

**NATURE’S HARVEST OR MAN’S PROFIT:  
ENVIRONMENTAL SHORTCUTS IN THE  
DEREGULATION OF GENETICALLY MODIFIED  
CROPS**

Comment\*

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\* Selected as the Book 2 Outstanding Student Article by the Volume 43 Board of Editors. This award, made possible through the generosity of Ms. Holland O’Neil, was presented to the author, Elizabeth Hill, at the Texas Tech Law Review’s annual spring banquet.

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“The U.S. is already the world leader in biotechnology, and we want to keep it that way. In 1991 alone, it was a 4 billion dollar industry; it should reach at least 50 billion dollars by the year 2000, as long as we resist the spread of unnecessary regulation.”

—Dan Quayle<sup>1</sup>

“Even minor tampering with nature is apt to bring serious consequences, as did the introduction of a single chemical (DDT). Genetic engineering is tampering on a monumental scale, and nature will surely exact a heavy toll for this trespass.”

—Eva Novotny<sup>2</sup>

## I. THE (DE)REGULATION OF BIOTECHNOLOGY IN AGRICULTURE

By 2050, the world’s population will climb to nine billion people.<sup>3</sup> Demands on sustainable agriculture will reach levels never before seen in history.<sup>4</sup> In combination with overexploitation of environmental resources and dwindling water supplies in many regions, world-feeding challenges could culminate to what scientists term a “perfect storm.”<sup>5</sup> Experts contend that “[n]avigating the storm will require a revolution in the social and natural sciences concerned with food production.”<sup>6</sup> One company claims it holds the solution to provide for the world’s burgeoning hunger needs; Monsanto Company, the world’s agricultural biotechnology leader, proposes its products “enable farmers to produce more crops while

1. *The World According to Monsanto* (Television documentary 2008) (directed and produced by Marie-Monique Robin under the original title, *Le monde selon Monsanto*).

2. *Eva Novotny Quotes*, FINEST QUOTES, [http://www.finestquotes.com/author\\_quotes-author-EVA%20NOVOTNY-page-0.htm](http://www.finestquotes.com/author_quotes-author-EVA%20NOVOTNY-page-0.htm) (last visited Jan. 16, 2012).

3. See *Total Midyear Population: 1950-2050*, NEGATIVE POPULATION GROWTH, [http://www.npg.org/facts/world\\_pop\\_year.htm](http://www.npg.org/facts/world_pop_year.htm) (last visited Jan. 16, 2012).

4. See H. Charles J. Godfray et al., *Food Security: The Challenge of Feeding 9 Billion People*, 327 SCIENCE 812, 812 (2010).

5. See *id.*

6. See *id.* at 817.

conserving more of the natural resources that are essential to their success.”<sup>7</sup> By utilizing biotechnology, Monsanto designs genetically modified (GM) crops in an effort to maximize the desirable traits within the plant.<sup>8</sup> On the South Plains of Texas, where cotton is king, as much as 91% of the cotton planted is genetically modified.<sup>9</sup> Across the nation, Monsanto’s GM seeds for corn, soybeans, and cotton account for the majority of each of those varieties.<sup>10</sup> In fact, the United States’ GM crops account for half of all GM acreage in the world, mounting to approximately 165 million of the 330 million acres grown worldwide in 2009.<sup>11</sup>

Yet, as revolutionary and ideal as Monsanto’s answer appears, the world as a whole has yet to embrace it.<sup>12</sup> The science of genetic engineering has met more than just trivial hesitation.<sup>13</sup> Much of the criticism surrounding biotechnology focuses on alleged poor testing and regulation.<sup>14</sup> Organic and conventional growers contend that the U.S. policy of a presumption against risk in agricultural biotechnology threatens their interests by failing to address the harms of cross-contamination.<sup>15</sup> Many American growers worry their plight could resemble that of Percy Schmeiser, an eighty-year-old canola farmer from Canada.<sup>16</sup> Schmeiser became an international symbol for the individual farmer when he fought back after Monsanto filed suit against him in 1998.<sup>17</sup> Schmeiser, who had grown his own canola seed for over fifty-five years, discovered that Monsanto’s GM canola seed had blown in and contaminated his custom-bred crop.<sup>18</sup> In a surprising move, Monsanto demanded Schmeiser pay for any seed used with their patented technology despite the fact that Schmeiser

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7. *Our Commitments: Sustainable Agriculture*, MONSANTO COMPANY, <http://www.monsanto.com/ourcommitments/pages/default.aspx> (last visited Jan. 16, 2012) (select “Sustainable Agriculture” tab at bottom of page).

8. See Nigel G. Halford, *From Primitive Selection to Genetic Modification, Ten Thousand Years of Plant Breeding*, in *PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS* 3, 16 (Nigel G. Halford ed., 2006).

9. See *Adoption of Genetically Engineered Crops in the U.S.: Upland Cotton Varieties*, USDA: ECONOMIC RESEARCH SERVICE, <http://www.ers.usda.gov/data/biotechcrops/ExtentofAdoptionTable2.htm> (last visited Jan. 16, 2012).

10. See *Adoption of Genetically Engineered Crops in the U.S.*, USDA: ECONOMIC RESEARCH SERVICE, <http://www.ers.usda.gov/data/biotechcrops> (last visited Jan. 16, 2012).

11. See *Cultivation of GM Plants: Rapid Increase Worldwide, Cautious Start in Europe*, GMO COMPASS, [http://www.gmo-compass.org/eng/agri\\_biotechnology/gmo\\_planting/](http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/) (last visited Jan. 16, 2012).

12. See Luc Bodiguel & Michael Cardwell, *Genetically Modified Organisms and the Public: Participation, Preferences, and Protest*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 11, 11-13 (Luc Bodiguel & Michael Cardwell eds., 2010).

13. See *id.*

14. See *id.* at 12.

15. See KEITH AOKI, *SEED WARS* 60 (2008).

16. See *id.* at 49-57.

17. See *id.*; *Monsanto Can., Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, para. 4-7 (Can.).

18. See AOKI, *supra* note 15, at 49.

was a victim of the cross-contamination.<sup>19</sup> Rather than destroying his seed and starting over, Schmeiser harvested his crop as usual that year.<sup>20</sup> When Monsanto promptly filed suit, public outrage immediately shifted in Schmeiser's favor with a demand that Monsanto drop the suit and pay to have Schmeiser's seed restored.<sup>21</sup> Monsanto proceeded, however, and ultimately the Canadian Supreme Court recognized Monsanto's patent protections but denied the company any damages from Schmeiser.<sup>22</sup> Since Schmeiser's story, American growers have shared in the serious concern regarding the potential harms posed by cross-contamination to their own crops.<sup>23</sup>

In looking to remedies for cross-contamination, critics to the current regime of GM crop deregulation allege the United States Department of Agriculture (USDA) intentionally shortened the environmental evaluation procedures, which resulted in GM crops released to the market prior to full compliance with federal regulations.<sup>24</sup> In recent cases, plaintiffs, including organic farmers and the Center for Food Safety, claimed that the USDA created a fast track for release permits for Monsanto's new GM varieties.<sup>25</sup> Thus far, federal judges have agreed.<sup>26</sup>

This Comment will discuss how National Environmental Policy Act (NEPA) violations prevail within the USDA's deregulation of GM crops.<sup>27</sup> No specific statutory scheme exists other than operation within the already existing scheme of NEPA while avoiding excessive regulation.<sup>28</sup> Part II of this Comment will review the history of biotechnology and development of U.S. policy to promote, and not hinder, the industry, allowing substantial leeway in approval and supervision of GM crops. Part III of this Comment will discuss the recent Supreme Court review of GM crop deregulation in *Monsanto Co. v. Geertson Seed Farms* from its origination in a California district court. In Part IV, this Comment will analyze the USDA's problematic deregulation process and how federal district judges are reluctantly stepping in to regulate and enforce the parameters of NEPA. In conclusion, Parts V and VI will provide recommendations for specific

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19. *See id.* at 49-50.

20. *See id.*

21. *See id.* at 50-51.

22. *See Schmeiser*, 1 S.C.R. at para. 105.

23. *See, e.g., Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2749 (2010) (challenging unconditional deregulation of GM alfalfa and requesting injunction); *Ctr. for Food Safety v. Vilsack*, No. C 10-04038, 2010 WL 3835699 (N.D. Cal. Sept. 28, 2010) (claiming environmental and human health damages from GM crops).

