



An Agricultural Law Research Article

Some Thoughts on the American Approach to Regulating Genetically Modified Organisms

by

Rebecca Bratspies

Originally published in KANSAS JOURNAL OF LAW AND PUBLIC POLICY
16 KAN. J. L. & PUB. POL'Y 393 (2007)

www.NationalAgLawCenter.org

SOME THOUGHTS ON THE AMERICAN APPROACH TO REGULATING GENETICALLY MODIFIED ORGANISMS

*Rebecca Bratspies**

It's part of our cultural tradition—"If it can be done, do it. Let's worry about the consequences later."¹

There is an old folk saying "to someone with a hammer, every problem looks like a nail." Like many folk sayings, it captures an important facet of human behavior—in this case, the limitations that available tools and ideas place on perspectives and thinking. This is a theme that resonates powerfully in the context of agricultural biotechnology. For those wanting to use or exploit biotechnology, it seems screamingly obvious that this technology will solve—in whole or in part—a host of problems, ranging from overuse of pesticides to global hunger and malnutrition. The technology is the hammer capable of pounding in all these many protruding nails in the collective international structure—a solution in search of problems.

There is nothing inherently wrong with such an approach—that is how many problems are ultimately solved. For those focused on solving any one particular problem, however, the connection between biotechnology and hunger, or biotechnology and reduced pesticide use, may not be so obvious. Other solutions may more closely address either the perceived roots of the problem or may offer a more attractive risk-reward profile.

Thus, one finds a scientist or an agribusiness company genuinely insisting that its technology is the solution to a problem, and feeling like they are pounding on closed doors. The persons tasked with solving these problems may be focused on entirely different sets of solutions; they may also view the proffered technological fix to be naked self-interest and self-promotion by its advocate. Is this a marketing problem, an information asymmetry, or does it point to a deeper misunderstanding of the role of the expert—particularly the

* Associate Professor, CUNY School of Law. I would like to thank Shalini Deo for research advice, Dean Michelle Anderson and my CUNY Law colleagues for their insightful suggestions, and the organizers and participants of the 2007 Kansas Journal of Law and Public Policy Symposium for discussions that helped shape this article. Finally, special thanks to Naomi Florence Schulz and B. Allen Schulz for their endless patience.

1. Andrew Maykuth, *Genetic Wonders to Come: Some See Boon, Others Catastrophe*, PHILADELPHIA INQUIRER, Jan. 10, 1986 at A01 (quoting Jeremy Rivkin).

scientific or technical expert—in making this kind of fundamental policy decision?

Opponents of genetically modified (GM) technology are often accused of being obstructionists—of creating impossible demands for certainty before approving of these new technologies. The clear implication is that these demands are wholly strategic: as this threshold of certainty cannot be reached, opponents really intend to block deployment of the technology. This criticism has often been used in attempts to discredit opponents of agricultural biotechnology. There are certainly those voices within the broader debate. However, biotechnology's advocates are often too quick to label any questioning of their claims of safety and benefit as a reactionary blocking strategy. By lumping those who want to question the process by which safety and risk are assessed with those determined to perceive risk at all costs, any questioning of the technology can easily be relegated to the Luddite margins.

There is a difference between a demand for certainty and a demand that appropriate questions be explored. The former focuses on results—whether the fruits of exploration point so conclusively to a particular outcome that no other explanation is tenable. The latter addresses process—whether the exploration has been structured in a fashion likely to uncover relevant information. Both sets of demands can be obstructionist; the Tobacco Institute's insistence that the link between cigarettes and cancer was “not proven” is perhaps the best example of how a demand for certainty can be wielded to prevent otherwise reasonable social actions.² Similarly, a common tactic to delay or prevent social activity is to “send it back for more study.” However, to suggest that demands for more—or more appropriate—study are always or even predominantly obstructionist is to caricature wholly legitimate and important public participation in public decision making.

A healthy society needs room for genuine dialogue, particularly around the process of evaluating and weighing risks to public safety. Many of the most significant questions surrounding agricultural biotechnology raise structural issues, in particular whether we have created an appropriate framework within which to make decisions about safety and efficacy. This article takes up that question and explores whether the United States regulatory system for agricultural biotechnology identifies and explores fundamental questions in a fashion reasonably likely to produce relevant answers.

To that end, this article explores the United States regulatory regime for agricultural biotechnology. Part I gives a brief overview of the critical role that trust plays in the regulation of biotechnology. Part II provides some

2. There are myriad tobacco related documents publicly available on the internet that chart out a strategy of arguing that the link between tobacco and health effects was “not proven.” One repository of such documents is Tobacco Documents.Org, Tobacco Documents Online, <http://tobaccodocuments.org> (last visited May 2, 2007). See Larry Breed, *Strategies of the Tobacco Industry*, <http://www.tobacco.org/resources/history/strategieslb.html> (last visited May 2, 2007) (summarizing this strategy).

background on the scientific innovations that led to the mass production of genetically modified organisms (GMOs) for use in commercial agriculture. This history is presented with an eye towards how it might either build or threaten trust in the technology. Part III evaluates the development of the United States regulatory regime, again through the lens of whether its history and evolution are likely to promote public trust in agricultural biotechnology. Part IV details some of the successes and failures of agricultural biotechnology over the decade it has been in widespread use and explores the ramifications those events might have for public acceptance of biotechnology. Part V makes normative proposals intended to bolster the credibility of regulatory agencies and reshape the regulatory dialogue in order to create public confidence that their needs and concerns are being incorporated into the regulation of GMOs.

I. WHY TRUST MATTERS

When citizens do not have confidence in the regulatory systems that purport to protect them, social trust breaks down. The lack of a transparent, well-organized regulatory system threatens public trust in biotechnology and more fundamentally in government itself. The success of agricultural biotechnology depends upon society's willingness to accept and consume food produced using this technology. This willingness hinges on the level of trust that the technology is being developed and used in a safe manner.³ Thus, the adequacy of regulatory oversight and information gathering are central to the future of the technology.

Social acceptance of biotechnology depends upon trust—trust that the many individuals and groups involved in the development, production and oversight of these crops are responsible, ethical and trustworthy.⁴

This needed trust is multilayered—the consumer must trust that the scientists know what they are doing in developing these crops, that the companies marketing and distributing the crops are operating in a legal and ethical manner, that the regulators are exercising proper oversight, that the farmers are obeying the regulations, and that the consumer is not being lied to or misled.⁵ Because the development, production and marketing of GM crops

3. See L.J. Frewer et al., *What Determines Trust in Information About Food-Related Risks? Underlying Psychological Constructs*, 16 RISK ANALYSIS 473 (1996).

4. See *id.*; see also L.J. Frewer et al., 'Objection' Mapping in Determining Group and Individual Concerns Regarding Genetic Engineering, 14 AGRICULTURE AND HUMAN VALUES 67, 78 (1997) (identifying trust as a central explanatory variable); see Dr. Lynn J. Frewer, Dr. Richard Shepherd, & Dr. Paul Sparks, *The Interrelationship Between Perceived Knowledge, Control and Risk Associated with a Range of Food-Related Hazards Targeted at the Individual, Other People and Society*, 14 J. FOOD SAFETY 19, 22 (1994) (emphasizing the central role that trust plays in public attitudes toward food safety and technology).

5. For a theoretical explanation of the role that trust plays in the success of biotechnology, see Harvey S. James, *Public Trust and Support for Biotechnology: Lessons for Post-Market Surveillance of GM Foods* (2004) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=517342 (last visited May 2, 2007).

requires the activities of so many different parties, there are multiple levels on which this process can break down, creating suspicion and mistrust. The presence or absence of trust dramatically affects communications about and perceptions of risk.⁶

The International Service for the Acquisition of Agri-Biotech Applications reports that grower adoption of GM crops continues unabated.⁷ Yet, at the same time, the Pew Initiative on Food and Biotechnology continues to find fairly low levels of public confidence in agricultural biotechnology.⁸ Although between 2001 and 2006 the number of respondents expressing outright opposition to GM crops decreased from 58% to 46%, the percentage of Americans supporting the technology remained constant (around 27%).⁹ It is even more striking that, in 2006, after a decade of widespread plantings of GM corn, cotton, soy, and canola, only 34% of respondents characterized GM foods as “basically safe,” while 29% characterized them as basically unsafe.¹⁰ After a decade of commercial exploitation of agricultural technology, public trust in the technology is still “up for grabs.”

Why do these levels of distrust exist? Consumers sense both a “reporting bias” on the part of industry (an incentive to overstate benefits and understate risks) and a “knowledge bias” in themselves (an inability to fully anticipate all contingencies). Thus, as to their relationship with biotechnology purveyors,¹¹ consumers feel systemically and strategically disadvantaged. This perception profoundly affects public dialogue over the risks and benefits of agricultural biotechnology. A transparent and thorough regulatory scheme can increase public confidence in this technology.¹²

Attitudes toward a broad range of biotechnology applications are powerfully influenced by the expected impact the technology will have on individuals and their families.¹³ Not surprisingly, as perceived risks increase,

6. *Id.* (providing a brief literature review); cf. Andrew J. Knight, *Does Application Matter? An Examination of Public Perceptions of Agricultural Biotechnology Applications*, 9 AG BIOFORUM 121, 126 (2006) (suggesting that the influence of perceived benefits from biotechnology outweighs trust as a statistically significant factor in attitudes toward biotechnology).

7. See CLIVE JAMES, INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS (ISAAA), GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2006 (2006), available at <http://www.isaaa.org/Resources/Publications/briefs/35/executivesummary/default.html> (last visited May 2, 2007).

8. PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, PUBLIC SENTIMENT ABOUT GENETICALLY MODIFIED FOOD (2007), <http://pewagbiotech.org/research/2006update/2.php>. (last visited May 2, 2007) (hereinafter “PEW INITIATIVE”).

9. *Id.*

10. *Id.* (The respondents expressing discomfort or safety concerns increase markedly when the conversation shifts from genetically modified (GM) plants to GM or cloned animals).

11. HARVEY S. JAMES, JR., THE EFFECT OF TRUST ON PUBLIC SUPPORT FOR BIOTECHNOLOGY: EVIDENCE FROM THE US BIOTECHNOLOGY STUDY 1997-98 (2003), available at <http://ssrn.com/abstract=380321> (last visited May 2, 2007).

12. PEW INITIATIVE, *supra* note 8, at 9.

13. *Id.*

public acceptance decreases, while as the expected benefits increase, so does public acceptance.¹⁴ A similar relationship has been found between uncertainty and public acceptance of agricultural biotechnology.

This relationship between risk, uncertainty, benefits and public acceptance—although not surprising—underscores just how critical a credible regulatory scheme is to the successful development of the technology. Indeed, Professor James reports that a credible oversight scheme and trust in the institutions promoting and overseeing agricultural biotechnology are the single biggest predictors of public acceptance of this technology.¹⁵ Although the Pew Initiative reports a less robust relationship between trust and acceptance, 50% of the Pew respondents identified trust in information sources as the most important factor in shaping their attitude towards biotechnology.¹⁶ Industry analysts routinely denigrate this relationship between trust and acceptance, characterizing it as the public, befuddled by technological complexity, “substituting trust for knowledge.”¹⁷ Such a description ignores the critical trust relationship at the heart of the regulatory state. Only when the public believes it has reason to trust that regulators are acting in the public interest will assessments of risks and benefits that underlie regulatory decisions be credible.

