

Unapproved Genetically Modified Corn: It's What's for Dinner

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ABSTRACT: The most notorious escapes of genetically modified organisms (“GMOs”) included products still in the testing phase that the U.S. Department of Agriculture (“USDA”) had never approved for sale or consumption. The USDA, more specifically, its subdivision, the Animal and Plant Health Inspection Service (“APHIS”), must change the current culture of noncompliance among growers. Changes in the regulation of field trials of GMO products would allow U.S. growers to certify to food distributors and importers of U.S. agricultural products that crops are what growers purport them to be and that unwanted and never-approved GMOs have not contaminated their products. Better regulation would shift the costs of preventing the escapes of these seeds on to the producers rather than farmers, who might suffer economic loss if GMO seed contaminates their crops, or the public, which suffers when agricultural markets across the globe are disrupted by discovering unwanted GMO strains in food or other agricultural products.

I. INTRODUCTION.....	826
II. DEFINING AND REGULATING GMOS.....	829
A. WHAT ARE GMOs?.....	829
B. CURRENT U.S. REGULATORY FRAMEWORK.....	831
1. The Principles and History of Biotechnology Regulation.....	831
2. The Process of Biotechnology Regulation.....	832
C. INTERNATIONAL GMO REGULATION.....	834
III. RISKY BUSINESS: ISSUES IN CURRENT REGULATION.....	836
A. GM-RELATED ECONOMIC DISRUPTIONS.....	837
B. DAMAGE TO NEIGHBORING FIELDS.....	839
C. ENVIRONMENTAL RISKS.....	842
1. Biodiversity.....	842

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2. Pesticide Resistance.....	843
D. STALLED REFORM ACTIONS	845
IV. PROPOSED REGULATORY CHANGES.....	846
A. NOTIFICATION INCLUDING RISK ASSESSMENT	847
B. CONTAINMENT.....	848
1. Isolation Distance.....	848
2. Submission of Containment Plan	849
3. Administrative Penalties for Escape.....	849
C. MAPPING FIELD TRIALS.....	850
V. CONCLUSION	851

I. INTRODUCTION

In May 2013, the USDA announced that a farmer had found an unapproved variety of genetically modified (“GM”) wheat growing in Oregon.¹ The farmer reportedly found the wheat growing in his field and sprayed it with herbicide.² After the wheat did not die, he sent a sample to Oregon State University for testing.³ Testing revealed that the wheat was genetically engineered to resist herbicide and was of a type that Monsanto Company field tested between the years 1998 and 2005 over several states.⁴

This discovery came at a time when questions regarding the safety of genetically modified organisms (“GMOs”) were on the rise, and the debate continues today.⁵ The fact that no government agency had ever approved any

1. TADLOCK COWAN, CONG. RESEARCH SERV., R43100, UNAPPROVED GENETICALLY MODIFIED WHEAT DISCOVERED IN OREGON: STATUS AND IMPLICATIONS 1 (2013), available at <http://www.fas.org/sgp/crs/misc/R43100.pdf>.

2. *Unapproved Genetically Modified Wheat Found in Oregon*, USA TODAY (May 29, 2013), <http://www.usatoday.com/story/news/nation/2013/05/29/genetically-modified-wheat/2370533/>.

3. *Id.*

4. COWAN, *supra* note 1, at 1. Monsanto Company tested the wheat with APHIS approval in 100 field trials across 16 states with testing in Oregon beginning in 2001. *Id.* If a product is being “field tested” or is in the “field trial” stage, the product is being planted outdoors to allow the company to gather initial planting data. However, it has not yet been approved for sale, so it can still be considered experimental.

5. In January 2014, General Mills announced that it would stop using GMO products to make its cereal, Cheerios. Bruce Horovitz, *Cheerios Drops Genetically Modified Ingredients*, USA TODAY (Jan. 2, 2014), <http://www.usatoday.com/story/money/business/2014/01/02/cheerios-gmos-cereals/4295739/>. While anti-GMO activists heralded the move, others were critical, stating that the decision was likely made for marketing purposes, especially considering that Cheerios previously contained little material from GM products. Richard Levick, *Are GMO-Free Cheerios the First Domino?*, FORBES (Jan. 9, 2014), <http://www.forbes.com/sites/richardlevick/2014/01/09/are-gmo-free-cheerios-the-first-domino/>. The debate over the labeling of GMO products, and, more generally, GMO safety has continued in attempts to sway public opinion to either side. See Jayson Lusk & Henry I. Miller, Op-Ed., *We Need G.M.O. Wheat*, N.Y. TIMES (Feb. 2, 2014), <http://www.nytimes.com/2014/02/03/opinion/we-need-gmo-wheat.html?hp&rrref=opinion&>.

GM wheat variety added to the controversy.⁶ The government never approved this GM crop for sale “because of worldwide opposition to genetically engineered wheat.”⁷ In the days following the discovery, the U.S. Department of Agriculture (“USDA”) asked trading partners to be “understanding,” stating that the GM variety was safe for human consumption and that “there was no sign that genetically engineered wheat had entered the commercial market.”⁸ These assurances, however, were not enough to prevent Japan and Korea from barring U.S. wheat imports pending the results of testing, a significant setback considering that the United States is the world’s largest exporter of wheat.⁹

This was not the first finding of an unapproved GMO that had escaped from field trials;¹⁰ there have been nearly two dozen instances of noncompliance with biotechnology regulations since the mid-1990s.¹¹ Farmers’ increasing use of GMOs has had a significant impact on agriculture worldwide and many of the effects have been beneficial, such as “decreas[ing] herbicide and pesticide use, lower[ing] production cost, and increas[ing] yields.”¹² Still, the continued use of these products poses credible risks.¹³ Some

But see David Schubert, Op-Ed., *Why We Need GMO Labels*, CNN (Feb. 3, 2014), <http://www.cnn.com/2014/02/03/opinion/schubert-gmo-labeling/>. The battle over labeling GMO foods has recently gone to court. *See Cox v. Gruma Corp.*, No. 12-CV-6502 YGR, 2013 WL 3828800, at *2 (N.D. Cal. July 11, 2013) (referring to the FDA the issue of whether products that contain GMOs can be labeled as “natural”).

6. *Unapproved Genetically Modified Wheat Found in Oregon*, *supra* note 2.

7. Charles Abbott, *U.S. Finds Unapproved Genetically Modified Wheat in Oregon*, REUTERS (May 29, 2013, 7:20 PM), <http://www.reuters.com/article/2013/05/29/us-wheat-monsanto-idUSBRE94S1GD20130529>.

8. *Id.*; *Unapproved Genetically Modified Wheat Found in Oregon*, *supra* note 2.

9. Victoria Shannon, *Japan and South Korea Bar Imports of U.S. Wheat*, N.Y. TIMES (May 31, 2013), <http://www.nytimes.com/2013/06/01/business/global/japan-and-south-korea-bar-us-wheat-imports.html>.

10. *See* Carey Gillam, *U.S. Farm, Food Groups Want Better Oversight of GMO Field Trials*, REUTERS (Aug. 21, 2013, 3:55 PM), <http://www.reuters.com/article/2013/08/21/us-usa-food-gmos-idUSBRE97K14A20130821> (noting that other incidents of GMO escape have occurred in the past including the discovery of Bayer rice in the food supply in 2006); *see also infra* note 101 and accompanying text.

11. *Biotechnology: Noncompliance History*, ANIMAL & PLANT INSPECTION SERVICE, http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa_compliance_and_inspections/ct_compliance_history (last updated Apr. 8, 2014).

12. Margaret Sova McCabe, *Superweeds and Suspect Seeds: Does the Genetically-Engineered Crop Deregulation Process Put American Agriculture at Risk?*, 1 U. BALT. J. LAND & DEV. 109, 112 (2012). Additionally, pro-GMO publicists see the crops as a method to solve an impending world population food crisis. *See* Luc Bodiguel & Michael Cardwell, *Genetically Modified Organisms and the Public: Participation, Preferences, and Protest*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 13 (Luc Bodiguel & Michael Cardwell eds., 2010).

13. *See* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 736 (2003) (“It is also likely that the U.S. conception of ‘scientific risk’ will need to be broadened so that concerns about allergenicity, safety, and environmental issues [can] be considered.”).

of these risks are environmental, like certain documented phenomena,¹⁴ while other threats stem from the high amount of uncertainty in predicting the effects of these products.¹⁵ GMOs also have the potential to affect the global economy, largely because there are several sectors of the world's population who are opposed to GMOs, and GMOs, like all plants, do not respect borders, having the potential to spread or cross-contaminate with other plants.¹⁶

Regulating these products requires balancing the interests of the producers and the public at large to protect and encourage the beneficial effects of GMOs while attempting to insulate markets, the environment, and consumers from risks. One key level of the approval process for a GM product has garnered less oversight than others: the field trial. Field trials are an important step in the debut of a novel GMO, and they merit more attention than they presently receive.

This Note argues that Animal and Plant Health Inspection Service ("APHIS"), the USDA, and the Environmental Protection Agency ("EPA") must alter vital parts of the regulations regarding field testing of GM crops in the United States. Modifying how agencies regulate field testing is essential to prevent the escape of unapproved GM crops¹⁷ into the environment, neighboring fields, and the food supply, due in large part to the evidence that such incidents have the potential to disrupt international agricultural markets.