24. *See Geertson Seed Farms*, 130 S. Ct. at 2750-51; *Ctr. for Food Safety*, 2010 WL 3835699, at \*1.

25. *See sources cited supra* note 24.

26. *See Geertson Seed Farms*, 130 S. Ct. at 2750-51; *Ctr. for Food Safety*, 2010 WL 3835699, at \*6-7.

27. *See infra* Part IV.

28. *See infra* Parts II, IV.

biotechnology policy and regulations that could account for the risk of harm presented to the environment without unduly stifling the industry.

## II. THE EMERGENCE OF U.S. BIOTECHNOLOGY INDUSTRY AND POLICY

### A. *The History of the Science Itself*

Although GM crops as defined today emerged only a couple of decades ago, genetic modification in agriculture has literally been around for ages.<sup>29</sup> Agricultural biotechnology has ancient origins tracing back thousands of years of recorded history when early farmers saved their best seed for the following year.<sup>30</sup> This practice evolved into blending the premium seeds to strengthen crops each year and ultimately crossing sexually compatible plants with the intent to enhance the desirable traits to create a stronger breed.<sup>31</sup> Early growers were limited to cross- and selective-breeding techniques between plants of the same species with the limited goal of increasing productivity.<sup>32</sup> The wheat plant used in Ancient Egypt, for example, showed thousands of years of cultivation through hybridization with no similar equivalent found in existence in the wild.<sup>33</sup> As with the ancient Egyptian wheat, many foods people eat today, such as cauliflower, broccoli, and Brussels sprouts, only emerged through hundreds and thousands of years of cross-breeding and experimentation.<sup>34</sup>

Following centuries of cultivation by growers who knew very little about the underlying science of their work, two nineteenth-century scientists took the rudimentary practices from the fields into the laboratory.<sup>35</sup> In 1859, Charles Darwin introduced his theory of natural selection to the world, proposing that species evolve and adapt from the blending of traits.<sup>36</sup> Darwin theorized that organisms evolve through a process of selective evolution with the fittest and strongest of each species surviving and multiplying over the weaker ones.<sup>37</sup> Darwin's theory posed a problem, however: if the traits of parent organisms simply blended in their offspring, as he and other scientists believed, then natural selection could not actually work.<sup>38</sup> Unbeknownst to Darwin, Gregor Mendel had actually already begun to address this problem in his monastery's garden through

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29. See Halford, *supra* note 8, at 5-6.

30. See *id.*

31. See *id.* at 6.

32. See *id.*

33. See *id.*

34. See *id.*

35. See *id.*

36. See *id.* (noting that "Darwin is regarded by many as the father of modern genetics").

37. See NIGEL G. HALFORD, GENETICALLY MODIFIED CROPS 1-2 (2003).

38. See *id.* at 2.

pollination experiments with pea plants.<sup>39</sup> Although unrecognized at the time, Mendel's research, later coined "Mendelian Laws," became the foundation of modern-day plant genetics and breeding.<sup>40</sup>

Throughout the twentieth century, both plant breeders and scientists continued to observe and experiment with the processes of natural selection and evolution in plant species.<sup>41</sup> Hybridization and seed breeding became objectives of the U.S. government through public seed distribution programs, with the requirement that seeds reach a level of superiority over common cultivars before distribution.<sup>42</sup> As scientific discovery progressed, the seed and agricultural industries made the pivotal shift from public to private domination.<sup>43</sup> Private firms discovered the lucrative market available in hybrid-seed sales to the American farmer, and the early stages of the genetic engineering market emerged.<sup>44</sup> By the 1940s, however, initial signs of strained relations between the private and public sectors were evident.<sup>45</sup>

In 1953, scientists James Watson and Francis Crick discovered the double helix present in deoxyribonucleic acid (DNA) and opened doors for the birth of recombinant DNA (rDNA).<sup>46</sup> The revolutionary scientists were the first to successfully insert a new gene into an existing gene in bacteria; biologists applied the revolutionary technology to plants for the first time in 1983.<sup>47</sup> Even with the labored time required to apply rDNA technology to the more complicated genetic structure of plants, researchers planted the first GM crop in the early 1990s, and by 1996, the first commercially available GM crop arrived on the agricultural scene in the United States.<sup>48</sup> Through genetic modification, the FlavrSavr tomato delayed ripening to allow a longer shelf life.<sup>49</sup> Once the FlavrSavr tomato appeared, a flurry of others followed, including corn, cotton, papaya, and soybean.<sup>50</sup> In the short history of GM crops, the U.S. agriculture industry has embraced

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39. *See id.* at 2-3 (noting Mendel discovered the blending of genetic traits allows the reappearance of characteristics so that variation continues).

40. *See id.* (noting Mendel found that some characteristics reemerged in later generations after apparent dormancy).

41. *See id.* at 12-13; AOKI, *supra* note 15, at 16-22.

42. *See* AOKI, *supra* note 15, at 16-17.

43. *See id.* at 17-22.

44. *See id.* at 21. In retrospect, public research was forced into limiting its scope to self-fertilized, rather than open-pollinated, breeds of corn varieties due to the ever-growing, private-sector dominance of funds. *See id.* at 20.

45. *See id.* at 21; *infra* Part II.C.

46. *See* STUART SMYTH ET AL., REGULATING THE LIABILITIES OF AGRICULTURAL BIOTECHNOLOGY 6-7 (2004).

47. *See id.*

48. *See id.* at 7 (noting that the first GM crop was 100 acres of tobacco planted in China intended for seed multiplication); Halford, *supra* note 8, at 6.

49. *See* SMYTH ET AL., *supra* note 46, at 7.

50. *See* Halford, *supra* note 8, at 30.

biotechnology by increasing usage of GM crops exponentially.<sup>51</sup> In 2010, GM crops represented the majority of total production nationwide of soybeans at 93%, cotton at 78%, and corn at 70%.<sup>52</sup> The United States also quickly accepted the role of global leader in biotech agriculture, now producing half of all GM crops by acreage worldwide.<sup>53</sup> With such vast coverage across the nation of GM crops in such a short period of time, the growing industry has already substantially impacted both society and the environment.<sup>54</sup>

### *B. Impacts of Genetic Modification in Agriculture*

Agriculture of any kind has a definite effect not only on the natural environment but also on the people who depend on it.<sup>55</sup> In the short history of GM crops, the American farmer and consumer alike have experienced the impact that such a dramatic paradigm shift entails.<sup>56</sup> The promises and hopes of scientists proved to live up to the potential once only imagined.<sup>57</sup> Plant biologists have successfully strengthened and increased productivity in crops by inserting more desirable genes through biotechnology, a critical benefit to a world with food shortage crises in many developing countries.<sup>58</sup> While the United States remains the leader in agricultural biotechnology, many countries with food shortages, such as those in Africa, strain to follow suit in an effort to increase food availability to the hungry.<sup>59</sup>

One primary focus of biotechnology thus far involves the insertion of genetic material resistant to pests and diseases.<sup>60</sup> By allowing farmers to apply fewer pesticides, GM crops have increased productivity while reducing the risks associated with pesticide applications.<sup>61</sup> Advocates of GM crops believe that biotechnology will continue to increase yields while

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51. *Adoption of Genetically Engineered Crops in the U.S.*, *supra* note 10.

52. *See id.*

53. *See* JAMES CLIVE, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, BRIEF 39: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2008, *available at* <http://www.isaaa.org/resources/publications/briefs/39/default.html>.

54. *See* Sujatha Sankula, *Crop Biotechnology in the United States: Experiences and Impacts*, in *PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS* 265, 266 (Nigel G. Halford ed., 2006).

55. *See* P.J.W. Lutman & K. Berry, *Environmental Impact and Gene Flow*, in *PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS* 265, 266 (Nigel G. Halford ed., 2006).

56. *See* Sankula, *supra* note 54, at 28.

57. *See* M.G. Edwards & G.M. Poppy, *Environmental Benefits of Genetically Modified Crops*, in *ENVIRONMENTAL IMPACT OF GENETICALLY MODIFIED CROPS* 23, 23-27 (Natalie Ferry & Angharad M.R. Gatehouse eds., 2009).

58. *See id.*

59. *See* Fikremarkos Merso Birhanu, *Genetically Modified Organisms in Africa: Regulating a Threat or an Opportunity?*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 227, 229-32 (Luc Bodiguel & Michael Cardwell eds., 2010).

60. *See* Edwards & Poppy, *supra* note 57, at 23-27.