The most important determinants of trust are a track record of good decisions and an unbiased source.¹⁸ Unfortunately, neither the regulatory institutions charged with overseeing agricultural biotechnology nor the biotechnology industry itself has developed the kind of track record likely to engender trust.¹⁹ Improving the trustworthiness and competence of the regulatory agencies charged with overseeing agricultural biotechnology is therefore critical, both to protect the public’s safety and to create public confidence that their interests are being protected. Proper regulation thus addresses both reality and perception.

14. JAMES, *supra* note 11, at 9.

15. *Id.* at 13.

16. PEW INITIATIVE, *supra* note 8, at 9.

17. Jeffrey D. Wolt & Robert K. D. Peterson, *Agricultural Biotechnology and Societal Decision-Making: The Role of Risk Analysis*, 3 *AGBIOFORUM* 39, 41 (2000).

18. Frewer et al., *supra* note 3, at 476.

19. In particular, recent failures at the Food and Drug Administration (FDA) seem to have dramatically reduced its credibility overall. According to the PEW INITIATIVE, the FDA was the most trusted institution for information on GM foods in 2001, with 41% of respondents expressing trust in the agency. By 2006, after a series of high profile regulatory failures involving FDA, trust in FDA had fallen to 29%. PEW INITIATIVE, *supra* note 8, at 9; For information on the regulatory issues that provoked this reduction in trust, see FDA Announces Series of Changes to the Class of Marketed Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), available at <http://www.fda.gov/bbs/topics/news/2005/NEW01171.html>; Testimony of David J. Graham Before the Senate Finance Committee Hearing, FDA, Merck and Vioxx Putting Patient Safety First? available at <http://www.senate.gov/~finance/sitepages/hearing111804.htm>. The message is clear: trust is ephemeral and can be lost. Regulatory failures in one context can erode trust in a regulator across the board.

II. HISTORY OF AGRICULTURAL BIOTECHNOLOGY IN THE UNITED STATES

Before exploring the history of agricultural biotechnology in the United States, it is important to lay out some parameters for discussion. Proponents of modern biotechnology like to characterize the development of biotechnology as a linear progression extending back in time to the first makers of beer and bread.²⁰ While it is certainly possible to characterize yeast-mediated food production as a form of biotechnology,²¹ in the context of genetic engineering, such a characterization smacks of *reductio ad absurdum* and thus does little to advance open dialogue. Such a use of the term "biotechnology" is so expansive as to be meaningless and has little relevance to the ongoing public discourse over GMOs. This article will use the term biotechnology to mean "modern biotechnology," as defined in the Cartagena Protocol²² to the Convention on Biodiversity.²³

20 For fairly typical examples of this characterization from a range of sources including an industry trade group, see BIO, Food Biotechnology, available at <http://www.bio.org/speeches/pubs/er/food.asp> (offering the conventional position of the biotechnology industry); OECD, RECOMBINANT DNA SAFETY CONSIDERATIONS 12 (1986), available at www.oecd.org/dataoecd/45/54/1943773.pdf; Donald Boulter, *Plant Biotechnology: Facts and Public Perception*, 40 PHYTOCHEMISTRY 1 (1995).

21. On one level, this claim is absolutely accurate. If biotechnology is defined broadly enough, its use in agriculture and manufacturing extends back for centuries, if not millennia. For example, the processes used to make beer, cheese, yogurt and bread could all qualify as biotechnology. The current public policy disputes do not refer to these conventional forms of biotechnology but instead to modern biotechnology—new and controversial techniques which involve the transfer of genes between species (genetic engineering/genetic modification) in a manner and at a speed not previously possible.

22. Article 3 of the Cartagena Protocol defines modern biotechnology as:

(The application of: (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY ART. 3 (2000), 39 I.L.M. 1027. The Organisation for Economic Co-Operation and Development (OECD) uses a slightly different definition, as does the Food and Agricultural Organization of the United Nations (FAO). See generally, <http://www.oecd.org/home>; <http://www.fao.org>.

The United States defines biotechnology as "the use of modern scientific techniques, including genetic engineering, to improve or modify plants, animals, and microorganisms." U.S. Department of State, Frequently Asked Questions About Biotechnology, http://usinfo.state.gov/ei/economic_issues/biotechnology/biotech_faq.html (last visited May 2, 2007). See generally U.S. Department of State, Glossary of Biotechnology, <http://usinfo.state.gov/journals/ites/0903/ijee/glossary.htm> (last visited May 2, 2007); United States Department of Agriculture (USDA), Agricultural Biotechnology: Glossary, <http://www.ers.usda.gov/Briefing/Biotechnology/glossary.htm> (last visited May 2, 2007).

All these definitions clearly focus on the techniques and technologies that create the controversy this article explores.

23. Convention on Biological Diversity (CBD), June 5, 1992, 31 I.L.M. 818, available at <http://biodiv.org/doc/legal/cbd-en.pdf>. The CBD defines biotechnology to be "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." *Id.* at art. 2.

A. A Brief Introduction to the Technology²⁴

Humans have spent millennia modifying food crops to suit their needs. Today's crops little resemble, in taste or agronomic characteristics, their wild, uncultivated relatives. Fairly early in human agronomic history, it became clear that desirable traits could be maximized and undesirable traits minimized if farmers selectively bred individual plants and animals. This selective breeding process began largely as a matter of trial and error, with no reliable means of predicting the outcome of any individual breeding attempt. At the dawn of the 20th Century, a growing understanding of Mendelian genetics²⁵ facilitated and systematized selective breeding, producing a bumper crop (so to speak) of hybrid crops developed to express particular traits. As farms consolidated and a national or even global food market developed, selection began to focus on traits deemed useful in a commodities market—delayed ripening, thick skins, and other traits that enable foodstuffs to withstand long-distance shipping. With the growth of giant food producers came an increased demand for crops exhibiting traits that enhanced processing.

Over time, these commercial pressures have prompted breeders to develop radically altered crops. In doing so, selective breeders labored under a significant constraint—they could only enhance or suppress traits already present in a species.²⁶ Modern genetic engineering freed breeders from the limitations imposed by the existing characteristics of a species. In a process called transformation,²⁷ genes can now be isolated and transferred to a food

24. See generally REBECCA M. BRATSPIES, AMERICAN LAW INSTITUTE-AMERICAN BAR ASSOCIATION, BIOTECHNOLOGY PRIMER FOR LAWYERS 1 (2003) (offering a more detailed explanation of the technology behind genetic engineering).

25. GREGOR MENDEL, EXPERIMENTS IN PLANT HYBRIDIZATION (1865), available at <http://www.mendelweb.org/MWpaptoc.html>. Working with pea plants, the monk Gregor Mendel conclusively demonstrated what are now fundamental laws of genetic inheritance. The so-called Mendelian Laws of genetics describe the heritability and independent assortment of traits. See COLD SPRINGS HARBOR LABORATORY, DNA FROM THE BEGINNING (2002), available at <http://www.dnafb.org/dnafb/> (last visited May 2, 2007); ROBIN MARANTZ HENIG, THE MONK IN THE GARDEN: THE LOST AND FOUND GENIUS OF GREGOR MENDEL, THE FATHER OF GENETICS (Houghton Mifflin Co. ed., 2000); MATT RIDLEY, GENOME: THE AUTOBIOGRAPHY OF A SPECIES IN 23 CHAPTERS (HarperCollins ed., 1999) (presenting explanations of these scientific principles in lay terms).

26. Because variety is ubiquitous in nature this constraint is less restrictive than first impressions. Breeders also use mutagenic techniques to attempt to create new traits within a species in order to facilitate selective breeding.

27. See Plant Protection Act (PPA), 7 U.S.C. §§ 7701-7772 (2000). There are three primary means to transform, or genetically modify, plants. The most common takes advantage of the unique properties of *Agrobacterium tumefaciens*, a soil bacteria that infects plants by transferring a plasmid of its own DNA into the target plant. By modifying the genes contained in this plasmid, *A. tumefaciens* infection can be a means to deliver desirable genes into plant cells instead of the bacteria's own infective genes (which cause Crown Gall disease). Because *A. tumefaciens* is a known plant pest, these transformations fall neatly within USDA's regulatory authority.

By contrast, USDA authority over the other primary methods of transforming plants—the “biolistics” or “gene gun” method and electroporation—are less clear. These are the various

crop across species, class, phylum and kingdom.²⁸ In other words, genetic engineering enables breeders to recombine genes themselves.²⁹ Genetic engineers thereby avoid the main constraint on selective breeding—the need to start with sexually compatible organisms. This technology can create organisms that do not—and could not—exist without such intervention.

The early developers of genetic engineering techniques recognized the potential risks inherent in of their new technology.³⁰ To respond to uncertainty about the possible consequences, the scientific community called for a voluntary moratorium on genetic engineering, pending further study.³¹ Under the auspices of the National Academy of Science, scientists from around the world met at Asilomar Conference Center in Pine Grove, California, to hammer out a set of safety precautions for genetic research.³² Known as the Asilomar Consensus Statement, the conference created a set of guidelines for genetic engineering research.³³ The Asilomar Consensus served as the basis for the National Institutes of Health (NIH) Recombinant DNA Research Guidelines issued in 1976.³⁴ These guidelines emphasized the importance of

techniques to which I will refer as “genetic engineering,” “bioengineering,” “genetic modification,” or “biotechnology.”

28. The first step towards the modern biotechnology revolution dates to Watson and Crick's 1953 discovery of the structure of DNA. James Watson and Fredrick Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953). This paper is generally considered to have ushered in the era of molecular genetics. See also J. Schell, *Transgenic Plants as Tools to Study the Molecular Organization of Plant Genes*, 237 SCI. 1176-83 (1987).

29. See, e.g., Stanley Cohen, A. Chang,, Herbert Boyer & Robert Helling, *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT. ACAD. SCI. 3240-44 (1973) (Stanley Cohen and Hubert Boyer had built upon Watson and Crick's work by successfully splicing a gene from one organism and moving it into another—the first use of recombinant DNA technology).

30. Stanley N. Cohen, *The Manipulation of Genes*, SCIENTIFIC AM. 24, 32 (1975). See, e.g., *Guidelines for Hybrid DNA Molecules*, 181 SCI. 114 (1973) (consisting of the letter from Maxine Singer and Dieter Soll to National Academy of Science and the National Institute of Medicine).

31. Paul Berg et al., *Letter from the Committee on Recombinant DNA Molecules of the National Academy of Science*, 185 SCI. 303 (1974).

32. Marcia Barinaga, *Asilomar Revisited: Lessons for Today?* 287 SCI. 1584-85 (2000) (containing a recent account of that historic meeting); see also HOUSE SUBCOMM. ON SCI. AND TECH., GENETIC ENGINEERING, HUMAN GENETICS AND CELL BIOLOGY; EVOLUTION OF TECHNOLOGICAL ISSUES, (SUPP REPORT II) 94th CONG., 2d Sess. 20, 91-99 (1976).

33. Paul Berg et al., *Asilomar Conference on Recombinant DNA Molecules*, 188 SCI. 991 (1975) (“(T)he evaluation of potential biohazards has proved to be extremely difficult. It is this ignorance that has compelled us to conclude that it would be wise to exercise considerable caution in performing this research.”); see, J.P. Swazey et al., *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 S. CAL. L. REV. 1019 (1978) (for an interesting account of the self-regulatory project); see also Paul Berg et al., *Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. NAT. ACAD. SCI. USA 1981, 1982 (1975).