Part II of this Note lays out a brief history of the GM process and explains the U.S. regulatory scheme for GMOs, discussing, for example, which federal regulatory agency currently regulates how a producer may conduct a field trial and how GMOs are ultimately approved for commercial use and sale. This Part compares the European and other international regulatory schemes to show how the finding of unapproved crops can disrupt the global agriculture markets.

14. Pesticide and herbicide resistance and cross-contamination have already been observed. *See infra* Part III.C.

15. Substantial concern exists regarding possible effects that have not yet been observed and a high degree of uncertainty is inherent in the process of trying to predict the ramifications of GMO use on the environment. *See* Emily Montgomery, *Genetically Modified Plants and Regulatory Loopholes and Weaknesses Under the Plant Protection Act*, 37 VT. L. REV. 351, 360 (2012) ("Much of the general concern associated with GM plant use stems from a lack of information regarding the long-term health and environmental impacts of GM plants. There is a fairly large degree of scientific uncertainty in a number of areas, notwithstanding the widespread use of GM plants.").

16. *See* McCabe, *supra* note 12, at 111 ("The results [of cross-contamination] can be devastating economically For example, in the Liberty Link Rice case . . . foreign trading partners banned U.S. long-grain rice because it was contaminated with GE material, which harmed many U.S. rice farmers.").

17. This Note uses the term "escape" to refer to the finding of a GM crop outside of its approved planting area. "Unauthorized release" is another common phrase to describe this type of occurrence.

Part III discusses the issues that the current GM regulatory system has triggered, beginning with the economic disruptions that the escape of GM seeds cause. Next, this Note shows that under the current system, there is potential for economic loss for organic and nonorganic farmers that present regulations do not address. Part III continues on to lay out the potential environmental risks posed by U.S. GM regulation, including the potential for loss of biodiversity and the inadvertent creation of pesticide- and herbicide-resistant organisms.

Part IV proposes solutions to address the current issues in the field trial approval and regulation process, including requiring a producer seeking approval of a field trial to submit a risk assessment and devise a containment plan. This Part also recommends that the Secretary of Agriculture review the current regulatory scheme for GMO field trials and propose changes to guarantee that the appropriate agencies enforce the necessary safety precautions, such as stronger reporting requirements and penalties for noncompliant companies.

II. DEFINING AND REGULATING GMOS

When a new industry emerges, additional regulations are necessary to facilitate the entry of new products into the market.¹⁸ When GMOs first arrived, the United States decided to rely on the administrative processes it already had in place, while those abroad largely created entirely new regulations.¹⁹ The original differences in GMO regulation persist in the laws and culture surrounding GMOs across the globe today.²⁰ This Part first provides a brief description of what GMOs are. Next, this Part presents the U.S. regulatory scheme for GMOs and lastly provides an overview of how governments abroad regulate GM products.

A. WHAT ARE GMOS?

Scientists transferred foreign DNA into a plant genome for the first time in 1983 and birthed the multi-billion dollar GM-product industry.²¹ Prior to this event, human attempts to produce improved species of organisms were limited to selective breeding efforts, meaning the use of natural selection or

18. See David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 YALE J. INT'L L. 81, 87 (2005) (noting that in regulating new biotechnologies like GMOs "policymakers faced a fundamental choice about the appropriate criteria to use in regulatory decision-making—whether to assess GM risk on the basis of the *products* themselves, or on the basis of the underlying *production processes*" (emphasis in original)).

19. See *infra* notes 71–77 and accompanying text.

20. See *infra* notes 71–72 and accompanying text.

21. Yves Bertheau & John Davison, *Introduction to the GM and Non-GM Supply Chain Co-Existence and Traceability*, in GENETICALLY MODIFIED AND NON-GENETICALLY MODIFIED FOOD SUPPLY CHAINS: CO-EXISTENCE & TRACEABILITY 3–4 (Yves Bertheau ed., 2013).

evolution to increase the occurrence of a desired trait.²² Researchers' use of transferred or recombinant DNA to genetically engineer the expression of chosen traits in commercially successful crops allowed them to create what "natural evolution" could never have achieved on its own:²³ combining the genes of wholly unrelated species together to produce "transgenic" organisms.²⁴

Agriculture companies invested in researching and creating GM crops to protect crop yields from a host of natural constraints that have adverse effects upon plant life.²⁵ Genetic engineers seek plant resistance to the effects wrought by weeds, insect pests, plant diseases, droughts, and floods.²⁶ One of the most common examples of GM crops is Bt corn, or corn which carries transferred genes from *Bacillus thuringiensis*, a soil bacteria, that allows the plant to produce Bt toxins, proteins capable of killing certain types of insect pests.²⁷ Another common modification is herbicide-resistance, meaning that plants are engineered to resist death if sprayed by a specific herbicide, such as Monsanto's Roundup.²⁸ This trait allows farmers to spray fields and kill the weeds that are competing with their crops for resources like soil nutrients, sunlight, and water, without killing the crops or having to resort to more labor-intensive methods, like traditional plowing or tilling.²⁹

Growers' commercial use of transgenic crops has increased exponentially over the last 20 years.³⁰ Farmers planted 1.7 million hectares of transgenic crops in 1996, compared with 44 million hectares in 2000,³¹ and in 2010, growers planted approximately 150 million hectares globally with GMOs.³² GMO use is especially high in the United States where "[i]n 2012, 94% of all cotton, 93% of all soybean, and 88% of all corn planted . . . by acreage was a GM variety."³³ Most transgenic crops are grown in the United States, Argentina, Brazil, Canada, and China, with the United States growing 55% of

22. Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297, 302 (2002) ("[S]elective breeding can only duplicate reproductive events that might occur in nature. By managing these reproductive events towards a particular end, the randomness that ordinarily drives natural selection can be channeled to achieve human goals.").

23. Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 WAKE FOREST L. REV. 93, 95 (2007).

24. Montgomery, *supra* note 15, at 355.

25. P. Christou & T. Capell, *Transgenic Crops and Their Applications for Sustainable Agriculture and Food Security*, in ENVIRONMENTAL IMPACT OF GENETICALLY MODIFIED CROPS 3, 7 (Natalie Ferry & Angharad M.R. Gatehouse eds., 2009).

26. *Id.* at 7-13.

27. Bratspies, *supra* note 22, at 304.

28. *See* Christou & Capell, *supra* note 25, at 7.

29. *See id.*

30. Bratspies, *supra* note 22, at 303.

31. *Id.*

32. Bertheau & Davison, *supra* note 21, at 4.

33. Montgomery, *supra* note 15, at 356.

all GM crops.³⁴ Members of the EU grow almost no GM crops,³⁵ due in large part to the fact that while “the European Union . . . acknowledges that there are benefits to agricultural biotechnology, it also has substantial concerns about the risks of that technology.”³⁶

B. CURRENT U.S. REGULATORY FRAMEWORK

The White House initially created the U.S. administrative framework for regulating biotechnology. The principles that the White House established provide a guide for the agencies charged with implementing regulations to reflect the U.S. stance on biotechnology throughout the administrative process.

1. The Principles and History of Biotechnology Regulation

The White House Office of Science and Technology Policy created the current regulatory scheme for GM products in 1986 when it issued a notice known as the Coordinated Framework for Regulation of Biotechnology (“Framework”).³⁷ Although Congress never enacted the Framework into law, the notice constitutes “the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products.”³⁸ With biotechnology in its infancy, President Ronald Reagan convened a “Cabinet Council Working Group” to bring some semblance of organization to the regulation of the new technology and pacify critics who alleged an ad hoc policy approach among the different government agencies in the field.³⁹

The Framework is founded upon two basic principles: (1) existing law is adequate to address the regulatory needs of GM products, and (2) “GM products inherently present no new risks beyond those of conventional analog organisms,” otherwise known as the substantial equivalence doctrine.⁴⁰ The substantial equivalence doctrine suggests that “GM products are presumed safe in the absence of physical differences from the analogous components of the progenitor organisms.”⁴¹ While the substantial equivalence doctrine was

34. Bertheau & Davison, *supra* note 21, at 4.

35. *Id.*

36. George Van Cleve, *Regulating Environmental and Safety Hazards of Agricultural Biotechnology for a Sustainable World*, 9 WASH. U. J.L. & POL'Y 245, 249 (2002). Much has been written about the differences in European and U.S. regulation of GMOs. See generally Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525 (1998).

37. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302-03 (June 26, 1986).

38. *Id.*

39. Sheryl Lawrence, *What Would You Do with a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 ECOLOGY L.Q. 201, 219 (2007).