61. *See id.*

reducing pesticide use to improve the overall efficiency of farming and food production.<sup>62</sup> Moreover, proponents contend that biotechnology allows improvement of food quality in addition to micronutrient compositions and functional ingredients.<sup>63</sup> Again, the potential for such enhancements is particularly pertinent for developing countries with food shortages.<sup>64</sup> While many scientific communities have celebrated the future vision of biotechnology, public opinion has not welcomed the breakthroughs as enthusiastically.<sup>65</sup>

### C. Public Responses to Biotechnology

Regardless of potential benefits, GM crops flooded onto the nation's agricultural plains, meeting both welcome arms and staunch resistance.<sup>66</sup> Much of the criticism has centered on the alleged poor testing and regulation of GM crops.<sup>67</sup> Additionally, opponents contend that the potential impacts on the environment and human health are, at least, unknown.<sup>68</sup> Much of the alleged risks to human health originate in the theory that the inserted gene will create allergens and even toxicity to humans.<sup>69</sup> In studies of consumer impressions of eating GM foods, overall public reception revealed a significant hesitancy.<sup>70</sup> Although general public concerns are prevalent worldwide, studies of European attitudes toward GM foods disclosed actual hostilities and beliefs that GM foods are the least moral or helpful of all GM technologies, including nanotechnology, pharmacogenetics, and gene therapy.<sup>71</sup> There, the European Union (EU) adopted an approach to genetically modified organisms (GMOs) based on the "precautionary principle": the view that where safety or results from a new technology are uncertain, then avoidance, or at the very least apprehension, should prevail.<sup>72</sup>

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62. See Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 409 (2002).

63. See Dietrich Rein & Karin Herbers, *Enhanced Nutritional Value of Food Crops*, in *PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS* 91, 91-92 (Nigel G. Halford ed., 2006).

64. See *id.* at 110.

65. See P. Christou & T. Capell, *Transgenic Crops and Their Applications for Sustainable Agriculture and Food Security*, in *ENVIRONMENTAL IMPACT OF GENETICALLY MODIFIED CROPS* 3, 13-16 (Natalie Ferry & Angharad M.R. Gatehouse eds., 2009); Halford, *supra* note 8, at 15-22.

66. See Bodiguel & Cardwell, *supra* note 12, at 11.

67. See Joshua B. Cannon, Note, *Statutory Stones and Regulatory Mortar: Using Negligence Per Se to Mend the Wall Between Farmers Growing Genetically Engineered Crops and Their Neighbors*, 67 WASH. & LEE L. REV. 653, 661 (2010).

68. See *id.*

69. See Bodiguel & Cardwell, *supra* note 12, at 23; McGarity, *supra* note 62, at 417.

70. See Bodiguel & Cardwell, *supra* note 12, at 23.

71. See *id.*

72. See Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 735 (2003).



While European attitudes harbored distinct hostility, American reception of GM food has also proven at least marginally resistant with the majority of consumers expressing an opposition to trying GM foods.<sup>73</sup> Americans hold more favorable attitudes, however, when provided with regulatory information supporting the safety of GM foods.<sup>74</sup> Considering that many of the current GM crops do not involve the production of food for human consumption, concerns have also arisen regarding the environmental risks associated with GM crops.<sup>75</sup>

#### *D. Environmental Concerns of Biotechnology in Agriculture*

A growing number of farmers who choose to align themselves with organic growth practices have raised the issue of gene-flow contamination.<sup>76</sup> As with all agriculture, crops tend to drift and blend with other nearby crops, especially those of similar species or makeup.<sup>77</sup> When a GM crop contaminates a neighbor non-GM crop, farmers lose their conventional seed line, often developed and bred for generations.<sup>78</sup> In some cases, once the contamination occurs, growers encounter extreme difficulty isolating their crops from the GM traits.<sup>79</sup> When faced with patent infringement litigation, some resort to eliminating their own crop in order to eliminate the GM crop.<sup>80</sup>

Furthermore, cross-contamination can affect not only neighboring nonfood crops but also neighboring crops intended for human consumption.<sup>81</sup> In the *StarLink Corn* case, one of the most well-known U.S. GM-crop contamination cases to date, taco shells tested positive for a GM variety of corn not approved for human consumption.<sup>82</sup> Much of the concern directed at the regulation of biotechnology in agriculture stems from the backlash of this controversy.<sup>83</sup> In a similar case of gene-flow commingling in 2006, GM rice not approved for human consumption

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73. See Bodiguel & Cardwell, *supra* note 12, at 23.

74. See *id.*

75. See Cannon, *supra* note 67, at 660.

76. See *id.*

77. See *id.* at 655; see also *Monsanto Can., Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, para. 97 (Can.) (ruling that a Saskatchewan farmer who farmed canola for more than fifty-five years infringed on Monsanto's Canadian utility patent when his crop was cross-contaminated with Monsanto's Roundup Ready canola seed).

78. See M.D.K. Owen, *Herbicide-tolerant Genetically Modified Crops: Resistance Management*, in ENVIRONMENTAL IMPACT OF GENETICALLY MODIFIED CROPS 115, 139-43 (Natalie Ferry & Angharad M.R. Gatehouse eds., 2009).

79. See Cannon, *supra* note 67, at 667-69.

80. See *id.*

81. See *id.*

82. See *Kramer v. Adventis CropScience USA Holding, Inc. (In re StarLink Corn Prod. Liab. Litig.)*, 212 F. Supp. 2d 828, 852 (N.D. Ill. 2002).

83. See Bodiguel & Cardwell, *supra* note 12, at 23.

appeared in long grain rice already present in the food market.<sup>84</sup> In both cases, the exact cause of the commingling was unknown.<sup>85</sup>

Nevertheless, the United States still embraced biotechnology with a greater readiness than the rest of the world.<sup>86</sup> Much of this appeared economically driven, as the federal government was more willing at the time to allow and encourage developments in biotechnology agriculture.<sup>87</sup> As the biotechnology market emerged in the United States, the industry, especially Monsanto, recognized the extraordinary opportunities for the taking.<sup>88</sup>

### *1. The Emergence of a Leader: Monsanto*

The biotechnology agricultural leader today, Monsanto, had beginnings in the seed and chemical horticultural industries in the early part of the twentieth century.<sup>89</sup> While Monsanto has continually striven to stay on the forefront of scientific progress, its offerings have garnered a reputation for legal controversy.<sup>90</sup> By the mid-1990s, Monsanto was poised to deliver its biotechnology solutions for agriculture to the world.<sup>91</sup> The tandem offerings of Roundup and Roundup Ready crops continue to provide what the company markets as the “full agricultural technology system.”<sup>92</sup> Roundup, the company’s patented broad-spectrum, nonselective herbicide, provides farmers with weed and pest control to protect their Roundup Ready crops.<sup>93</sup> Biotechnology provides an advantage of allowing Monsanto to develop seed that is resistant to glyphosate, the active ingredient in Roundup, which is essentially an enzyme inhibitor that prevents root development and modifies plant metabolism.<sup>94</sup> Therefore, farmers can apply Roundup to their Roundup Ready crops with the peace of mind that their crop will adequately resist any effects from the herbicide while intrusive weeds will not survive.<sup>95</sup> Considering the damage that weeds pose to crop yields and plant health, farmers flocked to Monsanto’s attractive offerings.<sup>96</sup>

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84. See *In re Genetically Modified Rice Litig.*, 251 F.R.D. 392, 393 (E.D. Mo. 2008).

85. See Cannon, *supra* note 67, at 667-69.

86. See SMYTH ET AL., *supra* note 46, at 43-44.

87. See Keith Aoki, *Malthus, Mendel, and Monsanto: Intellectual Property and the Law and Politics of Global Food Supply: An Introduction*, 19 J. ENVTL. L. & LITIG. 397, 408, 416 (2004).

88. See *id.* at 402-06; see *infra* Part IV.A.

89. See generally Aoki, *supra* note 87 (accounting the history of crop breeding and the transition to genetic engineering throughout the twentieth century).