34. See Decision of the Director of National Institutes of Health to Release Guidelines for Research on Recombinant DNA Molecules, 41 Fed. Reg. 27,902, 27,903 (July 7, 1976). The guidelines, as updated, are still applicable to research funded by the National Institutes of Health (“NIH”) or conducted at NIH, and compliance with the guidelines is a condition for continued NIH funding.

full environmental consideration of any possible future release of a genetically engineered species into the environment.³⁵ Until 1984, these guidelines—which applied to researchers funded by NIH—were the only formal regulatory control over recombinant DNA research.

B. “Ice-Minus” and the Foundation for Economic Trends

The first attempt at commercial application of this new biotechnology in agriculture came in 1983 when Advanced Genetic Sciences (AGS) applied for permission to field test a GM bacterium called “Ice-minus”.³⁶ “Ice-minus” was a genetically modified version of *Pseudomonas syringae*, a common plant bacterium. Unmodified *P. syringae* produces a protein that initiates the formation of ice crystals when the temperature drops, thereby causing frost damage to the plant.³⁷ Berkeley researcher Dr. Steve Lindow modified *P. syringae* so that it lacked the gene coding for this ice nucleation protein.³⁸ When sprayed on plants, “Ice-minus” bacteria enabled plants to resist frost damage (hence the name “Ice-minus.”).

After greenhouse testing proved successful, AGS applied for permission to field test the ice-minus bacteria. Through the Recombinant DNA Advisory Committee, NIH approved the field trials.³⁹ Jeremy Rivkin and the Foundation

35. *Id.* The accompanying Environmental Impact Statement (EIS) specifically identified dispersion of GMOs as an environmental hazard posed by these novel organisms. While the 1976 guidelines prohibited deliberate release of GMOs, the 1978 revisions to these guidelines gave NIH the power to waive the ban on deliberate release. Guidelines for Research Involving Recombinant DNA Molecules, 43 Fed. Reg. 60,109 (Dec. 22, 1978). The guidelines, as updated, are still applicable to research funded by the NIH or conducted at NIH and compliance with the guidelines is a condition for continued NIH funding.

36. Notice of Actions Under NIH Guidelines for Research Involving Recombinant DNA Molecules, 48 Fed. Reg. 24,548-50 (June 1, 1983).

37. Frost causes significant damage to crops in the United States. Accordingly, the potential demand for "Ice-minus" was very high. Were the field tests were successful, "Ice-minus" might then have offered a "high tech" alternative to the resource and labor intensive frost protection techniques then in use, such as smug pot and fan use on cold nights, physically covering of the plants, or adding additional insulation to plant roots. For a description of the "prior art" that the developers of this modified bacteria intend to replace, see *Method for Reducing Temperature at which Plants Freeze*, U.S. Patent No. 4,161,084 (July 3, 1978), available at <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetacft%2FPTO%2Fsearch-adv.htm&r=17&p=1&f=G&l=50&d=PTXT&S1=4161084&OS=4161084&RS=4161084>. See Snow Service, <http://www.telemet.com/snow/snomax.asp> (last visited May 2, 2007) (showing, somewhat ironically, that the same ice-nucleating protein the "Ice-minus" bacterium had been engineered to omit is heavily marketed to ski resorts as a means to enhance snowmaking. See JGI Microbes, *Finished Genome*, (2005), http://genome.jgi-psf.org/finished_microbes/psesy/psesy.home.html (stating that according to the Department of Energy (DOE), this protein is also used to create artificial ice islands to facilitate offshore oil drilling in cold oceans such as in the arctic).

38. Microorganism Inhibition of Frost Damage to Plants, U.S. Patent No. 4,432,160 (February 24, 1984), available at <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetacgi%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=4432160.PN.&QS=PN/4432160&RS=PN/4432160>.

39. Notice of Actions Under NIH Guidelines for Research Involving Recombinant DNA

on Economic Trends ("FET") sued in federal court, arguing that NIH had failed to comply with the National Environmental Policy Act (NEPA) by approving the release without conducting an Environmental Impact Assessment.⁴⁰ Among other questions, FET argued that NEPA required an exploration of how the "Ice-minus" bacteria prevent the growth of the ice-plus variety, and of the possible effects "Ice-minus" bacteria might have on ecosystems and even global weather patterns.⁴¹

Striking themes that continue to haunt regulation of GMOs, the D.C. Circuit court upheld a lower-court injunction, "emphatically" agreeing that NIH failed to display rigorous attention to environmental concerns.⁴² The D.C. Circuit directed NIH to consider the "broad[er] environmental issues attendant on deliberate release" of GMOs.⁴³ The court found that NIH had completely failed to consider "the possibility of various environmental effects," identifying as the most "glaring deficiency" NIH's failure to consider the effects of dispersal of the GMOs.⁴⁴ These failures could have led to extremely serious consequences—the devastating impact of invasive species on ecosystems has been well-documented. In an unusually frank contemporaneous comment, a researcher commented, "You remember the space program, when all those rockets were blowing up on the launching pad? Well, the science (of gene-splicing) is at that stage now."⁴⁵

After the FET lawsuit, the Environmental Protection Agency (EPA) reviewed and ultimately approved the proposed "Ice-minus" field tests. Local protests continued to hinder the experiments, as municipalities and citizens groups objected to having the test plots in their communities.⁴⁶ AGS did

Molecules, 48 Fed. Reg. 24,548-50 (June 1, 1983).

40. Found. on Econ. Trends v. Heckler, 756 F.2d 143 (D.C. Cir. 1985).

41. *Id.* at 147; see *Method for Reducing Temperature at which Plants Freeze*, U.S. Patent No. 4,161,084 (July 3, 1978), available at <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetatml%2FPTO%2Fsearch-adv.htm&r=17&p=1&f=G&l=50&d=PTXT&S1=4161084&OS=4161084&RS=4161084>. In retrospect, this last issue seems hyperbolic. At the time so little was known about GMOs (and the release was approved with so little documentation) that the overall tenor of concern seems justified. After all, in order for "Ice-minus" to work well, it must out-compete—or at least achieve parity with—the native "ice-plus" bacteria that already inhabit the plants. EPA itself concluded that "Ice-minus" would probably migrate outside the strawberry patch and could survive indefinitely. See Andrew Maykuth, *Genetic Wonders to Come: Some See Boon, Others Calamity*, PHILADELPHIA INQUIRER (January 10, 1986), available at <http://www.maykuth.com/Archives/gene86.htm>.

42. *Found. on Econ. Trends*, 756 F.2d at 146. (During the pendency of the lawsuit, the Environmental Protection Agency (EPA) assumed jurisdiction from NIH).

43. *Id.*

44. *Id.* at 153 (The court cites as the only consideration on the record that NIH gave to the problem of dispersal a single sentence in the administrative record stating that "(a)lthough some movement of bacteria toward sites near treatment locations by insect or aerial transport is possible, the numbers of viable cells transported has been shown to be very small; and these cells are subject to biological and physical processes limiting survival.").

45. Maykuth, *supra* note 41, (quoting William R. Harvey, then a researcher at Temple University).

46. Yvonne Baskin, *Testing the Future*, 10 ALICIA PATTERSON FOUNDATION REPORTER 4

nothing to help its cause by illegally applying recombinant insects to trees on a rooftop patio at its Oakland headquarters. The field tests ultimately took place in 1987 amidst a media storm.⁴⁷

This successful legal challenge forced the Reagan Administration to develop a more overarching regulatory policy to guide federal decision-making about agricultural biotechnology research and its products. To that end, the Office of Science and Technology Policy issued the Coordinated Framework for Regulation of Biotechnology ("Coordinated Framework").⁴⁸ The Coordinated Framework, which is described more fully in Part III, continues to govern regulatory decisions about agricultural biotechnology.

C. The Mid-1990s and Beyond

In February 1994, the first GM food, Calgene's FlavrSavr tomato reached the market. Despite a great deal of hype, the FlavrSavr was a failure, not because of concern about biotechnology, but for a very prosaic reason—it did not taste good. Calgene quietly removed the tomato from the market. The successful GM crops to date bear modifications designed to facilitate easier or more profitable growth of the crops, modifications like *Bacillus thuringiensis* (*Bt*) resistance, glyphosate tolerance, or a combination of the two traits. The first such products reached the market in 1996.⁴⁹

Since that time, plantings of GM crops have exploded. In 2006, 10.3 million farmers in 22 countries planted 252 million acres with biotech crops.⁵⁰ This marked a 60-fold increase from 1996, the first year of commercial availability.⁵¹ Also in 2006, the cumulative acreage dedicated to these novel

(1987), available at <http://www.aliciapatterson.org/APF1004/Baskin/Baskin.html>.

47. Marcia Barinaga, *Field Test of Ice-Minus Bacteria Goes Ahead Despite Vandals*, 326 NATURE 819 (1987).

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

49. See generally, Pew Initiative on Food and Biotechnology, Fact Sheet: Genetically Modified Crops in the United States available at <http://pewagbiotech.org/resources/factsheets/display.php3?FactsheetID=2> (providing overview of history); Paul Heald, *The Problem of Social Cost in a Genetically Modified Age*, 58 HASTINGS L. J. 87 (2006) (exploring an economic analysis of GMOs.)

50. See CLIVE JAMES, INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS (ISAAA), GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2006 37 (2006), available at <http://www.isaaa.org/Resources/Publications/briefs/35/executivesummary/default.html> (last visited May 2, 2007). The ISAAA is a not-for-profit organization that works to help make biotech crops available in developing countries. Bayer CropScience, Monsanto, Syngenta, Pioneer Hi-Bred and the UK's Biotechnology and Biological Sciences Research Council, among others, fund the ISAAA. Others have questioned the statistics that ISAAA compiles, as well as, qualitatively, the portrayal of bottom-up, demand-led expansion of these crops. See e.g., AARON DEGRASSI, GENETICALLY MODIFIED CROPS AND SUSTAINABLE POVERTY ALLEVIATION IN SUB-SAHARAN AFRICA: AN ASSESSMENT OF CURRENT EVIDENCE (2003), available at <http://allafrica.com/sustainable/resources/view/00010161.pdf>.

51. JAMES, *supra* note 50, at 37.

crops exceeded 1 billion acres.⁵² The United States continues to account for the lion's share of these plantings, though non-U.S. plantings—particularly in India, South Africa and the Philippines—are increasing rapidly. In 2006, GM crops comprised 89% and 83% of U.S. soybean and cotton acreage respectively, and 61% of the corn acreage.⁵³

Again, transgenic crops currently on the market were developed primarily to confer productivity or agricultural management advantages. They may also have produced some environmental benefits, but only coincidentally. Supporters of the technology claim that GM crops require fewer herbicide applications, thus helping the environment.⁵⁴ Critics not only dispute this claim of reduced pesticide usage,⁵⁵ but also warn of potential dangers, including threats to the ecosystems into which GM crops are introduced, decreased genetic biodiversity of crops, and unknown effects to humans from consuming GM foods.⁵⁶ More generally, critics complain that biotechnology reinforces industrial agriculture at the expense of more traditional methods of crop rotation and multiple plantings. There are no foods now on the market that were genetically engineered to provide retail consumers with improved quality, nutrition or particular safety benefits, such as reduced pathogens or allergenicity.

III. THE REGULATORY MATRIX

In theory, no genetically engineered organism is approved for commercial use until its proponent has demonstrated that the organism conforms with the standards set by federal law. These standards are intended to protect human health and the environment, while encouraging the development of new, potentially lucrative technologies. Unfortunately, the gap between theory and reality is significant. Part of the problem is that no regulatory agency has a clear statutory mandate to regulate agricultural biotechnology. As a result,

52. *Id.*

53. NATIONAL AGRICULTURAL STATISTICAL SERVICE, ACREAGE REPORT (2006) available at <http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-09-12-2006.pdf>.