40. *Id.*

41. *Id.*

evident in the original Framework, it was not until 1992 that a second Working Group specifically defined this guiding principle:⁴² “For GM foods and food components determined to be substantially equivalent to the parental products, the Working Group believe[s] that further safety concerns [are] likely to be ‘insignificant’ and the GM food [can] be treated for regulatory purposes just like the natural counterpart.”⁴³

2. The Process of Biotechnology Regulation

U.S. regulation of GMOs is divided among three federal agencies.⁴⁴ The EPA is responsible for monitoring implications for the environment through both the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act.⁴⁵ The Food and Drug Administration (“FDA”) focuses on the commercial use of GMOs in food under the Federal Food, Drug, and Cosmetic Act.⁴⁶ Lastly, the USDA regulates “the use of genetically modified plants, animals and microorganisms in agriculture” through the Federal Plant Protection Act (“PPA”).⁴⁷

The PPA specifically designates the USDA’s APHIS as the regulator of field trials.⁴⁸ The purpose of the PPA is to prevent “the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.”⁴⁹ Under the Act, the Secretary of Agriculture and APHIS are granted the ability to “prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance.”⁵⁰

Plant pests are defined as any nonhuman living entity capable of inflicting injury, disease or damage to plant life.⁵¹ Organisms that have been genetically engineered with any gene, whether donor, recipient, or vector, originating from a plant pest are regulated articles under the PPA.⁵² A noxious

42. Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 428 (2002).

43. *Id.* at 429.

44. Bratspies, *supra* note 22, at 311.

45. *Id.*

46. *Id.*

47. *Id.* at 311–12.

48. *See* Montgomery, *supra* note 15, at 362.

49. Plant Protection Act, 7 U.S.C. § 7712(a) (2013) (“The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction . . . or the dissemination of a plant pest or noxious weed within the United States.”).

50. *Id.*

51. *Id.* § 7702(14).

52. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe They Are Plant Pests, 7 C.F.R. § 340.1 (2014) (defining a regulated article as “[a]ny organism which has been altered or

weed is “any plant or plant product that can injure or cause damage to agricultural interests (such as crops, livestock, poultry, and irrigation), navigation, or the natural resources of the United States, public health, or the environment.”⁵³

To conduct a field trial, also referred to as a controlled environmental release, of a new and unapproved GMO in the United States, the potential grower must contact APHIS through the notification or permitting process.⁵⁴ A release permit is necessary if the GM product is a potential plant pest,⁵⁵ which effectively means “those designed to produce pharmaceutical and industrial compounds.”⁵⁶ However, growers conduct most GMO tests through the notification process.⁵⁷ “[N]otification is a streamlined procedure . . . by which regulated articles may be introduced into the environment” without awaiting agency review.⁵⁸ To use the notification process, a grower must certify that the regulated article in question is not listed as a noxious weed in the PPA.⁵⁹ The notification itself must include basic information about the producer intending to perform the field trial, the method used to genetically modify the product, the location, and the date and duration of the trial.⁶⁰ The grower must notify APHIS at least 30 days prior to the introduction of any environmental release, which would include any out-of-doors testing, like a field trial.⁶¹ Six months after the field test concludes, APHIS must receive reports on the field test results including generated data, observation methods, and any negative environmental effects.⁶²

After a field test, a grower may petition the USDA to grant its GM crop nonregulated status.⁶³ Once a particular product achieves nonregulated status, the “USDA places no restrictions or reporting requirements on the

produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa . . . and meets the definition of plant pest”).

53. Montgomery, *supra* note 15, at 365 (citing 7 C.F.R. § 360.100 (2012)).

54. *Id.* at 366.

55. *Biotechnology: Permits, Notifications, and Petitions*, U.S. DEP’T AGRIC.: ANIMAL & PLANT INSPECTION SERVICE, http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa_permits_notifications_and_petitions (last visited Nov. 12, 2014).

56. U.S. DEP’T OF AGRIC., AUDIT REPORT: ANIMAL AND PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS, at i (2005), available at <http://www.usda.gov/oig/webdocs/50601-08-TE.pdf>.

57. *Id.* at 2. According to the audit conducted by the Office of the Inspector General, about 97% of the GMO field trials in the United States in 2004 were performed through the notification process. *Id.*

58. Blake Denton, Comment, *Regulating the Regulators: The Increased Role for the Federal Judiciary in Monitoring the Debate over Genetically Modified Crops*, 25 UCLA J. ENVTL. L. & POL’Y 333, 348 (2006–2007) (quoting U.S. DEP’T OF AGRIC., *supra* note 56, at 62).

59. 7 C.F.R. § 340.3(b)(1) (2014).

60. *Id.* § 340.3(d)(2).

61. *Id.* § 340.3(d)(3)(iii).

62. *Id.* § 340.3(d)(4).

63. *Id.* § 340.6.

distribution of the crop in the United States.”⁶⁴ The USDA must fulfill the requirements of the National Environmental Policy Act (“NEPA”), under which the agency must draft an environmental impact statement (“EIS”) if it is making any decision “significantly affecting the quality of the human environment.”⁶⁵ On occasion, however, the USDA will issue an environment assessment instead, a statement which explains why granting nonregulated status would not affect the human environment, voiding the need for an EIS.⁶⁶

C. INTERNATIONAL GMO REGULATION

A government must balance the need for a steady food supply for its people with its country’s values and particular views regarding food safety.⁶⁷ In 2010, the United States exported \$115 billion in agricultural products around the world⁶⁸ to primary importers in the EU, Japan, China, Canada, Mexico, Taiwan, and South Korea.⁶⁹ The United States is a principal exporter of mainstay crops like corn, wheat, cotton, and soybeans.⁷⁰ The laws that regulate GMOs in the United States and other countries and regions such as Japan and the EU differ due to contrasting levels of trust regarding new technology, the government’s ability to prevent accidents, and food safety.⁷¹

The EU created entirely new laws for GMOs, whereas the United States decided to regulate GMOs under existing law.⁷² The United States “permits a

64. Bratspies, *supra* note 22, at 314 (citing 7 C.F.R. § 340.1).

65. 42 U.S.C. § 4332(c) (2012).

66. 40 C.F.R. § 1508.9(a)(1) (2013) (“*Environmental assessment*: (a) Means a concise public document for which a Federal agency is responsible that serves to: (1) Briefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact. . . .”); 40 C.F.R. § 1508.13 (2014) (“*Finding of no significant impact* means a document by a Federal agency briefly presenting the reasons why an action, not otherwise excluded . . . will not have a significant effect on the human environment and for which an environmental impact statement therefore will not be prepared. It shall include the environmental assessment or a summary of it and shall note any other environmental documents related to it” (emphasis in original) (citations omitted)).

67. See Echols, *supra* note 36, at 525 (“Both the EU and the U.S. must assure their citizens of a safe food supply, while responding to significant differences in cultural influences and consumers’ ideas about what is safe to eat.”).

68. *Fast Facts About Agriculture*, AM. FARM BUREAU FED’N, <http://www.fb.org/index.php?action=newsroom.fastfacts> (last visited Nov. 12, 2014).

69. CHARLES E. HANRAHAN ET AL., CONG. RESEARCH SERV., 98-253, U.S. AGRICULTURAL TRADE: TRENDS, COMPOSITION, DIRECTION, AND POLICY 11 (2011), available at <http://www.fas.org/sgp/crs/misc/98-253.pdf>.

70. *Id.* at 13.

71. See Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 176 (2006) (“Until recently, consumers in the United States have appeared to be relatively trusting and uninformed of a technology that in Europe has triggered extensive public debate, due in part to a history of food and environmental concerns, lack of transparency, and suspicion towards the government.”).

72. *Id.*; Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303, (June 26, 1986) (“Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques . . . these laws as currently

great deal of industry self-regulation,” while the EU does not.⁷³ The Japanese government “now mandates the segregation of unapproved biotechnology food and feed ingredients from the export channel.”⁷⁴ Regulatory differences and diverse opinions on the safety of GMOs in food mean that accidents have broad economic impacts.⁷⁵ For example, when StarLink corn, a GM crop only approved for animal feed, was discovered in exports intended for human consumption, it significantly disrupted the national and international agricultural markets,⁷⁶ and the discovery of the Oregon GM wheat caused key importers like Japan and Korea to suspend U.S. wheat imports.⁷⁷

To address international regulatory differences, working groups created the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in 2000, which “seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology.”⁷⁸ A key feature of the Cartagena Protocol is the precautionary principle—the idea that when determining whether to pursue a course of action, if there is not full scientific certainty or certainty is impossible under the circumstances, risk avoidance will guide the decision-making process.⁷⁹ This principle is diametrically opposed to the principle that guides U.S. biotechnology regulation, the substantial-equivalence doctrine, which makes broad assumptions regarding the risks that new GMO products present.⁸⁰ To date there are 166 parties to the Cartagena Protocol; the United States is not among them.⁸¹ This typifies the disparity in both attitudes and laws relating to GM products that exists between the United States and the international community.⁸²

Given that this disparity primarily results from varying levels of concern over possible environmental effects of GMOs, countries differ in their

implemented would address regulatory needs [of products created by the new techniques] adequately.”). Controversy surrounds the decision to fit biotechnology, a multi-billion dollar industry, into laws that were created years before the techniques and methods routinely used today were thought possible. See McGarity, *supra* note 42, at 405 (“[D]isagreement over the adequacy of existing regulatory oversight stems from the fact that the statutes that form the underlying regulatory framework were not enacted with biotechnology in mind and therefore leave several serious institutional and interpretational questions unresolved.”).