90. See AOKI, *supra* note 15, at 50-52.

91. See Aoki, *supra* note 87, at 403.

92. See AOKI, *supra* note 15, at 50.

93. See *id.* at 50-51.

94. See *id.*

95. See *id.* at 51.

96. See *id.* at 50.

With the development of Roundup and Roundup Ready crops, along with buyouts of smaller agricultural entities, Monsanto has grown to be the world's largest biotechnology company and exercises near total power over global biotechnology in farming.<sup>97</sup> Unsurprisingly, Monsanto has gone to great lengths to ensure its breakthrough products are legally protected.<sup>98</sup> Maintaining an active presence in the courts, both within and outside the United States, Monsanto has fought to protect its patent technologies and pushed for deregulation of its GM products.<sup>99</sup> When faced with even small infringements, Monsanto spared no expense to track down and pursue litigation against farmers who illegally used any of Monsanto's patented products when direct warnings to cease failed.<sup>100</sup> Although a general consensus among farmers embraced the offerings of Monsanto, many proponents for organic and conventional methods resisted Monsanto's growing domination of agriculture in the United States.<sup>101</sup>

## 2. *Evil Empire or Hunger Hero?*

Today, Monsanto is not only a rising Fortune 500 company, but also an unrivaled political power—plagued with decades of controversy.<sup>102</sup> Some opponents maintain staunch resistance to any product Monsanto manufactures due to the company's past involvement with destructive chemicals.<sup>103</sup> Originally known as Monsanto Chemical Company,

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97. *See id.*

98. *See id.* at 51.

99. *See Monsanto Can., Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, para. 27 (Can.) (ruling that a Saskatchewan farmer who had farmed canola for more than fifty-five years infringed on Monsanto's Canadian utility patent when his crop was cross-contaminated with Monsanto's Roundup Ready canola seed); *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1352 (Fed. Cir. 2004) (holding McFarling infringed a Monsanto patent when he saved and later planted the seed); *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1385 (Fed. Cir. 2004) (holding that damages for patent infringement are not limited to anticipated profits, but where a liquidated damages clause allowed fees 120 times the price of the technology fee, Monsanto's contractual provision for liquidated damages violated state law); *Monsanto Co. v. Byrd*, No. 7:99-CV-154-F1, 2000 U.S. Dist. LEXIS 22793, at \*23-24 (E.D. Mo. Dec. 7, 2000) (holding that farmers may not invoke the PVPA provision § 2543 allowing seed replanting as a defense to patent infringement liability).

100. *See Schmeiser*, 1 S.C.R. at para. 11-12.

101. *See, e.g., Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010); *Ctr. for Food Safety v. Vilsack*, No. C 10-04038, 2010 WL 3835699, at \*2 (N.D. Cal. Sept. 28, 2010).

102. *Fortune 500, Our Annual Ranking of America's Largest Corporations*, CNN MONEY (May 3, 2010), [http://money.cnn.com/magazines/fortune/fortune500/2010/full\\_list/101\\_200.html](http://money.cnn.com/magazines/fortune/fortune500/2010/full_list/101_200.html) (ranked 197 out of 500 in 2010); Brian Tokar, *Monsanto: A Checkered History*, 28 THE ECOLOGIST, No. 5, at 254 (1998) (accounting Monsanto's controversial history of Agent Orange, massive environmental disasters due to chemical explosions and pollution, and the alleged back-room deals with federal administration, including the highly publicized debacle of Times Beach that ultimately sent the Reagan-appointed, Environmental Protection Agency's administrator to jail for perjury and obstruction of justice).

103. *See Tokar, supra* note 102, at 254. *See generally* Peter H. Schuck, *The Role of Judges in Settling Complex Cases: The Agent Orange Example*, 53 U. CHI. L. REV. 337 (1986) (accounting the massive litigation battle between Monsanto, Dow Chemical, and other manufacturers of Agent Orange and the victims of severe birth defects due to its use during the Vietnam War).

Monsanto dropped “Chemical” from its name in 1964 in an effort to better represent its diverse offerings.<sup>104</sup> Despite the company’s name change, however, many continue to identify Monsanto as the manufacturer of the tragic and fatal herbicide, Agent Orange, ultimately used by the U.S. Armed Forces in Vietnam.<sup>105</sup> Since then, Monsanto remained controversial, coming under fire as an agricultural chemical supplier during the so-called “Green Revolution” in the 1970s.<sup>106</sup> Some have titled Monsanto the “most despised company in America.”<sup>107</sup> Since dropping “Chemical” from the company name and shifting its focus to the potential in biotechnology, Monsanto framed the advantages of biotechnology to include the ability to genetically alter crops that require fewer chemical treatments.<sup>108</sup>

Although Monsanto’s offerings were initially widely accepted in the United States, Monsanto encountered considerable resistance in Europe, where a more dominant attitude prevailed, preferring natural and organic methods in agriculture.<sup>109</sup> Anti-biotechnology attitudes first developed in Europe and then spread back to the U.S. to interest groups and activists that openly campaigned against Monsanto’s alleged capitalistic drive to introduce biotechnology at the expense of environmental concerns and human safety.<sup>110</sup> Extreme public and even governmental pressure bore down on Monsanto when the company began licensing efforts for its developed “Terminator” technology, a genetic engineering practice that renders crops sterile to eliminate any chance of farmers saving their seed for the following year.<sup>111</sup> Monsanto ultimately decided not to release Terminator technology.<sup>112</sup>

Additional concerns center around Monsanto’s products that threaten the organic and conventional growers in the agriculture industry.<sup>113</sup> Entire campaigns have launched directed toward Monsanto with the stated purpose to protect organic consumers and cultivators.<sup>114</sup> The *Millions Against Monsanto* campaign, sponsored by the Organic Consumers Association, touts Monsanto as a bully to the small farmer and deceiver of the American

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104. See Tokar, *supra* note 102, at 254.

105. See generally Schuck, *supra* note 103, at 337; Tokar, *supra* note 102, at 255.

106. See Aoki, *supra* note 87, at 402 (noting that the public was protesting the disastrous effects of chemicals on plant diversity and environmental health).

107. Tim King, *Abnormal Cancer Rates at Fort Detrick Tied to Monsanto’s Agent Orange*, SALEM-NEWS (Jan. 6, 2011, 1:08 PM), <http://www.salem-news.com/articles/january062011/fort-detrack-tk.php>.

108. See Aoki, *supra* note 87, at 403.

109. See *id.* at 404.

110. See *id.*

111. See *id.*

112. See *id.*

113. See, e.g., *Millions Against Monsanto*, ORGANIC CONSUMERS ASS’N, <http://www.organicconsumers.org/monsanto> (last visited Jan. 16, 2012) (providing site visitors the option to join the campaign, donate money, and receive bumper stickers or t-shirts).

114. See *id.*

people.<sup>115</sup> In addition to public awareness campaigns, opponents targeted their challenges to Monsanto through appeals to GM crop deregulation decisions by the Animal and Plant Health Inspection Service (APHIS), a division of the United States Department of Agriculture (USDA).<sup>116</sup>

In recognizing the regulatory gaps and inconsistencies in the introduction of GM crops onto the plains of the United States, opponents began seeking remedies in the federal courts.<sup>117</sup> Initially these efforts proved ineffective, resulting in setbacks and dismissals when plaintiffs sought class-action certification in seeking damages for market-price diminishments due to the GM contamination in the rice supply.<sup>118</sup> In 2008, however, the landmark case, *Geertson Farms, Inc. v. Johanns*, directed attention to the controversy of GM crops and the shortened deregulation process.<sup>119</sup>

Ultimately in 2010, the Supreme Court heard the appeal by Monsanto after the district judge granted conventional alfalfa farmers an injunction against the continued deregulation of GM alfalfa.<sup>120</sup> The *Geertson Seed Farms* case brought attention to the inconsistencies and gaps in the regulatory scheme of introducing new GM crops to the market.<sup>121</sup> As with many areas involving furiously paced technology, the governmental and legislative response to the introduction of GM crops was reactive, delayed, and fragmented—reflecting a misunderstanding of the potential impact of biotechnology.<sup>122</sup>

### III. BIOTECHNOLOGY LAW AND POLICY IN THE U.S.

#### A. Government Response and Regulation

With the emergence of biotechnology in the 1980s, the federal administration publicly expressed the need for regulation to protect both

115. See *10 Things Monsanto Does Not Want You to Know*, ORGANIC CONSUMERS ASS'N, <http://www.organicconsumers.org/monsanto/ten-things-monsanto.pdf> (last visited Jan. 16, 2012).

116. See, e.g., *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2746 (2010) (appealing the APHIS's decision to deregulate Roundup Ready alfalfa); *Ctr. for Food Safety v. Vilsack*, No. C 10-04038, 2010 WL 3835699, at \*2 (N.D. Cal. Sept. 28, 2010) (claiming both environmental and human health concerns from GM crops).