54. See, e.g., Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L. J. 47, 55 (2001); Haley Stein, *Intellectual Property and Genetically Modified Seeds: The United States, Trade and the Developing World*, 3 NW. J. TECH. & INTELL. PROP. 160, 175 (2005).

55. Steve Connor, *Farmers Use as Much Pesticide with GM Crop, US Study Finds*, The Independent (July 27, 2006) available at <http://www.commondreams.org/headlines06/0727-06.htm>; see also Charles M. Benbrook, *Genetically Engineered Crops and Pesticide Use in the United States: The First Nine Years*, available at http://www.biotech-info.net/Full_version_first_nine.pdf.

56. Union of Concerned Scientists, "Risks of Genetic Engineering", available at http://www.ucsusa.org/food_and_environment/genetic_engineering/risks-of-genetic-engineering.html. Cf. generally, websites devoted, in part, to this issue: Center for Science in the Public Interest, <http://www.cspinet.org/biotech/>; Friends of the Earth, <http://www.foe.org/camps/comm/safefood/biopharm/index.html>; and Greenpeace, <http://www.greenpeace.org/international/campaigns/genetic-engineering>. There are a host of critical writings, far too many to adequately cite here.

there are no coherent overarching government policies capable of ensuring that this new technology is safely explored and exploited.

A. *Birth of a regulatory regime—OSTP during the Reagan Years*

In response to the successful Foundation on Economics Trend lawsuit described above, the Reagan administration convened an interagency working group to consider how to regulate biotechnology. The working group was explicitly tasked with achieving a “balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.”⁵⁷ In its 1984 proposal for the Coordinated Framework for Regulation of Biotechnology, the Office of Science and Technology Policy (OSTP) made the goals of the Coordinated Framework clear. Although it began with a clear statement that “(t)he fundamental purpose of the Working Group is to insure that the regulatory process adequately considers health and environmental safety consequences of the products and processes of the new biotechnology as they move from the research laboratory to the marketplace,”⁵⁸ the proposal focused far more on the needs of industry for “sensible” regulation that would not stifle innovation than on the needs of the public for rigorous regulation to protect public safety.⁵⁹ The proposal similarly emphasized the United States’ commitment to reducing barriers to trade in biotechnology.⁶⁰ A comparable degree of commitment to preserving environmental safety is less evident in either the proposal or the ultimately adopted Coordinated Framework.

The Coordinated Framework purported to describe the comprehensive

57. Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23302-01, 23303 (June 26, 1986).

58. Proposal for a Coordinated Framework for Biotechnology, 49 Fed. Reg. 50856, 50857 (December 31, 1984).

59. *Id.* The proposal provided in relevant part:

The Working Group recognizes the need for a coordinated and sensible regulatory review process that will minimize the uncertainties and inefficiencies that can stifle innovation and impair the competitiveness of U.S. industry. . . .

The importance of addressing the emerging commercial aspects of biotechnology in a coordinated and timely fashion is captured in the recent report by the Congressional Office of Technology Assessment which warned: ‘Although the United States is currently the world leader in both basic science and commercial development of new biotechnology, continuation of the initial preeminence of American companies in the commercialization of new biotechnology is not assured.’

Id. This focus on competitiveness reflected a contemporaneous sense that the United States had lost its competitive edge in the electronics industry. Determined to ensure that the nascent biotechnology industry did not suffer the same fate, the government sent a clear message that “regulatory agencies were not to stand in the way of biotechnology.” See, Mary Jane Angelo, *Embracing Uncertainty, Complexity and Change: An Eco-Pragmatic Reinvention of First Generation Environmental Law*, 33 *ECOLOGICAL L. Q.* 105, 171 n. 328 (2006). As a result, there was no new legislation directly responsive to the challenges posed by biotechnology, and agencies instead adapted existing regulatory programs.

60. Coordinated Framework, *supra* note 57, at 23303.

federal regulatory policy for ensuring the safety of biotechnology research and products. It announced that no new laws would be needed to respond to challenges posed by this new technology. Instead, products of biotechnology would be regulated under "a mosaic" of existing laws based upon the products' intended use. Thus, food would be regulated under the Federal Food Drug and Cosmetic Act, pesticides under the Federal Insecticide Fungicide Pesticide and Rodenticide Act, agricultural plants under the Plant Protection Act, and so on.⁶¹ EPA and the United States Department of Agriculture (USDA) are involved before GM crops can be produced commercially and thus regulate the environmental release of plants derived from agro-biotechnology. The United States Food and Drug Administration (FDA), on the other hand, has regulatory authority only over the marketing of GM crops as food for humans and animals.⁶² Each agency regulates under the authority of a handful of federal statutes, each with its own mission and regulatory structure, none of which were enacted to address biotechnology.⁶³

The Coordinated Framework offered some framing principles for U.S. regulation: biotechnology poses no unique risks; the products of biotechnology should be regulated, not the process; existing laws should be used to regulate the products of biotechnology (no new legislation is needed); and any gaps should be addressed through coordination among agencies and designation of lead agencies as appropriate.

The central principle behind the Coordinated Framework is the idea of "substantial equivalence"⁶⁴—that GMOs are functionally equivalent to their unmodified counterparts and should be treated accordingly. A major problem with "substantial equivalence" is that it permits agencies to act simultaneously as regulators and promoters for this new technology. The conflict is particularly acute at USDA, which has a statutory mission of developing new markets for the United States' agriculture.

The Coordinated Framework assumes that "(b)y the time a genetically engineered product is ready for commercialization, it will have undergone substantial review and testing during the research phase, and thus, information regarding its safety should be available."⁶⁵ However, the limited nature of regulatory review shapes the development of safety information in a fashion that does not promote a full consideration of all risks associated with these novel organisms. Because of the assumption of substantial equivalence, the onus and burden of proof is on the authorities to prove that a GMO is unsafe

61. *Id.*

62. See Rebecca Bratspies, *Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 605 (Spring 2003).

63. Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297, 312 (2002).

64. See, e.g., Jan-Peter Nap et al., *The Release of Genetically Modified Crops into the Environment*, 33 PLANT J. 1, 10 (2003); Rebecca M. Bratspies, *Consuming (F)ears of Corn: Public Health and Biopharming*, 30 AM. J. L. & MED. 371, 390 (2004).

65. See generally, Coordinated Framework, *supra* note 57.

before they may impose use restrictions. This is directly contrary to the European approach and has led to jockeying in the international trade context.⁶⁶

B. Current United States Regulatory Practices

The Coordinated Framework remains the United States' basic organizing principle for regulating GMOs. The Coordinated Framework fits the products of genetic engineering into an already-existing set of laws and regulations. Because these laws were drafted before the development of this technology, they are not always well suited to their new tasks. With no single agency considering the full range of problems posed by GM crops, regulatory gaps are inevitable. Each agency concentrates on its own narrow piece of the GM universe while overarching questions of safety often go unexplored.

At its most superficial, the regulatory regime established by the Coordinated Framework is very easy to describe: the FDA is responsible for food safety, the EPA is responsible for microbes and pesticides, and USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for all plants. In practice, however, the regulatory interactions are far more complex than this deceptively simple division of authority. Many GM products fall into multiple categories. For example, a corn plant that has been engineered to produce its own pesticide is a plant, a pesticide, and a food, so it falls under the purview of all three agencies. Each of the three agencies uses different laws to govern the products of biotechnology, and most of these laws were passed well before the advent of biotechnology. What follows is a brief overview of the relevant regulatory regimes.

1. FDA

FDA is responsible for food safety under the authority of the Federal Food, Drug, and Cosmetics Act (FDCA).⁶⁷ This Act empowers FDA to, *inter alia*: identify and remove adulterated foods from the human food supply, regulate food labeling, and approve all food additives. The FDCA applies to all food, including GM foods. However, no statutory provisions of the FDCA expressly regulate GMOs, nor do any FDA regulations specifically apply to these novel foods. Instead, FDA treats GM foods, again, as the "substantial equivalent" of conventional foods. As a result, foods produced from plants modified through genetic engineering are not treated any differently from conventional foods.

The FDCA authorizes FDA to protect the food supply from becoming "adulterated," meaning from foods that "bear[] or contain[] any poisonous or

66. For a discussion of these differences, see Rebecca Bratspies, *Trail Smelter's (semi)Precautionary Legacy*, in *TRANSBOUNDARY HARM IN INTERNATIONAL LAW: LESSONS FROM THE TRAIL SMELTER ARBITRATION* (R. BRATSPIES AND R. MILLER, EDS, 2006).

67. 21 U.S.C. § 301, *et seq.*

deleterious substance which may render it injurious to health.”⁶⁸ FDA also has authority to regulate food additives, defined as substances that are intended for use in food, that may reasonably be expected to become a component of food, or that otherwise may affect the characteristics of food.⁶⁹ A food additive must receive FDA approval prior to its use in a food product. Both the gene inserted into a transgenic food plant and the protein produced by that gene clearly fall within the definition of food additives.

In theory, this regulatory framework should give FDA all the regulatory authority it needs to effectively oversee GM food crops.⁷⁰ In practice it does not work that way. FDA treats GM foods as the substantial equivalent of conventional crops, a crucial regulatory decision that drastically limits the scope of FDA’s review. Under this “substantial equivalence” analysis, GM crops are treated as mere variants of existing, well-accepted foods with no different or greater safety concerns.

The FDCA contains a provision exempting food additives that are “generally regarded as safe” (GRAS) from the requirement of pre-market approval and/or labeling. Relying upon the principle of substantial equivalence, FDA determined 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.” In light of this determination, FDA presumes that most GMOs will be GRAS.⁷¹ In fact, FDA justified its decision not to mandate specific labeling for foods derived from GM plants based upon this GRAS presumption.

It is the food additive manufacturer, not the FDA that determines whether a GMO is GRAS in the first instance. A manufacturer need not report a GRAS determination to FDA, but the agency does offer a voluntary consultation process.⁷² Thus, at most, the vaunted FDA pre-market “approval” of GMOs amounts to FDA reviewing GRAS determinations that manufacturers

68. Federal Food Drug and Cosmetics Act, 21 U.S.C. § 342(a)(1) (2000).

69. 21 U.S.C. §348(a) (2000).

70. FDA has no authority over “biopharmed” or industrial crops as they are not intended to produce foods. However, the possibility of cross-contamination is significant. FDA, of course, has regulatory authority over any drugs produced from biopharming, under its normal drug approval process. However, that drug approval process will not consider the potential health effects of cross-contamination from biopharm crops.

71. See Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J. L. REFORM 403, 408 (2002); see also Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL’Y & L. 257, 270 (2000). This GRAS presumption was challenged in court, and upheld, in *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166 (D.D.C. 2000).

72. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, (May 29, 1992); GUIDANCE ON CONSULTATION PROCEDURES: FOODS DERIVED FROM NEW PLANT VARIETIES (October 1997) available at <http://www.cfsan.fda.gov/~lrd/consulpr.html>.

voluntarily submit for review.⁷³

Critics label this reliance on “substantial equivalence” as misguided because it relies wholly on chemical similarity, with no biological, toxicological, or immunological data to back up the assumption of safety. This regulatory policy does not seem to contemplate the possibility that a company might perpetuate a fraud by concealing important information about a GM food. Most of the time, food manufacturers have a fairly clear incentive not to expose the public to *known* risks, but known risks are not the main concern. This policy creates little incentive for manufacturers to explore *possible* risks and to develop the kind of information that would enable a full assessment of food safety.