73. Echols, *supra* note 36, at 533–34.

74. Strauss, *supra* note 71, at 173.

75. *Id.* at 173.

76. *Id.* at 173. The discovery of StarLink in food “caus[ed] a drop in Japanese imports of U.S. corn by 1.3 million metric tons . . . in 2001.” *Id.*

77. Shannon, *supra* note 9.

78. *About the Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://bch.cbd.int/protocol/background> (last visited Nov. 12, 2014).

79. Bratspies, *supra* note 22, at 318.

80. *Supra* notes 40–43 and accompany text.

81. *Parties to the Protocol and Signature and Ratification of the Supplementary Protocol*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://bch.cbd.int/protocol/parties/> (last visited Nov. 12, 2014).

82. See Strauss, *supra* note 71, at 186.

approach to regulating the release of the products into the environment, especially at the field trial and approval stages.⁸³ The EU proceeds in testing GMO products through its Deliberate Release Directive, which uses the precautionary approach and the EU member states revised the directive in 2004 to “require[] full traceability, and labels . . . accompany[ing] all GM-derived products, even if the final product lacks foreign DNA or protein.”⁸⁴ Because environmental effects of GM products may be “irreversible,” the EU requires a “notification procedure before a GM product is placed on the market, a period of public comment, an assessment report, and principles for environmental risk assessment,” once again paying homage to the precautionary approach.⁸⁵ Conflict over the use of the precautionary principle versus the substantial equivalence doctrine, as employed by the United States, Canada, and Argentina,⁸⁶ resulted in dispute settlement proceedings before the World Trade Organization in 2003.⁸⁷ So long as opinions regarding the need to regulate GMOs differ worldwide, conflicts will likely continue to arise, whether the issue is testing, approval, or labeling.⁸⁸

III. RISKY BUSINESS: ISSUES IN CURRENT REGULATION

The current U.S. regulatory scheme for unapproved GM products is weak because it fails to adequately address the ability of GM products, unlike their natural counterparts, to disrupt global markets,⁸⁹ cause farmers economic loss,⁹⁰ and alter plant and wildlife ecology.⁹¹ Tightening the regulation of GMO field trials and enforcing compliance with those regulations, as noted by several reports in past years,⁹² would address those issues.

83. See Winickoff et al., *supra* note 18, at 87 (“Whereas the United States has embraced the products approach to GM agriculture, the European Union and its member states have tended to adopt the more precautionary process approach.”).

84. *Id.* at 88–89.

85. Strauss, *supra* note 71, at 179.

86. Maria Gabriela Balboa, *Legal Framework to Secure the Benefits While Controlling the Risks of Genetically Modified Foods: A Comparison of the Cartagena Protocol and Three National Approaches*, 31 TEMP. J. SCI. TECH. & ENVTL. L. 255, 278 (2012).

87. Winickoff et al., *supra* note 18, at 82. The dispute moved to arbitration in 2008, which was then suspended. *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm (last visited Nov. 12, 2014).

88. Labeling GM products has recently become a controversial topic in the United States. See *supra* note 5. Twenty-two other nations already require the labeling of GM food. Strauss, *supra* note 71, at 181.

89. See *infra* Part III.A.

90. See *infra* Part III.B.

91. See *infra* Part III.C.

92. See *infra* Part III.D.

A. GM-RELATED ECONOMIC DISRUPTIONS

The economic impact of GMO escapes, whether the escapes are into the food supply or the environment at large, is immediate and widespread.⁹³ One of the most well-known incidents that highlights the need for proper regulation of GM products, including field testing, is the discovery of StarLink corn in taco shells and other food.⁹⁴ Aventis CropScience USA Holdings, Inc. (“Aventis”) created a corn seed capable of producing Cry9C, a protein that when ingested can kill certain insects.⁹⁵ In the approval process for StarLink:

The EPA noted that Cry9C had several attributes similar to known human allergens, and issued only a limited registration, permitting StarLink use for such purposes as animal feed, ethanol production and seed increase, but prohibiting its use for human consumption. Consequently, segregating it from non-StarLink corn, which was fit for human consumption, became of utmost importance.⁹⁶

Those findings led the EPA to designate special methods for handling StarLink to prevent it from commingling with other corn varieties.⁹⁷ Growers planted StarLink on approximately 350,000 acres in 2000, the year in which its production reached the highest mark.⁹⁸ In September 2000, Kraft Foods’

93. See *infra* note 101 and accompanying text.

94. Bodiguel & Cardwell, *supra* note 12, at 13.

95. *Kramer v. Aventis CropScience USA Holding, Inc. (In re StarLink Corn Prods. Liab. Litig.)* 212 F. Supp. 2d 828, 833–34 (N.D. Ill. 2002).

96. *Id.* at 834.

97. The special methods are described as follows:

[T]he EPA required special procedures with respect to StarLink. These included mandatory segregation methods to prevent StarLink from commingling with other corn in cultivation, harvesting, handling, storage and transport, and a 660-foot “buffer zone” around StarLink corn crops to prevent cross-pollination with non-StarLink corn plants. . . . Aventis [was] responsible for ensuring these restrictions were implemented, obligating it (a) to inform farmers of the EPA’s requirements for the planting, cultivation and use of StarLink; (b) to instruct farmers growing StarLink how to store and dispose of the StarLink seeds, seed bags, and plant detritus; and (c) to ensure that all farmers purchasing StarLink seeds signed a contract binding them to these terms before permitting them to grow StarLink corn.

Id.

98. *Id.* at 835. The initial registration issued to Aventis capped StarLink cultivation at 120,000 acres. *Id.* at 834. Aventis petitioned for the limit to be raised to 2.5 million acres in January, 1999. *Id.* The EPA raised the limit but only after amending the registration to require that Aventis do the following:

- (a) inform purchasers (i.e. “Growers”) at the time of StarLink seed corn sales, of the need to direct StarLink harvest to domestic feed and industrial non-food uses only;
- (b) require all Growers to sign a “Grower Agreement” outlining field management requirements and stating the limits on StarLink corn use;
- (c) deliver a Grower Guide, restating the provisions stated in the Grower Agreement, with all seed;
- (d) provide all Growers with access to a confidential list of feed outlets and elevators that direct grain to domestic feed and industrial uses;
- (e) write to Growers prior to

taco shells, normally sold in Taco Bell restaurants, tested positive for Cry9C, “prompting Kraft Foods to recall the more than 2.5 million boxes of the product believed to be in distribution.”⁹⁹ Other economic fallout included U.S. food producers substituting U.S.-grown corn with imported corn, Japan and South Korea discontinuing imports of U.S. corn, and grain elevators requiring costly testing of corn shipments to determine whether Cry9C had contaminated the corn.¹⁰⁰

Other such escapes include Prodigene in 2002, Bt 10 in 2004, Event 32 in 2006, and LibertyLink rice 601 and 604 in 2006.¹⁰¹ All of those seed varieties were unapproved at the time of discovery, and all of them had escaped from field tests or research sites.¹⁰² The Oregon wheat discovery is only the most recent in a series of these events, which together have cost

planting, reminding them of the domestic and industrial use requirements for StarLink corn; (f) write to Growers prior to harvest, reminding them of the domestic and industrial use requirements for StarLink corn; (g) conduct a statistically sound follow-up survey of Growers following harvest, to monitor compliance with the Grower Agreement.

Id. at 834–35.

99. Barnaby J. Feder, *Companies Act to Keep Bioengineered Corn Out of Food*, N.Y. TIMES (Sept. 27, 2000), <http://www.nytimes.com/2000/09/27/business/companies-act-to-keep-bioengineered-corn-out-of-food.html>.

100. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d at 834–35.

101. Margaret Rosoo Grossman, *Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort*, in THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES, *supra* note 12, at 321 n.158. The biotech company ProdiGene field tested corn in Nebraska that later contaminated the soybeans planted in the field the next year causing the USDA to order the destruction of 500,000 bushels of soybeans, fined the company \$250,000 and ordered it to pay \$3 million in damages all because the company failed to comply with the conditions in the issued permit. Andrew Pollock, *Spread of Gene-Altered Pharmaceutical Corn Spurs \$3 Million Fine*, N.Y. TIMES (Dec. 7, 2002), <http://www.nytimes.com/2002/12/07/us/spread-of-gene-altered-pharmaceutical-corn-spurs-3-million-fine.html>. Syngenta alerted authorities in 2004 that it had mistakenly distributed Bt10, an unapproved corn variety to farmers from 2001 to 2004, which “resulted in numerous rejected corn shipments to Japan and the EU.” CTR. FOR FOOD SAFETY, CONTAMINATION EPISODES WITH GENETICALLY ENGINEERED CROPS 1–2 (2006), available at <http://www.co.lake.ca.us/Assets/BOS/GE+Crops+Committee/3.+Contamination+episodes+with+genetically+eng+crops.pdf>. Dow AgroSciences pulled corn from the market after Event 32 escaped from a research plot and contaminated other hybrid corn plantings. *Dow AgroSciences, USDA Address Low Levels of Regulated Corn Seed Event*, SEED TODAY (Feb. 22, 2008), http://www.seedtoday.com/articles/dow_agrosciences_usda_address_low_levels_of_regulated_corn_seed_event-54060.html. In 2006, a rice mill revealed that rice it had received was contaminated by GM rice, a serious issue as Bayer Crop Science, who bought Aventis after the StarLink episode and was the patent holder of LibertyLink, the contaminating strain, had abandoned GM rice in 2001 after field trials because, like wheat, no one would buy GM rice, which ultimately meant that LibertyLink had most likely been in the food supply for five years. Marc Gunther, *Attack of the Mutant Rice*, FORTUNE (July 2, 2007, 3:56 PM), http://archive.fortune.com/magazines/fortune/fortune_archive/2007/07/09/100122123/index.htm.