117. See *Geertson Seed Farms*, 130 S. Ct. at 2748; *Ctr. for Food Safety*, 2010 WL 3835699, at \*2.

118. See generally *In re Genetically Modified Rice Litig.*, 251 F.R.D. 392, 393 (E.D. Mo. 2008) (dismissing the suit ruling that the predominance requirement for class action was not met and that "plaintiffs varying claims for damages are not amendable to class-wide adjudication").

119. See *Geertson Farms, Inc. v. Johanns*, No. C 06-01075, 2007 WL 776146, at \*2 (N.D. Cal. Mar. 12, 2007).

120. See *Geertson Seed Farms*, 130 S. Ct. at 2751.

121. See *id.*

122. 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, 2231-42 (2004) (recognizing the many gaps and yet overlap of regulatory attempts during the first ten years of GM crops).

human health and the environment.<sup>123</sup> President Reagan assigned the White House Office of Science and Technology Policy (OSTP) with the challenge of assessing and deliberating what regulatory practices should govern GMOs.<sup>124</sup> The first policy released was the 1984 Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) including the stated intent “to achieve 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.”<sup>125</sup> After deliberating on how to accomplish this task, the OSTP determined that GMOs were “not fundamentally different from conventional products” and that regulation should govern the product, rather than the process, based on the manner of its use.<sup>126</sup> The Coordinated Framework chose to fit the regulation of GMOs within the already-existing federal laws through the coordination of the USDA, along with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).<sup>127</sup> Each agency was charged with a role: the USDA should ensure the GMOs were safe to grow, the EPA should ensure that GMOs were safe for the environment, and the FDA should ensure that food developed from GMOs was safe for consumption.<sup>128</sup>

After several years of this regulatory approach and the cross-contamination controversy of tacos, the OSTP recognized the problem with cross-contamination from GM crops in the environment.<sup>129</sup> In 2002, the Coordinated Framework, along with the USDA, the EPA, and the FDA, outlined additional testing requirements for both plants and food developed through biotechnology.<sup>130</sup> The purpose of the 2002 update included three specific objectives: (1) field tests should consist of confinement based on the level of risk to health and environment; (2) in the case of unknown or unacceptable risks, strict confinement should ensue with GM materials prohibited from seeds, commodities, and products; and (3) cross-contamination should remain minimal, although some low levels of

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123. *See id.* at 2216.

124. *See* Margaret Rosso 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* 299, 300 (Luc Bodiguel & Michael Cardwell eds., 2010).

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

126. *See* Grossman, *supra* note 124, at 300.

127. *See id.*

128. *See id.*

129. *See id.* at 300-01; *see also* Mandel, *supra* note 122, at 2203-07 (detailing the *StarLink* cross-contamination case).

130. 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. 50,578 (Aug. 2, 2002).

biotechnology-produced gene presence could prove acceptable.<sup>131</sup> Each agency reportedly worked to increase the level of testing and requirements to release GM crops and food into the public realm, yet little coordination between the three agencies actually remained.<sup>132</sup>

In the field of GM agriculture, the APHIS with its Biotechnology Regulatory Services (BRS) set out the primary regulatory work and operated independently of the EPA.<sup>133</sup> Through the 2000 Plant Protection Act (PPA), the USDA holds the authority to regulate plant pests and, therefore, uses this authority to apply to GM crops.<sup>134</sup> Through the PPA, the APHIS determines which organisms are considered plant pests with a broad enough definition to include all GM crops to date.<sup>135</sup> The early process of introducing GM crops includes field trials to evaluate the potential impact of the crop on the environment.<sup>136</sup> The field trial procedure applies to both standard environmental releases, in addition to experimental releases of GM plants that could pose potentially elevated risks to the environment.<sup>137</sup>

All of the eventual deregulation of GM crops has occurred through the supervision of the APHIS.<sup>138</sup> To also comply with NEPA, however, regulators must conduct an Environmental Impact Statement (EIS), evaluating any risks presented by the crop to the environment and how such risks may require additional regulatory provisions prior to the crop's release.<sup>139</sup> This provision is supposed to require the coordination of the two agencies, the USDA and the EPA, in overseeing the crop's introduction to the market.<sup>140</sup>

The recent litigation, however, attacking the regulation and now deregulation processes brought attention to the missing link to the legislative requirements for release of GM crops: the required EIS to assess the potential environmental impact of any event capable of significantly affecting the environment was not fully completed prior to the release of GM crops.<sup>141</sup> In *Geertson Seed Farms*, the APHIS, along with the EPA, released GM alfalfa without a complete EIS, but rather a shortened Environmental Assessment (EA).<sup>142</sup> Due to the biotechnology statutory

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131. See Grossman, *supra* note 124, at 301.

132. See generally Mandel, *supra* note 122, at 2230-46 (reviewing the agency's attempts at biotechnology policy coordination that eventually deteriorated).

133. See Grossman, *supra* note 124, at 301.

134. See *id.* at 301-02.

135. See *id.* at 302.

136. See *id.* at 301-02.

137. See *id.*

138. See *id.* at 303-04.

139. See *id.* at 304.

140. See *id.* at 304 & n.27.

141. See generally *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2750-51 (2010) (noting that the APHIS elected to only conduct an EA prior to GM alfalfa release).

142. See *id.* at 2751.

scheme dating back to NEPA, federal judges hearing these claims have attempted to determine whether the EA actually satisfies the original NEPA requirements with regards to GM crops.<sup>143</sup>

*B. Environmental Assessment (EA) v. Environmental Impact Statement (EIS)*

President Nixon signed into law the National Environmental Protection Act (NEPA) of 1969 on January 1, 1970, creating the requirement that federal agencies must prepare an EIS when taking any action that could have a significant effect on the environment.<sup>144</sup> In addition to the EIS requirements, NEPA established the Center for Environmental Quality (CEQ), charged with the federal oversight of any governmental actions that would amount to environmental changes.<sup>145</sup> When a federal agency brings forward a proposed action, the first determination is whether any action is even necessary.<sup>146</sup> The agency may qualify for an exemption if the proposed action does “not have a significant effect on the human environment.”<sup>147</sup>

When the agency expects a modest or unknown impact, however, then the agency may alternatively choose to conduct an EA.<sup>148</sup> The stated purpose of an EA is to:

- (1) Briefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact[.]
- (2) [a]id an agency’s compliance with the Act when no environmental impact statement is necessary[, or]
- (3) [f]acilitate preparation of a statement [EIS] when one is necessary.<sup>149</sup>

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143. *See id.*

144. *See* EMMETT B. MOORE, THE ENVIRONMENTAL IMPACT STATEMENT PROCESS AND ENVIRONMENTAL LAW 1 (2d ed. 2000).

145. *See id.* at 7.

146. *See generally id.* at 6-7 (describing federal agency procedure).

147. 40 CFR § 1500.5(l) (2010).

148. *See id.* § 1508.9; *see also* MOORE, *supra* note 144, at 13-14 (outlining the EA and EIS processes).

149. § 1508.9.



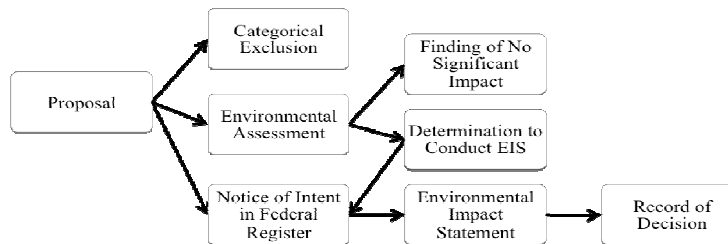


Figure 1. Environmental Determination Flowchart.<sup>150</sup>

When an agency finds no significant environmental impact after the completion of an EA, the result is called a “Finding of No Significant Impact” (FONSI).<sup>151</sup> If after conducting an EA, however, the agency determines the possible impact could prove significant, then the agency must file a Notice of Intent (NOI) in the Federal Register, which may include a list of potential impacts anticipated.<sup>152</sup> Placement in the Federal Register serves the purpose of providing the public with notice and the opportunity to comment on the proposed action.<sup>153</sup>

Following the NOI, the agency should conduct or request that the EPA conduct an EIS.<sup>154</sup> The EIS is a “detailed written statement as required by section 102(2)(C) of the Act” conducted due to any “major federal action significantly affecting the quality of the human environment.”<sup>155</sup> Once completed, the agency must publish the findings of the EIS for public availability in a Record of Decision (ROD) and should include the agency’s decision regarding the action.<sup>156</sup>

In 2004, after the completion of field trials of GM alfalfa, the APHIS allowed the distributor, Monsanto, to petition for deregulation.<sup>157</sup> As an effort to streamline the deregulation process, the APHIS allowed a “draft” EA rather than the more extensive EIS prior to deregulating the crop.<sup>158</sup> Growers and environmentalists had attempted for several years to challenge the shortcuts taken in the deregulation of GM crops.<sup>159</sup> Until recently,

150. *See id.*

151. *See* 40 CFR § 1508.13 (2010).