In January 2001, the FDA proposed regulations that would have required manufacturers to submit data and information about plant-derived bioengineered foods or animal feeds at least 120 days prior to commercial distribution.⁷⁴ This mandatory process would have replaced the voluntary consultation process. It would also have required companies to provide FDA with data and information on plant-derived bioengineered foods to be consumed by humans or animals.⁷⁵ One of the first acts of the incoming Bush administration was to suspend and withdraw these rules for further consideration.⁷⁶ They have never been reissued.

In June 2006, FDA issued new guidance encouraging manufacturers to contact the agency early in their product development process in order to address safety issues.⁷⁷ The recommendation focused on avoiding “possible intermittent, inadvertent introductions into the food supply of proteins from biotech crops under development.”⁷⁸ This recommendation has not been applied to plants engineered to endogenously produce pesticides, or to be resistant to herbicide application—the overwhelming majority of GMOs currently on the market.

Although FDA is tasked with both enforcing EPA tolerances for

73. U.S. FOOD AND DRUG ADMINISTRATION, LIST OF COMPLETED CONSULTATIONS ON BIOENGINEERED FOODS, *available at* <http://www.cfsan.fda.gov/~lrd/biocon.html>.

74. See Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4706-38 (proposed January 19, 2001) (to be codified at 21 C.F.R. pts. 192, 592).

75. Press Release, U.S. Department of Health & Human Services, FDA Announces Proposal and Draft Guidance for Food Developed Through Biotechnology (Jan. 17, 2001), *available at* <http://www.cfsan.fda.gov/~lrd/hbbioen3.html>.

76. Memorandum from the Assistant to the President and Chief of Staff, White House Office, to the Heads and Acting Heads of Executive Departments and Agencies, 66 Fed. Reg. 7702 (January 24, 2001) (directing that regulations sent to the Office of the Federal Register, but not yet published, be withdrawn, and that regulations already published but not yet in effect be postponed).

77. FDA, GUIDANCE FOR INDUSTRY: RECOMMENDATIONS FOR EARLY FOOD SAFETY EVALUATION OF NEW NON-PESTICIDAL PROTEINS PRODUCED BY NEW PLANT VARIETIES INTENDED FOR FOOD USE, *available at* <http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0369-gdl0002.pdf>.

78. *Id.* at 3-4.

pesticides in food and removing food contaminated with unapproved pesticides or the unintended, unauthorized presence of unapproved transgenic material,⁷⁹ it neither engages in any systematic compliance-monitoring of GM foods nor monitoring of the same for contamination. This point of concern will become even more pressing once GMOs developed elsewhere in the world begin to reach the international commodities market. Such GMOs may be imported into the United States without pre-market FDA approval or subsequent FDA monitoring. A number of recent legislative proposals would have statutorily expanded FDA's oversight of GMOs,⁸⁰ but, to date, none of these proposals have made it out of committee.

2. EPA

EPA's authority over GM crops stems largely from its regulatory oversight over the human health and environmental consequences of pesticides, arising under both the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)⁸¹ and the FDCA.⁸² This responsibility includes the duty to determine acceptable tolerances for pesticide residues in food. Because most of the GM crops currently on the market have been genetically modified to produce endogenous pesticides, EPA plays a critical regulatory role.

EPA has interpreted FIFRA's pesticide registration provisions to encompass plant produced pesticides (so-called "plant incorporated protectants" or "PIPs"). No plant that has been modified to endogenously produce a pesticide can be sold unless registered under FIFRA. Registration requires a demonstration that there will be no unsafe environmental or human dietary effects. As part of this analysis, no such GM food crop can lawfully be sold for planting until EPA has either established a tolerance level for the endogenously produced pesticide or has exempted the GMO from the tolerance requirement.⁸³ In the absence of a duly promulgated tolerance or exemption,

79. The unintended contamination of food crops with unauthorized and unapproved genetic material is a growing problem. See Bratspies, *Myths of Voluntary Compliance*, *supra* note 62; Bratspies, *Consuming (F)ears of Corn*, *supra* note 64, at 386-90.

80. Among the many introduced bills, H.R. 4813, the Genetically Engineered Food Safety Act, would have "amend[ed] the Federal Food, Drug, and Cosmetic Act with respect to the safety" of biotech foods. Genetically Engineered Food Safety Act of 2002, H.R. 4813, 107th Cong. (2002). This bill would have required a pre-market agency determination that a GMO is safe for human consumption, and it would have given the FDA a right to impose independent testing and to seek input from the National Academy's Institute of Medicine. *Id.* Similarly, S. 3095, the Genetically Engineered Foods Act, would have required that FDA to review and approve all genetically engineered foods prior to introduction into interstate commerce. Genetically Engineered Foods Act, S. 3095, 107th Cong. (2002). State legislatures are quite active in this area as well. For further information, see Pew Initiative on Biotechnology, Factsheet: State Legislative Activity Related to Agricultural Biotechnology in 2005-2006, <http://pewagbiotech.org/resources/factsheets/legislation/factsheet.php>.

81. 7 U.S.C. §136a(a)(2000). EPA's pesticide regulations are set out in 40 C.F.R. pts. 150-189.

82. See FIFRA and FDCA, as clarified by the Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996).

83. EPA may, by regulation, exempt any pesticide from some or all of the requirements of

or if the residue level detected in food exceeds the tolerance, the food is deemed adulterated under the FDCA and is subject to enforcement by FDA.⁸⁴ To date, EPA has registered only a few endogenously produced pesticides, and with one exception, all have been crops with genes that encode *Bt* proteins.⁸⁵ EPA has granted many of these *Bt* crops exemptions from the requirement for a tolerance level.⁸⁶

Under FIFRA, EPA has no regulatory authority over plants that do not produce pesticides. Thus, EPA's regulatory authority is narrow, and notably, it does not cover biopharmed crops, or crops modified to be resistant to herbicides.

3. USDA

USDA's primary duty with regard to genetically engineered crops is to evaluate whether there is risk that a novel organism will pose a plant pest risk when introduced into the environment or interstate commerce. USDA interprets this authority narrowly, treating GM crops exactly like their conventional counterparts and evaluating them for the same risks.

Under the Plant Protection Act, USDA has the authority to adopt regulations preventing the introduction and dissemination of plant pests.⁸⁷ Pursuant to this authority, USDA, through APHIS, regulates "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests."⁸⁸ The statute's implementing regulations define a plant pest as "(a)ny living . . . [organism] . . . which can directly or

FIFRA, if the pesticide is "of a character which is unnecessary to be subject to" FIFRA in order to carry out the purposes of the Act. 7 U.S.C. §136w(b)(2) (2000). EPA generally exempts pesticides that pose low probabilities of risk to the environment in the absence of regulatory oversight. See Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772 (July 19 2001) (Pesticides that do not qualify for exemption can still be approved for specific uses, but only if they do not "cause unreasonable adverse effects.").

84. FDCA, 21 U.S.C. § 408(1) defines any pesticide chemical residue contained in food as adulterated unless EPA has exempted the pesticide from the tolerance requirement, or EPA has issued a tolerance level and the residue in question complies with that tolerance level.

85. See Donna U. Vogt, U.S. Congressional Research Service, Food Biotechnology in the United States: Science, Regulation, and Issues RL30198 tbl. 2, 15 (Jan. 19, 2001).

86. Many *Bt* genes, and their proteins, have not shown toxicity to humans. EPA has therefore typically granted the *Bt* crops exemptions from the requirement for a tolerance level. See, e.g., 40 C.F.R. § 180.1155 (2002) (exempting CryIA(c)), 40 C.F.R. §180.1173 (2002) (exempting CryIA(b)). For an explanation of these decisions to exempt certain *Bt* genes and proteins, see 40 C.F.R. §180.1173 (1996); see also 40 C.F.R. §180.1155 (1995).

87. PPA, 7 U.S.C. § 7711(a).

88. 7 C.F.R. § 340.0(a)(2) n.1; see generally, Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 7 C.F.R. § 340 *et seq.* This definition may exclude the growing number of plants that are transformed using "gene gun" technology rather than through agrobacterium transformation. For an explanation of these techniques and their differences, see BRATSPIES, *supra* note 24, at 9.

indirectly injure[] or cause[] disease or damage in or to any plant.”⁸⁹

APHIS’s regulatory oversight of products of modern biotechnology is narrowly focused on whether these novel organisms might pose such a risk.⁹⁰ APHIS thus permits GM plants to be deregulated if field tests show that the GMO will not pose a plant pest risk.⁹¹ In conducting this regulatory review, APHIS treats GM crops exactly like their conventional counterparts and evaluates them for exactly the same risks. APHIS does not consider whether planting a GM crop modified to be resistant to a herbicide is likely to spread the trait of resistance more generally, nor does the agency consider the possible contamination that might result from pollen drift from GM plants to unmodified plants.

Like its sister agencies, APHIS starts from the assumption that products developed through biotechnology are “substantially equivalent” to their conventional counterparts. Indeed, the Coordinated Framework expects that in most cases, genetically engineered crops “will be improved, and would therefore not pose any new threat to humans, other animal species, or to the environment.”⁹² A 1988 analysis by the General Accounting Office (now the Government Accountability Office) (GAO) roundly criticized shortcomings in USDA’s oversight, echoing calls by the scientific community that certain regulatory decisions were “scientifically indefensible.”⁹³ In particular, GAO criticized the decision to exempt certain categories of GMOs from regulatory scrutiny “prior to developing scientific information on the behavior of these organisms in the environment.”⁹⁴

Moreover, APHIS typically does not require permits for field testing of GM food crops but instead permits purveyors to proceed under a notification procedure.⁹⁵ Since 1987, APHIS has authorized more than 10,000 field tests of GM crops.⁹⁶ Once a GM crop has been field tested, its developer can petition for non-regulated status and approval for commercial sales.⁹⁷ After a deregulation petition is granted, the subject plant is no longer considered a regulated article and is no longer subject to APHIS’s oversight. More than 60

89. 7 C.F.R. §340.1.

90. For a detailed discussion, *see generally*, Bratspies, *Illusions of Care*, *supra* note 63.

91. For a description of this process, *see* Petition for Determination of Nonregulated Status, 7 C.F.R. § 340.6(a) (2003). After receiving a petition, USDA publishes a notice in the Federal Register and accepts comments for sixty days. 7 C.F.R. § 340.6(d)(2) (2003). USDA has one hundred and eighty days to deny or approve the petition. 7 C.F.R. § 340.6(d)(3) (2003).

92. Coordinated Framework, *supra* note 48, at 23339.

93. U.S. Gen. Accounting Office, *Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms*, GAO/RCED-88-27, at 48 (June 1988).

94. *Id.* at 3.

95. Notification for the Introduction of Certain Regulated Articles, 7 C.F.R. § 340.3(a) (2003). This position contrasts sharply with the European Union’s regulatory approach.

96. BRS Factsheet: Biotechnology Regulatory Services, U.S. Department of Agriculture, http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/BRS_FS_FedReg_02-06.pdf (February 2006).

