] If APHIS issues a permit, the permit would specify the applicable conditions for the introduction of the regulated organism.[208] The proposal also provides a process for obtaining an exemption from regulation for organisms that are determined not to

201. *Id.* at 5292.
202. *Id.*
203. *Id.*
204. *Id.*
205. *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.* at 5293.
206. *Id.* at 5294.
207. *Id.*
208. *Id.*

pose a significant plant pest risk.[209] 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 into 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 twenty 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 *Bt*, potential risks to monarch butterflies caused by exposure to *Bt* pollen, cross-fertilization of neighboring farms resulting in loss of organic certification, and the prospect of superweeds that cannot be easily eliminated.[210] As can be seen from the description *supra* Part IV 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.[211] Although the three agencies do

209. *Id.* at 5295.

210. *See supra* notes 19-27 and accompanying text.

211. Interestingly, although the controversy over the regulation of GMOs has raged for over twenty years, in that time, very few cases have been litigated involving issues related to GMOs. Some of the few cases litigated include: Int'l Ctr. for Tech. Assessment v. Thompson, 421 F. Supp. 2d 1 (D.D.C. 2006) (upholding FDA's decision to allow unregulated commercialization of a genetically engineered ornamental fish); *In re* StarLink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828 (N.D. Ill. 2002); Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D.C. 2000) (finding that FDA's 1992 policy statement on GM foods was not arbitrary or capricious); Found. on Econ. Trends v. Thomas, 661

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.[212] 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 *supra*, 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.[213]

Currently, EPA's approach to GM microbial 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.[214] As to non-pesticidal GM microbes, EPA has drawn the regulatory threshold at intergeneric organisms and requires premanufacture notification and data submission for such organisms.[215] 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.[216] Moreover, USDA's approach is focused on deregulating GMOs.[217]

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,[218] FFDCA was amended to include a "safety" standard for

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F. Supp 713 (D.D.C. 1986) (dismissing for failure to present a justiciable case or controversy a suit seeking an order requiring EPA to modify the procedures under which it authorizes the release of GM pesticides into the environment).

212. *See supra* notes 86, 158 and accompanying text.

213. *See supra* notes 138, 87-90 and accompanying text.

214. *See supra* notes 139-41 and accompanying text.

215. *See supra* notes 152-56 and accompanying text.

216. *See supra* note 179 and accompanying text.

217. *See supra* note 178-92 and accompanying text.

218. 1996 Food Quality Protection Act, Pub. L. No. 104-170, 110 Stat. 1489

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.[219] Thus, as to pesticidal GM foods, EPA at least has a clear risk-based standard to guide its decisionmaking.

For non-pesticidal GM foods, on the other hand, FDA has not required any premarket 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.[220] 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 evaluating the regulation of transgenic plants.[221] The NRC 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.[222] 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 NRC report shows that this is not necessarily the case.

(codified in scattered sections of 7 U.S.C. §§ 136-136y (2000)).

219. 21 U.S.C. § 346a(c)(2)(A) (2000).

220. *See supra* notes 174-75 and accompanying text.

221. COMM. ON ENVTL. IMPACTS ASSOCIATED WITH COMMERCIALIZATION OF TRANSGENIC PLANTS, BOARD ON AGRIC. AND NATURAL RES., DIV. ON EARTH AND LIFE STUDIES, NAT'L RES. 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 USDA requesting that the National Academy of Sciences examine the scientific basis for an operation of 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 GM crops with non-pesticidal traits could affect agricultural and non-agricultural environments. *Id.* at 48-49.

222. *Id.* at 28-30.