152. *See id.* § 1508.22; *see also* MOORE, *supra* note 144, at 10 (describing the environmental impact assessment process).

153. *See* § 1508.22.

154. *See* MOORE, *supra* note 144, at 1.

155. 40 CFR § 1508.11 (2010); MOORE, *supra* note 144, at 10.

156. *See* §§ 1501.2(b), 1505.2; MOORE *supra* note 144, at 11.

157. *See* Grossman, *supra* note 124, at 303-04.

158. *See* Cannon, *supra* note 67, at 667-69.

159. *See id.*

however, the APHIS had exercised substantial freedom in its supervision of biotechnology without much interference from anyone.<sup>160</sup>

*C. Agency Coordination—or Lack Thereof*

Following the initial publication of the Coordinated Framework, the various federal agencies and the administration continued to work toward a consensus of how this policy would actually function in practical operation.<sup>161</sup> The interagency committee responsible for the coordination of science policy, the Biotechnology Science Coordinating Committee (BSCC), initially worked to define the range of GM organisms that would fall under federal oversight.<sup>162</sup> For unclear reasons, however, the BSCC was ultimately unable to reach a consensus in developing the policy in practice.<sup>163</sup> At that point in time, the George H.W. Bush Administration, under the representation of Vice President Dan Quayle, forwarded that task to the President's Council on Competitiveness, made up of federal agency and industry representatives responsible for the promotion of U.S. industry.<sup>164</sup> This turn marked a clear shift in U.S. biotechnology policy from the focus on risk regulation toward economic protection of the industry.<sup>165</sup>

In keeping with the Administration's policy, the White House Office of Science and Technology Policy (OSTP) assigned the primary responsibility of GM agriculture oversight to the APHIS under the umbrella of the USDA.<sup>166</sup> In the 1990s, the Administration released its plan to presume that biotechnology processes pose no per se risks to human health or the environment.<sup>167</sup> Since that time, the APHIS has maintained exclusive control over the regulation, deregulation, and supervision of biotechnology in agriculture.<sup>168</sup> And, up until the last several years, the APHIS has exercised that authority with little challenge from others.<sup>169</sup>

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160. See Marden, *supra* note 72, at 739.

161. See *id.*

162. See *id.* at 739-40.

163. See *id.* at 740.

164. See *id.*

165. See *id.* at 740-42.

166. See *id.* at 739.

167. See *id.* at 740.

168. See *id.* at 739.

169. See *supra* note 160 and accompanying text.

*D. The Case: Monsanto v. Geertson Seed Farms**1. District Case*

In 2007, the efforts to draw attention to the shortcuts in GM crop deregulation appeared successful when a California district judge granted an injunction against the further deregulation of GM alfalfa prior to the completion of the EIS.<sup>170</sup> In *Geertson Farms, Inc. v. Johanns*, the growers claimed that GM alfalfa created a critical risk of cross-contamination to their own conventionally grown alfalfa and that the APHIS violated NEPA by deregulating GM alfalfa without conducting an EIS.<sup>171</sup> As are all GM crops in recent history, the APHIS approved GM alfalfa after only completing an EA.<sup>172</sup> In fact, the APHIS granted Roundup Ready alfalfa nonregulated status in 2004, after only completing a “draft” EA.<sup>173</sup>

Both plaintiffs and defendants presented expert testimony alleging diverse results of the deregulation of GM alfalfa.<sup>174</sup> Plaintiffs presented environmental research supporting the theory that genetic modification creating alfalfa resistance to the commonly used herbicide Roundup caused the already easily spread crop the ability to become highly resistant and a so-called “super crop.”<sup>175</sup> Plaintiffs further alleged the genetic material inserted into Roundup Ready crops traveled and cross-contaminated other crops and weeds and inserted the same genetic resistance.<sup>176</sup> Plaintiffs’ expert testimony included the reference to already-developed problematic weeds, including pigweed, ragweed, and horseweed, which have become highly problematic to farmers due to their resistance to glyphosate as a direct result of cross-contamination.<sup>177</sup> Additionally, experts testified on behalf of the alfalfa farmers that the large number of alfalfa acreage in the nation should play a role in the decision to conduct an EIS because introducing Roundup Ready alfalfa would likewise introduce cross-contamination risks to one of the most prevalent crops in the nation.<sup>178</sup> Many areas of alfalfa growth are located in regions that are not currently exposed to glyphosate-resistant crops, resulting in an additional environmental risk of the potential spread to wheat, which is often rotated

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170. *See Geertson Farms, Inc. v. Johanns*, No. C 06-01075, 2007 WL 776146, at \*2 (N.D. Cal. Mar. 12, 2007).

171. *See id.*

172. *See id.*

173. *See Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2751 (2010).

174. *See Geertson Farms, Inc.*, 2007 WL 776146, at \*2.

175. *See id.*

176. *See Declaration of Doug Gurian-Sherman In Support of Plaintiffs Permanent Injunction* ¶ 13, *Geertson Seed Farms*, 2007 WL 1424401 (No. C 06-1075).

177. *See id.* ¶ 14.

178. *See id.* ¶ 16.

with alfalfa.<sup>179</sup> Plaintiffs claimed that the APHIS ignored all of these environmental effects in electing to merely conduct a draft EA rather than the full EIS.<sup>180</sup> Considering that no specific statutory scheme exists for biotechnology regulation, the APHIS was free to determine on its own whether it would complete an EA, taking only a few months, or an EIS, taking at least two years.<sup>181</sup>

Conversely, defendants, including the commissioner of the USDA, the EPA, and the APHIS, along with intervenor, Monsanto, argued that the APHIS satisfied its duty to research the environmental impact of GM alfalfa through the shortened EA with the determination of no significant impact (FONSI).<sup>182</sup> Defendants' expert testimony refuted the plaintiffs' allegations that the environmental impact could escalate to any level other than *de minimus*.<sup>183</sup> Defendants urged that even if the court determined an EIS was required, an injunction was not necessary because Roundup Ready alfalfa would, at first, only comprise 3.36% of all alfalfa grown and only 0.21% of overall glyphosate usage nationally.<sup>184</sup>

In analyzing the conflicting expert testimony, District Judge Charles Breyer held fast to the fact that the APHIS "acknowledged [the] risk that the genetically engineered gene [would] 'contaminate' organic and conventional alfalfa."<sup>185</sup> Judge Breyer further held that the APHIS did not adequately research the potential impact on the cross-contamination development of Roundup resistant weeds.<sup>186</sup>

By holding that an EIS is mandatory for GM alfalfa, Breyer then weighed in on what preliminary relief was available to the plaintiffs until the APHIS completed the full EIS.<sup>187</sup> Breyer turned to a line of cases from the Ninth Circuit that addressed environmental risks posed by violations of NEPA requirements.<sup>188</sup> Recognizing that the Ninth Circuit had granted

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179. *See id.*

180. *See Geertson Farms, Inc.*, 2007 WL 776146, at \*2.

181. *See id.*

182. *See* Declaration of Doug Gurian-Sherman, *supra* note 176, ¶ 71.

183. *See* Second Declaration of Paulette Pierson, Ph.D in Support of Monsanto Co.'s Memorandum on Proposed Permanent Injunction ¶ 51, *Geertson Seed Farms, Inc.*, 2007 WL 5356001 (No. C 06-1075).

184. *See id.*

185. *Geertson Farms, Inc.*, 2007 WL 776146, at \*1.