97. Restriction on the Introduction of Regulated Articles, 7 C.F.R. §340.0(a)(1) (2002).

genetically engineered plants have been deregulated under this process. Most of these deregulated plants endogenously produce the pesticide *Bt* or are engineered to be tolerant to herbicide exposure (or both traits in combination).⁹⁸

The second generation of GM plants pose an even greater challenge to adequate USDA regulation, particularly “biopharm”⁹⁹ crops that produce industrial or pharmaceutical compounds. Because the biopharm crops are not intended for food, they fall entirely outside FDA’s regulatory authority. Because they do not produce pesticides, they similarly are not within EPA’s purview. By elimination, USDA stands as the sole regulatory agency. Unfortunately, USDA has little experience or familiarity with the non-food compounds involved in biopharming,¹⁰⁰ some of which are known to have deleterious effects on human health.¹⁰¹ A limited “plant pest” analysis will not begin to cover the myriad risks that accompany the exciting new possibilities offered by these crops.

C. Gaps and Overlaps

The United States regulatory system for GMOs is a complex net woven from pre-existing regulatory strands. The problem is that, like all nets, this regulatory net has holes. Among the holes or gaps associated with biotechnology, some of the most pressing include: the risk of transferring herbicide resistance from crops to weeds; the prospect of biopharm industrial or pharmaceutical compounds entering the food chain; the lack of consumer choice because bio-engineered food is not labeled as such; the introduction new allergens and toxins into the food chain; and the certainty of unexpected consequences. Indeed, even USDA’s Advisory Committee on Biotechnology and 21st Century Agriculture concedes that statutes written before the development of modern biotechnology “may not be optimal to meet the needs of producers and consumers.”¹⁰² These statutes simply fail to cover the range of problems posed by GM crops. In particular, the advisory committee pointed to a few notable gaps in the United States regulatory scheme—transgenic animals, biopharming, adventitious presence, and the need to address imports of GMOs developed in other countries.¹⁰³

98. *Id.*

99. See *infra* note 100 (discussing “biopharming”).

100. Industry’s preferred term for this process is “plant made pharmaceuticals” or PMPs. Because I believe this term obscures the GM nature of these plants in an attempt to deflect conversation about the troubling issues their production raises, I deliberately choose to use the term biopharming.

101. See Bratspies, *Consuming (F)ears of Corn*, *supra* note 64, at 382-386.

102. USDA Advisory Committee on Biotechnology and 21st Century Agriculture, *Opportunities and Challenges in Agricultural Biotechnology: The Decade Ahead 5* (July 13, 2006) available at http://www.usda.gov/documents/final_main_report-v6.pdf. Despite this caveat, the overall tenor of this report was optimistic.

103. *Id.*

For example, the primary strategy for preventing cross-contamination between GM crops and conventional or organic crops are physical containment measures. Physical containment measures involve using planting distances or timing to prevent contamination of conventional crops with GM crops. Unfortunately, for existing GM crops, physical contamination measures have largely been ineffectual, either because the requirements are too lenient or because they are not being implemented. Indeed, a 2003 USDA survey found that approximately 20% of farms growing GM crops failed to comply with planting regulations intended to ensure physical containment.¹⁰⁴

Industry trade groups acknowledge that cross-pollination, adventitious commingling and other "causes" make it virtually impossible to assure that any U.S.-origin corn shipment is 100% non-GMO.¹⁰⁵ The same holds true for soybeans. There is no comprehensive domestic policy regarding adventitious presence of transgenic events in seed, grain, or food. This problem will only become more significant as other countries begin to develop and approve GMOs and thereafter seek approval to import these new organisms into the United States. There are real questions about whether the United States regulatory system will be able to cope with the possibilities that arise from considering the problem of contamination and adventitious presence of novel organisms that have not been through the United States regulatory procedures.

IV. REGULATORY FAILURES

Although this section is captioned regulatory failures, the author does not mean to suggest that agricultural biotechnology itself has been a failure. To the contrary, the story of GM crops to date includes significant successes as well as failures. On the success side, these crops have been extremely profitable for their manufacturers, and for the growers that have elected to plant them. The crops have produced increased yields, reduced damage from

104. Emily Gerseney, *USDA Survey Shows Biotech Rules Breaches*, WASHINGTON POST, Sept. 10, 2003. The survey itself can be found at http://www.nass.usda.gov/Publications/Corn_and_Biotechnology_Special_Analysis/bioc0703.pdf. An in-depth analysis of the prior year's data, conducted by the Center for Science in the Public Interest, reached similar conclusions. See, Gregory Jaffe, *Planting Trouble: Are Farmers Squandering Bt Corn Technology?*, at http://cspinet.org/new/pdf/bt_corn_report.pdf (June 19, 2003) (analyzing USDA data).

105. See Organic Trade Association, *Comments on Proposed Free Trade Agreement With the Republic of Korea* (March 23, 2006) available at <http://www.ota.com/pp/otaposition/frc/USTR/03-23-06.html>; Drew L. Kershen and Alan McHughen, *CAST Commentary: Adventitious Presence: Inadvertent Commingling and Coexistence Among Farming Methods*, (July 2005) available at <http://www.cast-science.org/websiteUploads/publicationPDFs/advenpresence%20rev.pdf>; Pew Initiative on Biotechnology, *Detecting Genetically Modified Organisms: Confronting the Limits of Testing to Resolve a Biotech Food Fight*, available at <http://pewagbiotech.org/events/0225/proceedings.pdf>. (discussing the problem); CropChoice, *Is GMO-free Production Possible? Costs and Methods of Crop Segregation*, (November 23, 2001) available at <http://www.cropchoice.com/leadstryd5d6-2.html?recid=517>.

some common pests, and in some cases have reduced pesticide applications. These successes are relatively straightforward and easy to understand from a bottom line business perspective.

Understanding the failures associated with agricultural biotechnology, by contrast, involves exploring the existing regulatory structure and measuring it against a vision of what regulation is supposed to accomplish in society. As such, it is a much more complex process that is far less intuitive. In light of this disparity between easy-to-understand successes, and difficult-to-grasp failures, the bulk of this section is devoted to teasing out those failures.

On many levels, the story of regulating GMOs in the United States has been a story of failure—failure on the part of industry to comply with laws and regulations promulgated to protect the public's safety and failure by both regulators and industry to take seriously the possibilities that this technology might contaminate the food supply or wreak environmental havoc. The meteoric rise of biotech crops only increases the urgency to study these failures with an eye towards overcoming them. The kinds of failures detailed below cannot be characterized as isolated incidents but must instead be considered the context in which these crops are sold, grown and harvested. The scope and scale of these regulatory failures is a powerful argument for caution going forward.

A. Failures of Regulatory Enforcement

In December of 2005, the U.S. Department of Agriculture Office of Inspector General (OIG) released a damning audit of USDA practices with regard to genetically engineered crops.¹⁰⁶ Among the violations cited were: failure to monitor whether GM crops were segregated, failure to test for contamination during and after field trials, failure to comply with shipping requirements designed to prevent inadvertent dispersal of unapproved GM crops, and failure to follow up on storage and disposal requirements.¹⁰⁷

The OIG concluded that weaknesses in the agency's internal management controls undermine its ability to oversee successfully the safe development of genetically engineered organisms.¹⁰⁸ In particular, the OIG concluded that APHIS did not comply with its own policy on the frequency of field test inspections and publicly understated the percentage of infractions it discovered in such inspections.¹⁰⁹ Since APHIS trumpets a low infraction rate as evidence

106. U.S. Department of Agriculture, Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits, Audit 50601-8-Te, <http://www.usda.gov.oig/webdocs/506010080TE.pdf> (Dec. 2005) (hereinafter "OIG Audit").

107. *Id.*

108. *Id.* at iv.

109. For instance, the OIG found that Plant Protection and Quarantine officers, the government officials who actually conduct the inspections, did not report or pursue the overwhelming majority of violations discovered during joint PPQ/OIG inspections. *Id.* at 9. Thus, the Biotechnology Regulatory Service (BRS) compliance infraction database improperly

that its monitoring program is effective, this latter finding is particularly troubling.

Further underscoring the tenuous nature of APHIS's compliance statistics, the OIG concluded that APHIS failed to obtain critical information necessary to carry out its oversight responsibility.¹¹⁰ As a result, the agency lacks basic information about the field test sites it approves and, at least in theory, monitors.¹¹¹ For example, APHIS does not even know where or whether the test fields have been planted.¹¹² Without that knowledge, the agency has no way to monitor compliance with the safety requirements that are the legal prerequisite for obtaining permission to grow experimental genetically engineered crops. The Union of Concerned Scientists recently documented these agency failures to monitor and enforce regulations as of most concern from a human safety perspective—those modified to produce pharmaceutical compounds.¹¹³

The OIG also found that APHIS does not require reporting of containment protocols for plantings conducted under the notification procedure or of the final disposition of experimental crops.¹¹⁴ Also, the OIG observed APHIS as extremely lax in pursuing delinquent field test reports, including information about environmental harms stemming from the tests. Since the major thrust of APHIS oversight is that it require applicants to follow procedures that will minimize the chance of inadvertent introduction of material from these unapproved genetically engineered crops to food crops, agriculture, the environment, and the food supply, these weaknesses cut to the very heart of the regulatory process and bring its legitimacy and competence into question. Moreover, the OIG criticized APHIS's inspection protocols as too informal and uncoordinated to be an effective regulatory compliance tool.¹¹⁵ As a result, even when inspectors are sent into the field, they are hamstrung.

Overall, the OIG concluded that APHIS "is relinquishing its regulatory

suggested a far lower rate of violations than were uncovered by inspections.

110. *Id.* at 13.

111. *Id.* at 14-18.

112. *Id.* at 6-8. APHIS may not know any more than the business address of the applicant, or the state and county in which the experimental test fields are planted.

113. Union of Concerned Scientists, UCS Uncovers Lax USDA Oversight of Pharma Crops, available at http://www.ucsusa.org/food_and_environment/genetic_engineering/usda-ventria-oversight.html (last visited September 9, 2007) (documenting APHIS failures with regard to pharma rice grown in North Carolina).

114. OIG Audit, *supra* note 106, at 13. Since these protocols are supposed to be the vehicle by which applicants detail their plans for containing the experimental GM crop within the test site, this lack is particularly troubling. In May of 2005, APHIS began requiring that written protocols be made available at the time of inspection. However, that change does not solve the problem. Without reviewing and approving these protocols *before* a notification planting, APHIS has no way of knowing whether the applicant's procedures will meet the performance standards imposed by regulation. Indeed, the OIG states that in a 2001 survey of notification protocols, APHIS discovered that some protocols may not be adequate to meet APHIS's field test performance standards. *Id.* at 22.

115. *Id.* at 28.

responsibilities in favor of self-certification"¹¹⁶ by GMO purveyors. Substantive review and oversight is replaced with blind acceptance of unverified industry promises to comply with performance standards. In the face of overwhelming evidence that these promises are not being kept,¹¹⁷ APHIS nevertheless refuses to put more stringent oversight and control protocols in place.

B. Failures of Regulatory Intent

In the past few years, a spate of court decisions have found that the agencies charged with administering the Coordinated Framework have failed to carry out their duties to protect the public and the environment. Two recent decisions finding that agency conduct violated the National Environmental Policy Act, (NEPA) might be particularly instructive for how courts will evaluate agency decisions into the future. NEPA instructs federal agencies to conduct a "coherent and upfront environmental analysis" to ensure informed decision making.¹¹⁸ Whenever substantial questions are raised as to whether a project *may* cause significant (environmental) degradation, NEPA requires that agencies take a "hard look" at the environmental effects of their planned action in order to ensure that the agency "will not act on incomplete information, only to regret its decision after it is too late to correct."¹¹⁹ These two cases decided the same week in February—*Geertsons Seed Farms v. Johanns*, and *International Center for Technology Assessment v. Johanns*¹²⁰—both criticized USDA for failing to fulfill its NEPA obligations before permitting release of a GM crop into the environment.