102. See *supra* note 101.

billions of dollars by throwing the international agricultural markets into disarray.¹⁰³

The fact that StarLink was found in the food supply in Saudi Arabia as recently as 2010 demonstrates that the ramifications of such events are long-lasting.¹⁰⁴ Even in cases such as StarLink, where the EPA issued strict requirements for handling the GM seed at issue and only issued limited approval, the EPA regulations did not include mechanisms to enforce compliance with the prescribed production and distribution procedures.¹⁰⁵ The lack of enforcement mechanisms resulted in litigation, *In re StarLink Corn Products Liability Litigation*, where plaintiffs claimed that the StarLink seed likely escaped primarily due to the company's unwillingness to adhere to the registration requirements.¹⁰⁶ Farmers whose corn was contaminated with StarLink brought suit under theories of economic loss, conversion, negligence, and nuisance.¹⁰⁷ The court denied the motions to dismiss on the negligence and nuisance claims,¹⁰⁸ and the case settled out of court.¹⁰⁹ Incidents like StarLink illustrate the need for regulatory reform that must begin with the first stage in the approval process, the field trial.

B. DAMAGE TO NEIGHBORING FIELDS

The escape of GM crops into neighboring fields poses a significant threat to the purity of the genetic material within that nearby crop. The threat is

103. No one has determined the exact costs of these escapes in the aggregate. More information is available about StarLink and LibertyLink as these were the larger-scale escape incidents. "The 2000 release of Aventis SA (SAN)'s StarLink corn cost as much as \$288 million in lost revenue and a yearlong drop in the grain's price. . . . The 2006 release of Bayer AG (BAYN)'s Liberty Link rice led to a \$750 million settlement in 2011 with about 11,000 U.S. farmers." Mark Drajem, *Escaped Wheat Shows Difficulty of Keeping Tests on Farm*, BLOOMBERG (May 31, 2013, 11:14 AM), <http://www.bloomberg.com/news/2013-05-31/escaped-wheat-shows-difficulty-of-keeping-tests-on-farm.html>. "The recall of StarLink genetically modified corn could cost companies . . . hundreds of millions of dollars as they attempt to find, retrieve and replace products that used the corn." Sarah Lueck et al., *Corn-Recall Cost Could Reach into the Hundreds of Millions*, WALL ST. J. (Nov. 3, 2000, 11:59 PM), <http://online.wsj.com/article/SB973211373330867246.html>. Even a "smaller" escape, the Oregon wheat discovery, caused prices of grain and wheat futures to fall and Japan to suspend wheat imports. Drajem, *supra*.

104. Rafaat M. Elsanhoty et al., *Prevalence of Genetically Modified Rice, Maize, and Soy in Saudi Food Products*, 171 APPLIED BIOCHEMISTRY & BIOTECHNOLOGY 883, 885-87 (2013) (detailing DNA testing that showed soybean and corn products tested positive for GM traces).

105. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d at 835. In the *StarLink* litigation, the plaintiffs alleged that "Aventis did not include the EPA-mandated label on some StarLink packages, did not notify, instruct and remind StarLink farmers of the restrictions on StarLink use, proper segregation methods and buffer zone requirements, and did not require StarLink farmers to sign the obligatory contracts." *Id.*

106. *Id.*

107. *See id.* at 852; Balboa, *supra* note 86, at 269.

108. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d at 852.

109. Kevin O'Hanlon, *StarLink Corn Settlement Also to Include Interest*, USA TODAY (Aug. 23, 2004, 5:55 PM), http://usatoday30.usatoday.com/tech/news/techpolicy/business/2004-08-23-starlink-snafu_x.htm.

significantly greater if that crop is certified organic because the USDA prohibits the labeling of products containing GM material as “organic.”¹¹⁰ If an organic crop becomes contaminated with seed from a nearby GM crop through pollen drift, the farmer may not be able to sell his crop as organic and will suffer economic loss if forced to sell the crop in the nonorganic market for a lower price.¹¹¹

Organic farmers must prevent GM seeds from cross-pollinating with their own crops because “[e]ven a small presence of GMOs can ruin organic fields and lead to economic loss from lack of certification.”¹¹² As the court in the *StarLink* litigation stated, “[o]nce airborne, corn pollen can drift over considerable distances, meaning that different corn varieties within a farm, and from neighboring farms, regularly cross-breed.”¹¹³ This leads to the conclusion that even conventional farmers, or those who are not certified organic producers, have an incentive to avoid the cross-pollination of their own seed with that of a GM field trial because cross-pollination with GM crops would threaten their seed lines and buyers could reject the harvested crop at market.

The current regulatory system does not require producers seeking to conduct a field trial to make any showing of containment procedures or perform assessments that specifically report containment success upon the conclusion of the trial.¹¹⁴ APHIS imposes civil penalties for accidental release,

110. 7 C.F.R. § 205.301 (2014). Under Section 205.301, “[a]ll products labeled as ‘100 percent organic’ or ‘organic’ and all ingredients identified as ‘organic’ in the ingredient statement of any product must not . . . [b]e produced using excluded methods” which are “[a] variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production.” *Id.* §§ 205.2, .301(f).

111. Angelo, *supra* note 23, at 108–09. A recent incident bears this out: A farmer discovered that his alfalfa crop was contaminated by a GM variety belonging to Monsanto after his crop was rejected for export. Lindsay Abrams, *Monsanto Could Get Away with GMO Contamination*, SALON (Sept. 16, 2013, 12:13 PM), http://www.salon.com/2013/09/16/monsanto_could_get_away_with_gmo_contamination/. It is not clear that Monsanto will face any responsibility for any economic loss; rather, “the government could decide just to let the marketplace handle the mixup.” Carey Gillam, *USDA Weighing What to Do in Case of GMO Alfalfa Contamination*, REUTERS (Sept. 16, 2013), <http://www.reuters.com/article/2013/09/16/usa-alfalfa-gmo-idUSL2NoHCoPM20130916>.

112. Debra M. Strauss, *Achieving the Food Safety Mandate: Bringing the USDA to the Table*, 33 HAMLIN J. PUB. L. & POL’Y 1, 43 (2011).

113. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d at 834.

114. See *supra* Part II.B.2. The regulations do require that the producer send in an “analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.” 7 C.F.R. § 340.3(d)(4). A producer’s failure to contain the tested GM product should fall within the definition of a “deleterious effect;” however, an assessment of containment that addresses the likelihood that commingling occurred is warranted by the significant effects of such events. See U.S. DEP’T OF AGRIC., LESSONS LEARNED AND REVISIONS UNDER CONSIDERATION FOR APHIS’ BIOTECHNOLOGY FRAMEWORK 2 (2007), available at <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/LessonsLearned10-2007.pdf>. This is true especially in light of the following finding by the Office of the Inspector General: “Our analysis of required

providing one incentive for manufacturers to contain their experimental products.¹¹⁵ Other incentives for producers to contain their GM products are the threats of litigation that could arise should the seed escape and the protection of their intellectual property (“IP”) rights in the seed.¹¹⁶

Organic farmers and seed groups have not had much success in court when seeking damages for economic loss or conversion, nuisance, or negligence. Furthermore, in a recent suit against Monsanto—*Organic Seed Growers and Trade Ass’n v. Monsanto Co.*—organic farmers and seed groups were also unsuccessful in their claim for future damages that would allegedly arise out of the company’s actions.¹¹⁷ The District Court for the Southern District of New York and the Federal Circuit dismissed the case on the grounds that the plaintiffs lacked standing “because the future harm they allege—that they will grow greater than trace amounts of modified seed, and therefore be sued for infringement by Monsanto—is too speculative.”¹¹⁸ In light of the relatively few instances where plaintiffs have been successful and the disparity in resources between the larger conglomerates and the smaller organic producers, litigation likely does not pose a significant enough threat to affect the economic calculations of these companies.

Seed companies are strict with the IP rights to their GM seed to the point that even if GM seed blows into a farmer’s field, thereby endangering his crop, the farmer could also face a second significant economic threat in the form of a lawsuit for patent infringement.¹¹⁹ Monsanto is the best example of a company that routinely employs this method of enforcing its IP rights.¹²⁰ As of 2012, “Monsanto ha[d] filed 136 lawsuits against American farmers, involving 400 farmers and 53 small businesses or farm companies and

reporting for high-risk pharmaceutical and industrial permits, other permits, and notifications in our sample found that applicants did not always submit progress reports in a timely manner, if at all.” U.S. DEP’T OF AGRIC., *supra* note 56, at 36.