186. *See id.*

187. *See id.*

188. *See id.*; *see also* Idaho Watersheds Project v. Hahn, 307 F.3d 815, 833 (9th Cir. 2002), *abrogated by* Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010) ("In the run of the mill NEPA case, the contemplated project, whether it be a new dam or a highway extension, is simply delayed until the NEPA violation is cured."); Nat'l Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722, 737 (9th Cir. 2001) (holding that "[w]here an EIS is required, allowing a potentially environmentally damaging project to proceed prior to its preparation runs contrary to the very purpose of the statutory requirement"); *id.* at 737 n.18 (noting that "in 'unusual circumstances' an injunction may be withheld, or, more likely, limited in scope"); Forest Conservation Council v. U.S. Forest Serv., 66 F.3d 1489, 1496 (9th Cir. 1995) (holding that defendants "should be allowed to present evidence to the court that 'unusual circumstances' weigh against the injunction sought"); Thomas v. Peterson, 753 F.2d

injunctive relief in cases where the NEPA violation is in a “run of the mill” case absent any “unusual circumstances,” Judge Breyer followed suit.<sup>189</sup> Although Breyer acknowledged the fact that some growers had already planted Roundup Ready alfalfa, making the case “not so ‘run of the mill,’” he reasoned that in balancing the harms, he would nonetheless issue injunctive relief but would do so prospectively to alleviate any potential harm to growers already utilizing the crop.<sup>190</sup> Defendants immediately petitioned the court to reconsider and eventually appealed to the Ninth Circuit.<sup>191</sup>

## 2. *The Ninth Circuit*

On appeal, defendants argued that Breyer failed to apply the correct legal standard of the four-factor test to obtain a permanent injunction, as set out by the Supreme Court decision in *eBay v. MercExchange, L.L.C.*, and argued that the district court presumed plaintiffs suffered irreparable harm.<sup>192</sup> The *eBay* four-factor test requires that a plaintiff show:

(1) [T]hat it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.<sup>193</sup>

The Ninth Circuit held that Judge Breyer had not erred and, indeed, had applied the four-factor test as set out in *eBay*.<sup>194</sup> Furthermore, the split Ninth Circuit affirmed the lower court’s decision reasoning that the legislative requirements did not allow the shortened deregulation process through an EA rather than the more extensive evaluation of an EIS.<sup>195</sup> Dissenting Circuit Judge Randy Smith, however, concluded that the district judge erred in not holding the requisite evidentiary hearing before granting the permanent injunction.<sup>196</sup> Again dissatisfied with the results, the USDA, Monsanto, and other defendants appealed.<sup>197</sup>

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754, 764 (9th Cir. 1985) (stating that “absent ‘unusual circumstances,’ an injunction is the appropriate remedy for a violation of NEPA’s procedural requirements”).

189. See *Geertson Farms, Inc.*, 2007 WL 776146, at \*1; *Idaho Watersheds Project*, 307 F.3d at 833; *Thomas*, 753 F.2d at 764.

190. See *Geertson Farms, Inc.*, 2007 WL 776146, at \*1.

191. See *Geertson Seed Farms v. Johanns*, 541 F.3d 938, 941 (9th Cir. 2008).

192. See *id.* at 943; *eBay v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

193. *Geertson Seed Farms*, 541 F.3d at 943.

194. See *id.* at 944.

195. See *id.* at 942, 947.

196. See *id.* at 948 (Smith, J., dissenting).

197. See *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2749 (2010).

### 3. Supreme Court

On appeal, the case reached the United States Supreme Court in 2010 and for the first time in history, the highest court would weigh in on the controversy surrounding GM crop deregulation.<sup>198</sup> Three years after the alfalfa farmers first filed their case in a California district court and six years after the first action of deregulation of GM alfalfa, Geertson Seed Farms would have their pleas about the regulatory processes heard by the United States Supreme Court.<sup>199</sup> Justice Alito delivered the opinion of the Court, addressing issues of standing for both petitioners and respondents and whether the district judge abused his discretion by granting an injunction.<sup>200</sup>

#### *a. What Was Left Unchallenged and Standing for Both Parties*

In appealing to the Supreme Court, Monsanto and other petitioners left unchallenged the district court's ruling that the APHIS violated NEPA, and rather opted only to appeal the district court's grant of relief through a permanent injunction pending the EIS.<sup>201</sup> This left open the ultimate question of whether the APHIS violated NEPA.<sup>202</sup> Respondents attempted to capitalize on petitioners' decision not to appeal the violation ruling, claiming that Monsanto and other petitioners lacked standing as their injury only resulted from the portion of the district court's decision left uncontested.<sup>203</sup> The Court rejected this argument, determining that even though petitioners failed to object to the NEPA violation ruling, petitioners adequately preserved the objection by contending that the APHIS's proposed remedy should replace the vacatur decision of the district court.<sup>204</sup> The Court further determined that regardless of whether petitioners challenged the NEPA violation, petitioners had standing based exclusively on the appeal of the permanent injunction because a favorable decision would redress the injury and allow petitioners to seek further deregulation.<sup>205</sup>

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198. *See generally id.* at 2749 (addressing the issues of regulation and deregulation of GM crops for the first time).

199. *See id.*; Geertson Farms, Inc., v. Johanns, No. C 06-01075, 2007 WL 776146, at \*2 (N.D. Cal. Mar. 12, 2007).

200. *See Geertson Seed Farms*, 130 S. Ct. at 2752-56, 2761-62.

201. *See id.* at 2752.

202. *See id.*

203. *See id.*

204. *See id.* at 2753-54.

205. *See id.* at 2754 (noting that for the purpose of standing the court "need not decide whether or to what extent a party challenging an injunction that bars an agency from granting certain relief must show that the agency would be likely to afford such relief if it were free to do so").

Likewise, petitioners attempted to shut the door on challenges to GM crop deregulation decisions by claiming that farmers, such as Philip Geertson, did not meet constitutional standing requirements.<sup>206</sup> Petitioners claimed that respondents failed to show the likelihood of suffering a cognizable injury without injunctive relief.<sup>207</sup> The Court rejected this argument as well and gave credence to both the environmental and economic claims by Geertson.<sup>208</sup> Although petitioners claimed that respondents failed to meet the “zone of interests” test of standing because “the risk of commercial harm ‘is not an interest that NEPA was enacted to address,’” the Court rejected that argument and ruled that, as the district court held, respondents’ injury had both “an environmental as well as an economic component.”<sup>209</sup>

*b. Nationwide Permanent Injunction*

The Court again noted that petitioners failed to challenge the district court’s ruling that the risk of contamination by GM alfalfa to conventional and organic alfalfa growers constituted a “significant environmental effect within the meaning of NEPA.”<sup>210</sup> The Court, therefore, declined to offer any opinion as to whether the district court’s vacatur of the APHIS’s deregulation was proper and only addressed propriety of the injunction.<sup>211</sup>

The Court applied the traditional, four-factor test to review a permanent injunction of an agency action, including that (1) the plaintiff demonstrates irreparable injury, (2) alternative remedies are inadequate, (3) equitable relief is warranted, and (4) the injunction would serve the public interest.<sup>212</sup> The Court previously applied this test in cases where plaintiffs sought a permanent injunction for a NEPA violation in *Winter v. Natural Resources Defense Council, Inc.* in 2008.<sup>213</sup>

Monsanto and petitioners alleged, however, that the district court failed to apply the correct test and incorrectly cited Ninth Circuit cases prior to *Winter*, leading to the conclusion that an injunction was the appropriate remedy for a NEPA violation in “the run of the mill NEPA case.”<sup>214</sup> The

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206. *See id.*

207. *See id.*

208. *See id.* at 2754-55.

209. *Id.* at 2755-56 (first quote quoting *Bennett v. Spear*, 520 U.S. 154, 162-63 (1997) (holding that the constitutional standing requirements of NEPA violations are not intended to address economic restitution)).

210. *See id.* at 2756 (noting that the “mere fact that respondents also seek to avoid certain economic harms that are tied to the risk of gene flow does not strip them of prudential standing”).

211. *See id.*

212. *See id.* (quoting *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (holding that a permanent injunction should not follow as a matter of course without these factors)).

213. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 15 (2008).