1. Geertsons Farm and GM Alfalfa

In 2005, APHIS granted Monsanto's petition to deregulate "Roundup Ready" alfalfa, a genetically modified version of alfalfa engineered to be resistant to Monsanto's "Roundup" herbicide.¹²¹ Organic and conventional farmers sued in federal court, challenging APHIS's decision to deregulate GM alfalfa without first conducting an environmental impact statement (EIS). The farmers alleged various significant impacts that necessitated an EIS, *inter alia*: that use of GM alfalfa would contaminate their non-GM alfalfa crops¹²² and

116. *Id.* at vi.

117. For example, according to the OIG Audit, the overwhelming majority of the shipments of experimental genetically engineered seeds in the United States occur in a fashion that violates APHIS regulations intended to ensure that unapproved genetically engineered seeds do not contaminate the environment or escape into the wild. *Id.* at 8.

118. *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208 (9th Cir. 1998) (citing *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 371 (1989)).

119. *Marsh*, *supra* note 119, at 371.

120. *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. 2007); *International Center for Technology Assessment v. Johanns*, 473 F.Supp.2d 9 (D.C. 2007).

121. *Monsanto Co. and Forage Genetics International; Availability Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate*, 70 Fed. Reg. 36917-01 (June 27, 2005).

122. Because alfalfa is pollinated by bees, there is a real possibility of insect-mediated

that planting of GM alfalfa would increase the likelihood that glyphosate resistance would develop in weed plants.¹²³ In a February 2007 decision that echoed the concerns raised by the very first field trial of a GM crop, a California District court agreed with the farmers, describing the decision not to conduct an EIS as “cavalier.”¹²⁴ In particular, the court applied the same adjective to APHIS’s explanation for its decision not to require an EIS, which hinged on the assertion that “weed species often develop resistance to herbicides.”¹²⁵ Rather than a rationale not to consider the development of such resistance to be a “significant environmental impact” for purposes of the National Environmental Policy Act (NEPA),¹²⁶ the fact that resistance is a likely or possible occurrence would seem to require an EIS. APHIS further stated that “good stewardship” is the primary means of staving off resistance (and presumably contamination of non-GM crops), yet the “finding of no significant impact” (FONSI) contains no definition or description of what kinds of conduct amounts to “good stewardship.”¹²⁷

The court also decried APHIS’s failure to consider the cumulative impacts of its decision to deregulate crops that have been genetically modified

pollen transmission from GM alfalfa to conventional or organic crops. Such transmission has been documented at distances of two miles. USDA/APHIS, Monsanto Company and Forage Genetics International Petition 04-110-01p for Determination of Non-Regulated Status for Roundup Ready Alfalfa Events J101 and J 163, Environmental Assessment and Finding of No Significant Impact at 4 (June 14, 2005) available at http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_ea.pdf (hereafter USDA/APHIS Alfalfa FONSI); Monsanto acknowledges that bee-mediated gene flow occurs and that adequate isolation is the preferred method for preventing such gene flow. Petition for Determination of Non-Regulated Status: Roundup Ready Alfalfa (*Medicago sativa* L) Events J101 and J163, at 285-86, available at http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf. Nonetheless, APHIS’s decision to wholly deregulate Roundup Ready alfalfa—removing the crop from APHIS’s jurisdiction—means that there will be no regulatory segregation controls whatsoever imposed upon GM alfalfa, let alone controls sufficient to ensure that GM alfalfa was not grown within two miles of conventional or organic alfalfa. Because 75% of the U.S. alfalfa crop is exported to Japan, and Japan has not approved GM alfalfa, these farmers are concerned that they will lose a \$500 million dollar export market. USDA/APHIS Alfalfa FONSI, at 3. *Geertson Seed Farms*, Complaint 2006 WL 1417538, at pars. 12, 14, 31, 34, 123. Organic farmers have the additional concern that contamination of their organic crops by GM alfalfa will destroy their ability to farm organically. *Id.* APHIS specifically rejected this latter concern on the ground that it would be up to organic farmers to develop protocols to prevent contamination. USDA/APHIS Alfalfa FONSI, at 5-6.

123. First Amended Complaint for Declaratory and Injunctive Relief at 119-121 and 123, *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. 2007).

124. *Geertson Seed Farms*, 2007 WL 518624 at *15; see also Andrew Pollack, *U.S. Agency Violated Law in Seed Case, Judge Rules*, NEW YORK TIMES (February 14, 2007). The court subsequently issued a preliminary injunction. *Geertson Seed Farms v. Johanns*, 2007 WL 776146 (N.D. Cal. March 12, 2007).

125. *Geertson Seed Farms*, 2007 WL 518624 at *9.

126. See National Environmental Policy Act, 42 U.S.C. 4321, *et seq.* NEPA serves as the “basic national charter for protection of the environment.” 40 C.F.R. § 1500.1(a). Whenever the consequences of a major federal action raise substantial questions “as to whether a project may cause significant [environmental] degradation” the agency must produce an environmental impact statement. *Marsh*, 490 U.S. at 371.

127. *Geertsons Seed Farms*, 2007 WL 518624 at *9.

that planting of GM alfalfa would increase the likelihood that glyphosate resistance would develop in weed plants.¹²³ In a February 2007 decision that echoed the concerns raised by the very first field trial of a GM crop, a California District court agreed with the farmers, describing the decision not to conduct an EIS as “cavalier.”¹²⁴ In particular, the court applied the same adjective to APHIS’s explanation for its decision not to require an EIS, which hinged on the assertion that “weed species often develop resistance to herbicides.”¹²⁵ Rather than a rationale not to consider the development of such resistance to be a “significant environmental impact” for purposes of the National Environmental Policy Act (NEPA),¹²⁶ the fact that resistance is a likely or possible occurrence would seem to require an EIS. APHIS further stated that “good stewardship” is the primary means of staving off resistance (and presumably contamination of non-GM crops), yet the “finding of no significant impact” (FONSI) contains no definition or description of what kinds of conduct amounts to “good stewardship.”¹²⁷

The court also decried APHIS’s failure to consider the cumulative impacts of its decision to deregulate crops that have been genetically modified

pollen transmission from GM alfalfa to conventional or organic crops. Such transmission has been documented at distances of two miles. USDA/APHIS, Monsanto Company and Forage Genetics International Petition 04-110-01p for Determination of Non-Regulated Status for Roundup Ready Alfalfa Events J101 and J 163, Environmental Assessment and Finding of No Significant Impact at 4 (June 14, 2005) available at http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_ea.pdf (hereafter USDA/APHIS Alfalfa FONSI); Monsanto acknowledges that bee-mediated gene flow occurs and that adequate isolation is the preferred method for preventing such gene flow. Petition for Determination of Non-Regulated Status: Roundup Ready Alfalfa (*Medicago sativa* L) Events J101 and J163, at 285-86, available at http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf. Nonetheless, APHIS’s decision to wholly deregulate Roundup Ready alfalfa—removing the crop from APHIS’s jurisdiction—means that there will be no regulatory segregation controls whatsoever imposed upon GM alfalfa, let alone controls sufficient to ensure that GM alfalfa was not grown within two miles of conventional or organic alfalfa. Because 75% of the U.S. alfalfa crop is exported to Japan, and Japan has not approved GM alfalfa, these farmers are concerned that they will lose a \$500 million dollar export market. USDA/APHIS Alfalfa FONSI, at 3. *Geertson Seed Farms*, Complaint 2006 WL 1417538, at pars. 12, 14, 31, 34, 123. Organic farmers have the additional concern that contamination of their organic crops by GM alfalfa will destroy their ability to farm organically. *Id.* APHIS specifically rejected this latter concern on the ground that it would be up to organic farmers to develop protocols to prevent contamination. USDA/APHIS Alfalfa FONSI, at 5-6.

123. First Amended Complaint for Declaratory and Injunctive Relief at 119-121 and 123, *Geertson Seed Farms v. Johanns*, 2007 WL 518624 (N.D. Cal. 2007).

124. *Geertson Seed Farms*, 2007 WL 518624 at *15; see also Andrew Pollack, *U.S. Agency Violated Law in Seed Case, Judge Rules*, NEW YORK TIMES (February 14, 2007). The court subsequently issued a preliminary injunction. *Geertson Seed Farms v. Johanns*, 2007 WL 776146 (N.D. Cal. March 12, 2007).

125. *Geertson Seed Farms*, 2007 WL 518624 at *9.

126. See National Environmental Policy Act, 42 U.S.C. 4321, *et seq.* NEPA serves as the “basic national charter for protection of the environment.” 40 C.F.R. § 1500.1(a). Whenever the consequences of a major federal action raise substantial questions “as to whether a project may cause significant [environmental] degradation” the agency must produce an environmental impact statement. *Marsh*, 490 U.S. at 371.

127. *Geertsons Seed Farms*, 2007 WL 518624 at *9.

to be resistant to glyphosate. Noting that “while the deregulation of one crop in and of itself might not pose a significant risk for the development of glyphosate resistant weeds, when all the crops are considered cumulatively such a risk may become apparent,”¹²⁸ the court found that APHIS had failed to take the “hard look”¹²⁹ required under NEPA. In fact, the Environmental Assessment specifically excluded the so-called “separate issue of the potential use of the herbicide glyphosate in conjunction with these plants.”¹³⁰

This division of inquiry smacks of sophistry. Farmers purchase and plant crops that have been genetically modified to be glyphosate resistant in order to take advantage of that resistance by using glyphosate to control weeds. It makes no sense to consider the environmental impact of the plants without doing so in the context that farmers planting the crop do so with the intention of using glyphosate to control weeds.

Once again, the Coordinate Framework creates gaps that hinder, rather than advance, regulatory competence. APHIS claims that such an evaluation is the province of EPA rather than USDA. The *Geertson* court noted that although “one would expect that some federal agency is considering whether there is some risk to engineering all of America’s crops to include the gene that confers resistance to glyphosate . . . ,” it is not at all clear that any agency has explored this question, or even considers the question to be within its regulatory jurisdiction.¹³¹

2. International Center for Technology Assessment—The Strange Tale of Creeping Bentgrass

Recently, significant effort has been devoted to genetically modifying creeping bentgrass (*Agrostis stolonifera*) and Kentucky bluegrass (*Poa pratensis*) to be resistant to glyphosate, the active ingredient in the herbicide Roundup. Because these are the primary grasses used for lawns and golf courses, such a modification might be extremely lucrative. The purveyor of this GMO, the Scotts Company, received permission from USDA to conduct a series of open air field tests in 2002 and 2003, and Scotts subsequently submitted a petition requesting that USDA/APHIS deregulate glyphosate-resistant creeping bentgrass.¹³² Environmental groups have raised significant objections focused on the enhanced potential for these grasses to become noxious weeds, and the fear that gene flow will spread glyphosate resistance to creeping bentgrass’ wild relatives. These environmental groups, in turn, petitioned USDA/APHIS requesting that GM Kentucky bluegrass be placed on the Federal Noxious Weed List.¹³³ When APHIS denied this petition, the

128. *Id.* at *10.

129. *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n. 21 (1976).

130. See generally, *Geertson Seed Farms*, 2007 WL 518624 (citing the Environmental Assessment, Administrative Record at 5501).

131. *Id.* at *11.

132. Environmental Impact Statement: Petition for Deregulation of Genetically Engineered Glyphosate-Tolerant Creeping Bentgrass, 69 Fed. Reg. 57,257 (Sept. 24, 2004).