115. See *Biotechnology: Noncompliance History*, *supra* note 11.

116. See *supra* notes 107–08 and accompanying text.

117. *Organic Seed Growers & Trade Ass’n v. Monsanto Co.*, 718 F.3d 1350, (Fed. Cir. 2013) (dismissing the case for lack of standing). The plaintiffs sought to invalidate Monsanto’s patents on GM seed and according to the OSGATA website: “This landmark lawsuit also seeks Court protection for family farmers who, through no fault of their own, may have become contaminated by Monsanto’s patented GE seed and find themselves accused of patent infringement.” OSGATA *et al. v. Monsanto*, ORGANIC SEED GROWERS & TRADE ASS’N, <http://www.osgata.org/osgata-et-al-v-monsanto/> (last visited Nov. 12, 2014).

118. *Monsanto*, 718 F.3d at 1360.

119. See Debra M. Strauss, *Liability for Genetically Modified Food: Are GMOs a Tort Waiting to Happen?*, SCITECH L., Fall 2012, at 8, 9 (“Monsanto vigorously enforces its intellectual property rights, aggressively pursuing farmers with seed contracts and lawsuits against those whose fields contain any of their GM crops even for the cross-pollination or seed drift into their fields, succeeding . . . because the law does not require intent to plant the patented GM seed.”).

120. See *id.* (explaining that Monsanto “has the means and motive to intimidate farmers into compliance”).

resulting in 70 judgments awarded to Monsanto against farmers totaling \$23,345,821.”¹²¹

C. ENVIRONMENTAL RISKS

Given the variables at play, predicting how introducing any new species of plant will impact the environment is difficult, if not impossible.¹²² That uncertainty is necessarily amplified when introducing a new and experimental crop, meaning that field trials present novel risks to the surrounding environment.¹²³ Since agencies rely on the substantial equivalence doctrine,¹²⁴ the U.S. regulatory framework does not sufficiently address environmental issues that could result from GMOs.¹²⁵

These environmental issues include the advent of GM pesticide- or herbicide-resistant crops, which has led to important changes in agricultural practices, most notably, the types of herbicides farmers use and the amount that they apply to crops such as corn, soybeans, and cotton.¹²⁶ While much of the science surrounding genetic engineering and its implications for the future is still uncertain, those altered agricultural practices could have important ecological effects, especially on biodiversity and the prevalence of herbicide-resistant plants.¹²⁷

1. Biodiversity

GMOs may threaten biodiversity in several respects. GM crops pose a threat to nontarget species that feed on the pest species, because they could ingest the poisoned prey and become poisoned themselves.¹²⁸ For instance, a beneficial insect feeds upon a corn borer who has Bt poison in its system; the toxin will also kill the beneficial insect, thus spreading the effect of the genetic modification further up the food chain than intended. Additionally, declines in populations of the pest/prey species could lead to a food shortage for the beneficial, nontarget species.

Bt corn is genetically engineered to kill members of the family *Lepidoptera*, which does include notable insect pests like the corn borer, but

121. *Id.* (citation omitted).

122. *See supra* note 15 and accompanying text.

123. *Id.*

124. *See supra* notes 39–43 and accompanying text.

125. *See supra* note 72 and accompanying text.

126. NAT'L RESEARCH COUNCIL, THE IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES 60 (2010).

127. Angelo, *supra* note 23, at 110; *see* NAT'L RESEARCH COUNCIL, *supra* note 126, at 60 (discussing the ecological impacts of herbicide-resistant crops on “soil quality, water quality, arthropod biodiversity, and weed communities”).

128. Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 59 (2001) (“[I]t may be inevitable that harmless insects or beneficial insects (i.e., insects that feed on pests) are poisoned, thus actually increasing the pest population and decreasing biological diversity among insects.”).

the Monarch butterfly is also a member of *Lepidoptera*.¹²⁹ In 1999, researchers discovered that pollen from Bt corn was toxic to Monarch butterfly larvae.¹³⁰ The public was immediately concerned and the EPA responded with studies demonstrating that the overall risk to the Monarch butterfly was low, however it was not nonexistent, and the EPA had made assumptions in approving Bt that “were scientifically unsound.”¹³¹

2. Pesticide Resistance

Similar to the warnings of a loss in biodiversity, environmental groups and scientists have cautioned for years that the agricultural industry’s extensive use of GM plants followed by the liberal application of herbicides and pesticides has the potential to create a planet overrun with “superbugs” and “superweeds.”¹³² These warnings sound like hyperbolic rhetoric bandied about by alarmists, but well-grounded reasons exist for concern about the prevalent use of GM products.¹³³

GM crops have the potential to cross-pollinate with related species to form novel genetic varieties that could become “new weeds or pests.”¹³⁴ Imbued with herbicide-resistance, these plants would be hardy and possibly difficult to control.¹³⁵ As illustrated by the Oregon wheat, a plant seed strain that escapes into the environment can be hard to trace, and farmers or regulators can find plants growing far from their original introduction sites.¹³⁶

In addition to the potentially “new” weeds that GM cross-pollination could create, the “old” weeds that the system intended to combat are likely to

129. Christou & Capell, *supra* note 25, at 8; see Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2212–13 (2004) (discussing the EPA response to the discovery of the implications of Bt corn use for the Monarch butterfly).

130. John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae* 399 NATURE 214, 214 (1999), available at <http://www.nature.com/scitable/content/Transgenic-pollen-harms-monarch-larvae-97961> (“[L]arvae of the monarch butterfly . . . reared on milkweed leaves dusted with pollen from Bt corn, ate less, grew more slowly and suffered higher mortality than larvae reared on leaves dusted with untransformed corn pollen or on leaves without pollen.”).

131. Mandel, *supra* note 129, at 2213.

132. See *Superweeds and Superbugs: Intro to GMO and Its Consequences on Our Food Supply*, MINDFUL WORD (Sept. 25, 2012, 6:12 AM), <http://www.themindfulword.org/2012/gmo-genetically-engineered-food/> (urging readers to buy organic to fight GMO-producing companies that are seeking approval of a new “stacked trait” variety of corn to overcome the resistance problems that have developed); see also ‘Superbugs’ Prompt Urgent Warning From Scientists, RODALE NEWS (Mar. 21, 2012), <http://www.rodalenews.com/gmo-corn> (“Call it ironic, call it scary—call it urgent, is what America’s leading agriculture scientists are saying about a new variety of superbug invading American farms.”).

133. See *infra* notes 140–44.

134. Angelo, *supra* note 23, at 107.

135. *Id.*

136. *Id.*; see also COWAN, *supra* note 1, at 1 (stating that testing on the Oregon wheat variety ended in 2005 and the variety was then found in 2013).

become increasingly resistant to herbicide over time.¹³⁷ Generic glyphosate is the active ingredient in the herbicide Roundup, which is the most commonly applied herbicide in the United States with approximately 180 to 185 million pounds applied in 2007 in the agricultural sector alone.¹³⁸ By planting Roundup Ready crops, plants engineered to resist glyphosate, farmers can spray fields and eliminate weeds that would choke their crops and reduce yields without tilling or manual labor.¹³⁹

The pervasive adoption of Roundup Ready varieties of corn, soybeans, and cotton followed by the application of Roundup or generic glyphosate, Roundup's active ingredient, has already led eleven species of weed to develop resistance to the chemical.¹⁴⁰ For the farmers whose fields are overrun with weeds that they can no longer kill with herbicide, this means resorting to labor-intensive methods, buying and spraying other herbicides, and most likely an overall decline in production or yield.¹⁴¹ An increase in plowing and tilling means expending more fuel and time on fields as well as reversing one of the main environmental benefits that the Roundup Ready system offered: no-till farming, which improves soil quality by allowing the soil to retain more organic matter and water, thereby reducing erosion and pesticide runoff.¹⁴²

In addition to the evolution of the aforementioned varieties of superweeds, insects threaten to become "super" as well, and just as difficult to

137. See Jack Kaskey, *Attack of the Superweed*, BLOOMBERG BUSINESSWEEK (Sept. 8, 2011), <http://www.businessweek.com/magazine/attack-of-the-superweed-09082011.html> (presenting a story of farmers who were formerly able to use Roundup effectively to kill weeds but now must resort to other methods).

138. ARTHUR GRUBE ET AL., U.S. ENVTL. PROT. AGENCY, PESTICIDES INDUSTRY SALES AND USAGE: 2006 AND 2007 MARKET ESTIMATES 14 (2011), available at http://www.epa.gov/opp00001/pestsales/07pestsales/market_estimates2007.pdf.

139. See William Neuman & Andrew Pollack, *Farmers Cope With Roundup-Resistant Weeds*, N.Y. TIMES (May 3, 2010), <http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html> (noting that the arrival of Roundup Ready crops in the market "allow[ed] farmers to spray their fields to kill the weeds while leaving the crop unharmed").

140. Kaskey, *supra* note 137; see Neuman & Pollack, *supra* note 139 ("[R]esistant species in at least 22 states [are] infesting millions of acres, predominantly soybeans, cotton and corn.").

141. Neuman & Pollack, *supra* note 139 ("[F]armers . . . are being forced to spray fields with more toxic herbicides, pull weeds by hand and return to more labor-intensive methods like regular plowing.").

142. David R. Montgomery, *A Case for No-Till Farming*, SCI. AM. (June 30, 2008), <http://www.scientificamerican.com/article/a-case-for-no-till-farmin>; see SJOERD W. DUIKER & JOEL C. MYERS, PA. CONSERVATION P'SHIP, BETTER SOILS WITH THE NO-TILL SYSTEM 17 (2002), available at http://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/nrcs142p2_017969.pdf ("[I]t is justified to expect lower pesticide losses from no-till fields than from conventionally tilled fields because of smaller runoff and reduced erosion rates."); JOHN HOROWITZ ET AL., U.S. DEPT. OF AGRIC., "NO-TILL" FARMING IS A GROWING PRACTICE 1 (2010), available at <http://www.ers.usda.gov/media/135329/eib70.pdf> (examining the effect of no or reduced tilling practices on organic matter in the soil and noting that "[t]illage practices also affect sediment and chemical runoff from farms").

eradicate.¹⁴³ Without the ability to manage insect populations, “[r]esistance to insecticides [becomes an] agricultural and public health problem.”¹⁴⁴ The EPA foresaw the advent of pesticide-resistant insects when it began requiring that Bt growers designate parts of their fields as “refuges” where they would plant non-Bt crops as part of its insect resistance management strategy.¹⁴⁵ Compliance with the requirement, however, has been muted, likely due to both farmers’ desire to put all of their available land into production and a lack of agency enforcement.¹⁴⁶ Agriculture companies developed Bt crops to decrease the use of pesticides in fields as the plant itself would provide the toxicity to kill pests and keep them from harming crops.¹⁴⁷ If resistance persists and surges among pest populations, “[c]ontinued reliance on chemical insecticides might thus be necessary,” reversing another of the intended benefits of developing GM crops.¹⁴⁸

D. STALLED REFORM ACTIONS

In 2005, after a comprehensive review by the Office of the Inspector General, a report highlighted the inadequacy of the current regulations.¹⁴⁹ The Office of the Inspector General found that APHIS needed to strengthen its own accountability for enforcing compliance with the regulations for conducting field tests of GM crops.¹⁵⁰ Even more damning was the conclusion that “weaknesses in APHIS regulations and internal management controls

143. Murphy, *supra* note 128, at 59; see Carey Gillam, *Pesticide Use Ramping Up as GMO Crop Technology Backfires: Study*, REUTERS (Oct. 1, 2012, 9:18 PM), <http://www.reuters.com/article/2012/10/02/us-usa-study-pesticides-idUSBRE8g100X20121002> (observing that pesticide use is increasing due to the rise of “hard-to-kill insects”); see also Lynne Peoples, *Pesticide Use Proliferating with GMO Crops, Study Warns*, HUFFINGTON POST (Oct. 18, 2012, 2:43 PM), http://www.huffingtonpost.com/2012/10/04/pesticides-gmo-monsanto-roundup-resistance_n_1936598.html (“[W]ithin six years of the GMO corn’s arrival, superbugs that could withstand Bt appeared.”).

144. William H. McGaughey & Mark E. Whalon, *Managing Insect Resistance to Bacillus Thuringiensis Toxins*, 258 SCI. 1451, 1452 (1992).

145. EPA’s *Regulation of Bacillus Thuringiensis (Bt) Crops*, U.S. ENVTL. PROTECTION AGENCY, <http://www.epa.gov/pesticides/biopesticides/pips/regofbt crops.htm> (last visited Nov. 12, 2014) (“EPA requires all farmers who use Bt crops to plant a portion of their crop with such a refuge. The aim of this strategy is to provide an ample supply of insects that remain susceptible to the Bt toxin.”).

146. Bloomberg News, *Makers of Genetically Modified Seeds Say More Farmers Evading EPA Rules*, WASH. POST (Feb. 13, 2012), http://articles.washingtonpost.com/2012-02-13/national/35445664_1_monsanto-corn-bt-gene-seeds (“About 41 percent of 3053 farmers inspected in 2011 failed to fully comply with the refuge requirement, according to data that Monsanto provided.”).

147. See R.H. Phipps & J.R. Park, *Environmental Benefits of Genetically Modified Crops: Global and European Perspectives on Their Ability to Reduce Pesticide Use*, 11 J. ANIMAL & FEED SCI. 1, 6–7 (2002), available at http://cib.org.br/wp-content/uploads/2011/10/estudos_cientificos_ambiental_32.pdf (examining whether the use of GM crops as a whole has led to a decline in pesticide use and specifically noting that after the introduction of Bt cotton in Arizona, insecticide use decreased by a large margin).

148. McGaughey & Whalon, *supra* note 144, at 1451; see Gillam, *supra* note 143.

149. U.S. DEP’T OF AGRIC., *supra* note 56, at i.

150. *Id.*

increase the risk that regulated genetically engineered organisms . . . will inadvertently persist in the environment before they are deemed safe to grow without regulation.”¹⁵¹ Two years later, APHIS published the conclusions of its own internal review and listed many broad categories of oversight that needed improvement, noting that it should consider revisions of Title 7 of the Code of Federal Regulations Section 340 (“Section 340”) to address the issues.¹⁵²

In response to this report, Congress weighed in by passing a law requiring the Secretary of Agriculture to respond to each charge in the report by “tak[ing] action” and promulgating regulations as he considered “appropriate” “[n]ot later than 18 months after the date of enactment of this Act,” June 18, 2008.¹⁵³ In October 2008, APHIS published proposed regulations in the Federal Register that were never adopted.¹⁵⁴ Thus, to date Section 340, the relevant section of the federal regulation relating to the field testing and permitting of GMOs, reflects no regulatory changes since before the publication of the Office of the Inspector General Report in 2005.¹⁵⁵

IV. PROPOSED REGULATORY CHANGES

The current approval process for field trials has evident flaws as shown by the StarLink and other seed escapes.¹⁵⁶ The EPA, the USDA, and APHIS must address these flaws to avoid the economic consequences, such as market disruption and financial loss for farmers, that result from the lack of compliance-enforcing mechanisms and the less certain environmental consequences that could arise from the escape of unapproved, experimental GM seeds. The Secretary of Agriculture should order a review of the notification and permitting process for GMO field trials to ensure that the relevant agencies include necessary precautions within the regulatory system to prevent GMO contamination.¹⁵⁷

151. *Id.*

152. U.S. DEP’T OF AGRIC., *supra* note 114, at 1–4.

153. Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, § 10204, 122 Stat. 1651, 2105.

154. Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. 60,008 (proposed Oct. 9, 2008) (to be codified at 7 C.F.R. pt. 340). The proposed regulations would have eliminated the notification process and required all applicants seeking permission to conduct a field trial to obtain a permit. *Id.* at 60,016. APHIS proposed this change because APHIS inspectors had had difficulty in ensuring compliance with section 340. *Id.*

155. *See* 7 C.F.R. §§ 340.0–9 (2014).

156. *See supra* note 101 and accompanying text; *see also* *Biotechnology: Noncompliance History*, *supra* note 11 (outlining nearly two dozen instances of noncompliance with biotechnology regulations).

157. The Secretary has the authority over this process through the PPA. *See supra* notes 49–50 and accompanying text.

A. NOTIFICATION INCLUDING RISK ASSESSMENT

As previously discussed, when GM products first began to enter the marketplace, the United States decided to use existing law to regulate the biotech products rather than creating any new regulations.¹⁵⁸ The manner in which regulators evaluate products for risks to the food supply, the consumer, and the environment reflects that stance.¹⁵⁹ Currently, the EPA and the USDA/APHIS assume any new GM product will not pose any risks if the producer can make a showing of “substantial equivalence” to the natural genetic variant of the plant.¹⁶⁰ The regulatory agencies must revise this approach to require a more comprehensive examination of the potential risks of the novel GMO with the EPA examining possible environmental risks¹⁶¹ and the USDA/APHIS responsible for determining the risk of possible agricultural effects, for instance, contaminating another producer’s crops.¹⁶²

In addition to the filed notification of the field trial, as is presently required, a grower should submit its own risk assessment including the results of its internal testing, which the relevant agency would assess to confirm that the results are scientifically sound when contrasted against current knowledge in the field.¹⁶³ This requirement would be in addition to the formal notification of the intent to conduct a field trial presently required, which includes at a minimum the location, the duration of the trial, expected or desired results, and basic information about the GMO, for example what kind of crop it is and the genetic modification that the producer made in creating it.¹⁶⁴

The risk assessment itself should include a scientific analysis that demonstrates that the company considered how the GM product is likely to fare in the environment, the level of risk the product will pose to target and nontarget species, and lastly, an escape analysis.¹⁶⁵ An escape analysis would take into account the surrounding area, weather, company’s containment procedures, and would, under optimal circumstances, demonstrate that the

158. See *supra* Part II.B.1.

159. See *supra* Part II.B.2.

160. See *supra* Part II.B.1.

161. See Angelo, *supra* note 23, at 161–65 (urging the use of biological study to create a decision-making framework that would better address environmental issues posed by GMOs).