133. A noxious weed is “any plant or plant product that can directly or indirectly injure or

International Center for Technology Assessment (ICTA) and the Center for Food Safety sued in federal district court alleging first that USDA/APHIS failed to adequately consider whether Roundup Ready creeping bentgrass is a "plant pest," as defined under the Plant Protection Act, and second that the agency violated NEPA by failing to properly assess the potential environmental impacts associated with field trials of both GM grasses.¹³⁴ Judge Henry Kennedy Jr. of the D.C. U.S. District Court found APHIS's denial of the noxious weed petition to be based upon an arbitrary and capricious interpretation of its statutory duties.¹³⁵ The court similarly concluded that APHIS's failure to inquire whether field testing these GMOs might "affect significantly the quality of the human environment"¹³⁶ had also been arbitrary and capricious and inconsistent with the agency's own regulations.¹³⁷ The court thus permanently enjoined APHIS from processing any similar field test request without first investigating whether the activity might significantly affect the quality of the human environment.

Together, *Geertson Seed Farm*, *Center for Food Safety*, and *ICTA* indicate that APHIS has systematically failed to fulfill its NEPA obligations with regard to GM plants, and indicates a willingness on the part of federal courts to intervene.

C. Failures of Regulatory Structure and Imagination.

A regulatory regime that is not enforceable is often worse than no regulatory regime. Not only does the public go unprotected, but such a regime engenders cynicism about the integrity and trustworthiness of government institutions.¹³⁸

Unfortunately, a litany of examples underscores the inability of the regulatory agencies to enforce the unwieldy regulatory system they oversee vis-à-vis agricultural biotechnology. StarLink corn is perhaps the best known example¹³⁹ of how the regulatory system can fail to keep unapproved GMOs

cause damage to crops . . . or other interests of agriculture . . . the natural resources of the United States, the public health or the environment." 7 U.S.C. §7702(10) (2000). Listing has significant consequences—listed noxious weeds are prohibited or restricted from entering the United States and subject to restrictions on interstate movement. *Id.* §7712(f)(1) (2000).

134. *International Center for Technology Assessment v. Johanns*, 473 F. Supp. 2d 9, 13 (D. D.C. 2007) (hereafter *ICTA*).

135. *Id.* at 26.

136. 7 C.F.R. §372.5(d) (2007).

137. *ICTA*, *supra* note 134, at 29-30. See also *Center for Food Safety v. Johanns*, 451 F. Supp.2d 1165, 1183-86 (D. Haw. 2005) (reaching an identical conclusion about similar filed test permits).

138. See generally, Richard G. Peters, Vincent T. Cavello, and David B. McCallum, *The Determinants of Trust and Credibility in Environmental Risk Communication: An Empirical Study*, 17 RISK ANALYSIS 43 (1997) (identifying a strong relationship between perceptions of government commitment to environmental regulation and perceptions of credibility and honesty).

139. Bratspies, *Myths of Voluntary Compliance*, *supra* note 63, at 593.

out of the food system, but unfortunately there are many other such examples. In the past few years, there have been well-publicized instances of unapproved GMOs commingling with crops intended for human consumption.¹⁴⁰ Taken together, these incidents undermine a cornerstone assumption of the United States' regulatory strategy: voluntary self-policing can be a viable, long-term strategy for managing this revolution in agriculture. Nothing shatters public confidence in a regulatory system more than when an agency approves products but does not conduct follow-up compliance and enforcement activities.

The technology holds untold promise; however, that promise will never be realized without a comprehensive and scientifically rigorous regulatory system that ensures environmental and human health issues are adequately addressed and in a way that is credible to the public. The United States does not currently have such a regulatory system, to its detriment. Protecting the public's interest in this context will require government to assume a far more active role than the hands-off attitude that has been the hallmark of conventional agricultural policy.

For example, one of the most innovative uses for biotechnology is in biopharming—using plants (and animals) to produce industrial or pharmaceutical compounds.¹⁴¹ Biopharming might offer the potential to provide patients with the benefits of greater and faster access to medicines. Moreover, production of industrial and pharmaceutical compounds in plants might significantly reduce facility and production costs, potentially making it relatively easy to scale production to increased or varying demands. The largest controversy surrounding biopharming involves the use of food crops for producing non-food compounds. Proponents argue that food crops are a natural choice for biopharming because of the extensive body of knowledge that already exists about their biology, agronomic properties, and cultivation.¹⁴² Opponents counter that the risk of contaminating the food

140. See e.g., European Commission, *Bt 10: Commission Requires Certification of U.S. Exports to Stop Unauthorized GMO Entering the European Union*, (reporting on the illegal presence of *Bt 10*, an unapproved GM corn in shipments received in the EU) available at http://gmo-crl.jrc.it/doc/BT10_EUROPA-PressRelease-certification.pdf; EPA Fines Syngenta \$1.5 Million for Distributing Unregistered Genetically Engineered Pesticide, <http://yosemite.epa.gov/opa/admpress.nsf/e987e762f557727d852570bc0042cc90/2df47c51f639be4e8525724b0069655c!OpenDocument>; Colin Macilwain, *US Launches Probe into Sales of Unapproved Transgenic Corn*, NATURE (March 22, 2005) available at <http://www.nature.com/news/2005/050321/full/nature03570.html>; *Contaminated Rice Flows to Global Market*, (reporting on the contamination of conventional rice destined in part for export markets with Bayer's unapproved Liberty Link 601 Rice) available at <http://www.zawya.com/story.cfm/sidZAWYA20070218031349/SecMain/pagHomepage>; John Henry, *Tainted Rice Testing Farmers Trust*, 23 ARKANSAS BUSINESS 1 (Dec.4, 2006); *Europe Warns on Rice from US*, INTERNATIONAL HERALD TRIBUNE (Sept. 22, 2006).

141. See *supra* note 100 (discussing the term "biopharming").

142. See, e.g., BIO, *Plant Made Pharmaceuticals: Frequently Asked Questions*, available at <http://www.bio.org/healthcare/pmp/factsheet2.asp>; see also Bindu Dey, *Are We Ready for PMPs?* (May 12, 2004) available at <http://www.pharmabiz.com/article/detnews.asp?articleid=21817&>

supply is so high that food crops ought never be used for biopharming.¹⁴³

Although few biopharmed compounds are currently on the market,¹⁴⁴ there are many such crops in various stages of clinical or field trials. Since 2001, biopharm experimental test permits have been issued in 14 states.¹⁴⁵ Unfortunately, the same culture of carelessness has carried over into experimental biopharming, which is the biotechnology-mediated production of industrial¹⁴⁶ and pharmaceutical¹⁴⁷ compounds in plants. Biopharm crops have been tested in fields across the country under the same *laissez-faire* standards used for first-generation GM crops¹⁴⁸—with minimal and poorly enforced safety precautions based on physical containment.¹⁴⁹

Not only have regulators not taken the threats posed by this technology seriously, neither have growers. In the last decade, biotech companies and research universities have violated even those minimal safety precautions more than a hundred times.¹⁵⁰ Because many of these open-air field tests of experimental biopharm crops take place in the cornbelt, these violations put the

sectionid=46&z=y (asserting that “the obvious choice of plants for PMPs is the GM food crops.”).

143. See generally, Bratspies, *Consuming (F)ears of Corn*, *supra* note 64; see also USDA Advisory Committee, *supra* note 102, at 9.

144. Prodigene markets tryptophan produced through biopharming, and in January 2006, USDA’s Center for Veterinary Biologics (CVB) gave regulatory approval for the first plant-made vaccine to Dow AgroSciences’ Animal Health division and their ConcertTM product, a vaccine to improve animal health.

145. Arizona, California, Florida, Hawaii, Iowa, Kansas, Kentucky, Missouri, Nebraska, South Carolina, Texas, Virginia, Washington and Wisconsin.

146. For example, APHIS just completed an Environmental Assessment of transgenic safflower genetically modified to produce a carp protein. APHIS, *Availability of an Environmental Assessment for a Proposed Field Release of Genetically Engineered Safflower*, 72 Fed. Reg. 5263 (February 5, 2007). The theory behind this genetic modification is to produce a crop that can be used as a food source for aquaculture, thus alleviating some of the pressure that demand for fish meal in aquaculture places on fisheries.

147. The European Commission recently approved its first biopharmed product manufactured with ingredients derived from biotech goats. <http://www.emea.europa.eu/humandocs/PDFs/EPAR/atryn/H-587-PI-en.pdf>. The drug’s ingredients include proteins from the milk of biotech goats. The pharmaceutical treats the rare blood-clotting disorder antithrombin deficiency. The product is expected to enter the marketplace this year. See, Q & A: GTC’s Geoffrey Cox, available at <http://www.redherring.com/Home/15291> (estimating that the product will reach the European Market at the end of 2007 and the US market in 2008.).

148. For an in-depth exploration of some of these requirements, see Bratspies, *The Illusion of Care*, *supra* note 63; see also Gregory N. Mandel, *Gaps, Inexperience Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. Rev. 2167 (2004).

149. See e.g., *Center for Food Safety v. Johanns*, 451 F.Supp.2d. 1165 (D. Haw. 2006); see also Bratspies, *Consuming (F)ears of Corn*, *supra* note 64.

150. APHIS, Compliance and Enforcement, available at <http://www.aphis.usda.gov/brs/compliance.html>. Unfortunately APHIS considers this to be a low number of violations, and therefore a success story. Others are far less sanguine about the conclusions to be drawn from this number. See, e.g., Academia/Industry Violated USDA Rules, available at <http://pewagbiotech.org/buzz/display.php3?StoryID=114>.

food supply at a high risk for contamination.¹⁵¹ As biotech crops expand, and as more biopharming crops are developed, these failures must be confronted.

The USDA Advisory Committee on Biotechnology and 21st Century Agriculture articulated serious concerns around this topic. One portion of the Committee argued that "the federal government should not approve the use of food crops for the production of medical and industrial substances, even if the substances are deemed safe, because no regulatory process or containment system can assure that these products will never enter the food supply."¹⁵² Other committee members believed that a tiered risk approach could ensure the safety and integrity of the food and feed supply adequately.¹⁵³ For both groups, it is clear that the Federal government's capacity to address the issues of containment and to generate public confidence in that containment system remained a critical issue.

V. CONCLUSION

The United States' approach to regulating GMOs can be described charitably as a creative attempt to regulate an emerging technology with existing laws. However, the regulatory pastiche that evolved from this attempt enlists a patchwork of agencies, statutes and regulations pressed into service from vastly different contexts, and originally intended to further different goals. As a result, too many of the central questions for agricultural biotechnology fall into the grey zones between statutory regimes—where agencies act with dubious legal authority. The system lacks transparency and does not permit the kinds of public participation necessary to generate public confidence in the regulatory process.

The time is ripe to improve the regulation of agricultural biotechnology. New legislation is needed to protect humans and the environment. With new legal authority and better regulations, a strong—but not stifling—system can be established that independently reviews and approves products that are safe for consumers and the environment. Such a system is essential if consumers are to have confidence in biotechnology, and we are to meet the challenges that transgenic animals and biopharming will pose to human and environmental safety.

151. Indeed, in 2002, the Office of Science and Technology Policy acknowledged the significance of this risk. See Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants, 67 Fed. Reg. 50,587 (Aug. 2, 2002) ("As the number and diversity of field tests increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced under field tests with commercial seeds or grain may also increase. This could result in intermittent, low-levels of biotechnology-derived genes, and gene products occurring in commerce that have not gone through all applicable regulatory reviews.").

152. USDA Advisory Committee, *supra* note 102, at 9.

153. *Id.*