162. Lawrence, *supra* note 39, at 282 (“[Existing law] must be revised to require a holistic review of the entire GMO and all of its potential impacts on the environment, its progeny, and the consumer who ultimately utilizes the GMO or its derivative products.”).

163. See *id.* at 283 (suggesting an assessment “in which all of the potential risks reasonably posed by a novel transgenic organism are considered prior to regulatory approval of the organism or product for commercial marketing”).

164. 7 C.F.R. § 340.3(d) (2014).

165. See Lawrence, *supra* note 39, at 283. (“The assessment must include the potential harms to any ecosystem in which the organism might survive.”).

risk of unintentional release into the environment is low.¹⁶⁶ The escape analysis would establish that the company has taken adequate precautions and, if the GMO should escape, provide guidance for regulatory authority about how the escape might have occurred.¹⁶⁷ An escape analysis is necessary because, as past experience has shown, these products can escape from testing sites and affect markets, the environment, and neighboring fields.¹⁶⁸ The EPA and the USDA/APHIS should require the company to consider these possibilities before planting and show how it will address the issues.

B. CONTAINMENT

The highest burden that the applicable regulations should place on a company seeking to conduct a field trial is that of proving that it has the means of containing the experimental GMO.¹⁶⁹ The possibility of escape will likely always exist since it is not feasible that a company would be able to prevent all animals from entering the field and transporting seeds, or to stop the wind from blowing them out of the designated area. However, the grower can and must lower the likelihood of escape through conscientious methods, like the use of an isolation distance.

1. Isolation Distance

A grower should plant experimental crops at an isolation distance commensurate with the risk that the plant poses as demonstrated to the USDA by the company's risk assessment. The EPA has required isolation distances or buffer zones before, such as when it only provided limited approval for StarLink.¹⁷⁰ APHIS could determine the necessity and width of the buffer zone by the totality of the circumstances of the proposed planting. If the surrounding fields are certified organic, the GM plant is likely to pose a higher risk of economic damage if it escaped,¹⁷¹ and the company has the ability and responsibility to control for this, either by choosing another location or widening the buffer between the field trial subject and the neighboring fields. The company should also post notices to inform the public that the plots are experimental to discourage entry into the field. This would also alert nearby

166. See U.S. DEP'T OF AGRIC., *supra* note 114, at 2 (discussing the prospect of asking notification applicants to submit paperwork that "addresses the [possibility of] unauthorized release of regulated articles to include dispersal, commingling, and persistence due to climate, animal incursion, or human error").

167. See *id.*

168. See *supra* Parts III.A–C.

169. See Mandel, *supra* note 129, at 2236 ("Regulatory gaps also exist with respect to the failure to properly inform growers regarding the proper manner for use and containment of genetically modified crops.")

170. See *supra* notes 97–98.

171. See *supra* note 111 and accompanying text.

growers, allowing them to be mindful of “volunteer” plants that may escape the trial and to take their own precautions to mitigate the risk if they desire.

2. Submission of Containment Plan

The isolation distance should be one part of a company’s larger, detailed containment plan.¹⁷² Companies must employ differing containment methods commensurate with the risk posed by the product.¹⁷³ As previously discussed, the environmental risks these products pose can translate into severe repercussions for the surrounding landscape, whether it is a risk to a nearby farmer’s field or the risk that the GMO has the potential to exacerbate the previously observed superweed phenomena.¹⁷⁴

Currently the regulations for the notification process require growers to ensure, at the close of a field trial, that all seeds or other genetic matter that could lead to subsequent plants in following years are destroyed.¹⁷⁵ But the regulation simply reads that the producer should eliminate his product “upon termination” of the field trial, whereas a specified length of time, perhaps within one month or two weeks, would be preferable in the interest of limiting exposure and providing definite guidelines.¹⁷⁶ APHIS in its guidelines should limit the length of field trials to the time necessary for a company to observe the performance of its product.¹⁷⁷ If the product is not performing as hoped, the company should kill the field, rather than run the risk of escape for any longer than necessary.

3. Administrative Penalties for Escape

Any company willing to perform these field trials through either the permitting or notification process should be prepared to accept the consequences if the product ultimately escapes.¹⁷⁸ Companies’ failure to comply with mandated regulations is a theme underlying the StarLink fiasco and other such escapes from research tests and field trials.¹⁷⁹ As such, the EPA and USDA/APHIS should write stronger administrative penalties into the regulations for companies whose products escape during a field trial.¹⁸⁰

172. See *supra* note 165–68 and accompanying text.

173. See Angelo, *supra* note 23, at 160–61 (discussing the value of an evaluation system based upon assessing the risk of exposure of a GMO through consideration of its biological character).

174. See *id.* at 162.

175. 7 C.F.R. § 340.3(c) (2014).

176. See U.S. DEP’T OF AGRIC., *supra* note 56, at iv (“APHIS does not specify when GE crops must be destroyed, or ‘devitalized,’ following the field test.”).

177. See *id.*

178. See *id.* (recommending that permit applicants “provide proof of financial responsibility, in the event of an unauthorized GEO release”).

179. See Denton, *supra* note 58, at 350 (“An internal examination of the USDA revealed the flaws in its current system of voluntary compliance and self-reporting.”).

180. See *Biotechnology: Noncompliance History*, *supra* note 11. Companies have been penalized for failure to notify APHIS of releases, for failure to plant where designated, and for failing to

The Secretary of Agriculture, in his review, should ensure that these sanctions are specific to GM articles rather than plant pests or noxious weeds more generally in light of the risks inherent in GMOs that are not present in other types of plants.¹⁸¹ The penalties should be tailored to the categories of damage that can result from escape: violators should pay the government fines in the event of a proven escape, should pay for any costs associated with removing the product from the environment, and violators should compensate farmers if their fields are contaminated by GM seeds. After a company receives a penalty under these regulations, the regulations should bar that manufacturer from suing the farmers for IP infringement because the penalty should be considered conclusive evidence establishing that the fault lies wholly with the company.¹⁸²

C. MAPPING FIELD TRIALS

In 2005, the Office of the Inspector General created a report that stated, in essence, that APHIS failed to oversee field trials.¹⁸³ APHIS' lack of oversight is due in part to its lack of awareness of where and when GMO producers are conducting field trials.¹⁸⁴ The Inspector General recommended that producers submit global positioning system ("GPS") coordinates of the growing locations, especially considering that a grower can ask for approval for a field trial that it will conduct at multiple sites across several states.¹⁸⁵ The location information is necessary to trace a product that escapes from its origin point—the field trial—and contaminates other fields. Statistical information regarding how much land growers use for field trials, the state of the area surrounding the field trial, and the duration of field trials could

conduct field trials in a manner that would ensure that the test product "would not persist in the environment." *Id.*

181. See *supra* Parts III.A–C.

182. Without such a provision, a company could be fined by APHIS and then sue local farmers for patent infringement, which would likely recoup the value of the fine for the company and possibly result in a net gain. See *Biotechnology: Noncompliance History*, *supra* note 11 (listing the value of civil fines awarded by APHIS that are usually between \$1000 and \$30,000); cf. *supra* note 119 and accompanying text (noting the value of patent infringement suits).

183. Denton, *supra* note 58, at 350 ("The Office of the Inspector General found inadequacies in, among other areas, the record keeping system of APHIS, monitoring of GM crops, and APHIS' lack of control over the disposal of experimental GM crops after field tests were complete." (citations omitted)).

184. *Id.* at 349 n.111 ("The Office of Inspector General determined that APHIS lacked basic information about the field tests that it approved including where crops were being grown and what becomes of the crops at the end of the field tests." (citation omitted)).

185. U.S. DEP'T OF AGRIC., *supra* note 56, at ii ("Without knowing the locations of all planted field test sites, including their global positioning system (GPS) coordinates, APHIS cannot effectively monitor permit and notification holders' compliance with field test requirements.").

provide guidance for future regulatory actions.¹⁸⁶ The Secretary should recommend that the agencies require growers to submit the GPS coordinates of their field studies in the regulations for performing a field trial, especially in light of the fact that APHIS is supposed to have the power to monitor and inspect field trials, which would seem to be impossible without knowing the exact locations of these trials.¹⁸⁷

V. CONCLUSION

The number of high profile GM escapes that have contaminated the food supply and other fields has proven that the current regulation of GMO field trials is inadequate. The United States can avoid the economic costs that GM escapes cause in the domestic and international agricultural markets as well as litigation arising from these incidents through improved oversight by APHIS, the USDA, and the EPA. Unapproved and experimental crops should receive some share of regulation where they presently receive nearly none.

Though GM crops provide many benefits to society, the public should not bear an inordinate share of the costs of these products. These costs include a food supply contaminated by unapproved products, not intended for human consumption, and export/import markets fluctuating wildly upon the announcement of another GM discovered outside of its intended sphere. The regulation of the tests of these products must change to better protect markets and consumers.

186. Angelo, *supra* note 23, at 157 (“[The] submission of specified data should be required to enable the reviewing agency to make an informed decision based on scientific data as to whether the GMO should be permitted to be released into the environment.”).

187. *See supra* note 185.