214. *Geertson Seed Farms*, 130 S. Ct. at 2756 (quoting *Geertson Farms, Inc. v. Johanns*, No. C 06-01075, 2007 WL 776146, at \*1 (N.D. Cal. Mar. 12, 2007)). “[A]n injunction delaying the contemplated

Court noted that whereas the proper standard mandates that an injunction should only issue if all four factors are satisfied, the district court applied an injunction as the proper remedy “except in unusual circumstances.”<sup>215</sup> Respondents attempted to mitigate the district court’s apparent application of the incorrect standard by arguing that such references to “run of the mill” NEPA cases were merely “descriptive rather than prescriptive.”<sup>216</sup> The Court declined to address whether this characterization of the district court’s reasoning was sound and opted only to evaluate whether an injunction should stand.<sup>217</sup>

The Court held that none of the four factors supported the injunction.<sup>218</sup> In evaluating the injunction order in context of the dispute between the parties, the Court recognized that the original complaint by respondents centered on the *full* deregulation of GM alfalfa without a complete EIS.<sup>219</sup> Conversely, Judge Breyer’s remedy not only vacated the APHIS’s agency decision, but also permanently enjoined *any* deregulation, full or partial, and enjoined all planting of GM alfalfa nationwide.<sup>220</sup> The Court concluded this remedy extended beyond the district court’s cause to intervene considering that the APHIS had yet to take action in any manner other than the full deregulation, and perhaps, *could* effectuate a partial deregulation in compliance with requirements by law.<sup>221</sup> Rather than analyzing each of the four factors in the traditional test, the Court offered the prior analysis to show that “it [was] clear that the order enjoining any deregulation whatsoever [did] not satisfy the traditional four-factor test for granting permanent injunctive relief.”<sup>222</sup>

The Court then focused specifically on the irreparable-injury prong of the test, offering two independent reasons respondents failed to satisfy this factor.<sup>223</sup> First, if the APHIS was to attempt partial deregulation, and such actions were arguably still in violation of NEPA, then respondents could file suit again and seek preliminary relief.<sup>224</sup> The Court reasoned that with

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government project is proper ‘until the NEPA violation is cured.’” *Id.* at 2756; see *Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 833 (9th Cir. 2002), *abrogated by Geertseed Farms*, 130 S. Ct. 2743.

215. *Geertson Seed Farms*, 130 S. Ct. at 2757.

216. *Id.*

217. *See id.*

218. *Id.* at 2758. Although the petitioners only focused their appeal on the portion of the injunction that prohibited the planting of GM alfalfa, the Court reasoned that the “broad injunction against planting cannot be valid if the injunction against partial deregulation is improper.” *Id.* at 2757 & n.4.

219. *See id.* at 2758.

220. *See id.*

221. *See id.* at 2758-59 n.5 (noting further that any prophylactic measures were unwarranted considering that the “APHIS has not yet invoked the procedures necessary to attempt a limited deregulation”).

222. *Id.* at 2759.

223. *See id.* at 2759-60.

224. *See id.* at 2760; see also 5 U.S.C. § 702 (2006); *id.* § 705 (providing judicial review and postponement of agency action “as may be required and to the extent necessary to prevent irreparable injury”).



this remedy always available, permanent injunction was, therefore, not necessary to prevent irreparable injury.<sup>225</sup> Second, the Court concluded that partial deregulation, as opposed to full deregulation, “need not cause respondents any injury at all, much less irreparable injury; if the scope of the partial deregulation is sufficiently limited, the risk of gene flow to their crops could be virtually nonexistent.”<sup>226</sup> By referencing studies presented by both sides at oral argument, the Court acknowledged that isolation distances could provide virtual elimination of gene-flow contamination.<sup>227</sup> In conclusion, the Court speculated that if the APHIS determined that a plan to provide a limited, closely supervised partial deregulation caused no significant effect, respondents would have significant difficulty showing irreparable injury.<sup>228</sup> A permanent injunction, however, “improperly relieve[d] respondents of their burden to make the requisite evidentiary showing.”<sup>229</sup>

The Court then briefly turned to petitioners’ additional claim that the district court erred by enjoining all planting of GM alfalfa nationwide.<sup>230</sup> The Court concluded that such a remedy also reached beyond the scope of the court’s cause to intervene for two reasons: (1) the same impropriety found in granting a permanent injunction against partial deregulation carried over into the nationwide ban; and (2) the nationwide injunction resulted in no practical effect absent the vacatur already in place.<sup>231</sup> In sum, the Court reversed the judgment of the Ninth Circuit and remanded the case for further proceedings.<sup>232</sup>

### *c. Dissent’s Concerns*

Justice Stevens entered the sole dissent, referencing undisputed facts that even in controlled settings, contamination can occur, and that the APHIS has an admitted limited capability to monitor and enforce restrictions on planting.<sup>233</sup> Justice Stevens further stressed that contamination indeed posed a threat of irreparable harm because “genetic

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225. See *Geertson Seed Farms*, 130 S. Ct. at 2760.

226. *Id.*

227. See *id.* at 2758; see also Brief in Opposition of Respondents Geertson Seed Farms, et al. at 9 n.6, *Geertson Seed Farms*, 130 S. Ct. 2743 (No. 09-475), 2009 WL 5112653 (referencing a study concluding “that in order for there to be zero tolerance of any gene flow between a [RRA] seed field and a conventional seed field, those fields would have to have a five-mile isolation distance between them”); *Geertson Seed Farms*, 130 S. Ct. at 2760 (providing argument by United States Solicitor General that the “APHIS may impose conditions on the deregulation of RRA via issuance of an administrative order” (quoting Tr. of Oral Arg. at 15-16)).

228. See *Geertson Seed Farms*, 130 S. Ct. at 2760.

229. *Id.*

230. See *id.* at 2761.

231. See *id.*

232. *Id.* at 2761-62.

233. See *id.* at 2762 (Stevens, J., dissenting).

contamination from [GM alfalfa] could decimate farmers' livelihoods and the American alfalfa market for years to come."<sup>234</sup> Justice Stevens stated that he would uphold the district court's injunction because, in his view, the degree of harm posed by contamination warranted the remedy.<sup>235</sup>

*d. Aftermath*

Following the Supreme Court opinion, both sides declared victory.<sup>236</sup> Monsanto immediately publicized the decision as a win for the GM seed developer and declared that farmers could return to planting GM alfalfa by the end of the year.<sup>237</sup> Conversely, the Center for Food Safety and conventional farmers triumphed the decision as it effectively left in place the district court's vacatur of the APHIS's deregulation and maintained their intent to contest any deregulation of GM crops without a full EIS.<sup>238</sup> As the dust settled from the battle in the Supreme Court, the fallout proved that the fight on and for the fields of America remained far from resolved.<sup>239</sup>

IV. HOW THE U.S. BIOTECHNOLOGY POLICY FALLS SHORT

*A. When Regulation Began to Fail by Failing to Begin*

Many of the gaps in GM crop and food regulation have existed since the emergence of biotechnology policy under the Reagan Administration.<sup>240</sup> With intent to promote industry growth, the Coordinated Framework determined three key approaches to GMOs: (1) any regulation would only focus on the end product; (2) approaches to regulation would presume a low risk from genetic modification; and (3) regulatory review of GM products could proceed under existing federal standards.<sup>241</sup> The proclaimed belief that GMOs were not substantially dissimilar to traditional organisms supported the Coordinated Framework's reasoning for the failure to provide

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234. *Id.*

235. *Id.* at 2766-67. Only eight justices participated in the opinion with Justice Breyer's recusal—his brother provided the district court opinion in question. See *Monsanto Wins Supreme Court Case*, HUFFINGTON POST (June 21, 2010, 2:21 PM), [http://www.huffingtonpost.com/2010/06/21/monsanto-wins-supreme-cou\\_n\\_619657.html](http://www.huffingtonpost.com/2010/06/21/monsanto-wins-supreme-cou_n_619657.html). Some criticized Justice Thomas's failure to recuse because he previously served as an attorney for Monsanto. See Michael Tomasky, *Supreme Court Justice Thomas Facing Possible Impeachment*, VETERANS TODAY (Jan. 29, 2011), <http://www.veteranstoday.com/2011/01/29/supreme-court-justice-thomas-facing-possible-impeachment/>.

236. See *Monsanto Wins Supreme Court Case*, *supra* note 235.

237. See *id.*

238. See *id.*

239. See *id.*

240. See Marden, *supra* note 72, at 736, 738-39; *supra* Part III.A.

241. See Marden, *supra* note 72, at 734, 738.

any new regulations for GMOs.<sup>242</sup> The initial, and continued, U.S. approach to GMOs, therefore, has remained a presumption against risk rather than legitimate consideration of risk potential.<sup>243</sup> With the stark contrast of the United States' no-holds-barred approach to GMOs to the EU's "precautionary principle," it is not surprising that American exporters have met resistance to GM seed and products in Europe.<sup>244</sup> Rather than providing any regulatory response to EU concerns of risk and safety, the U.S. government elected to attempt to force its way on to the fields of the world, threatening to sue "the European Commission in the World Trade Organization for banning imports of U.S. bioengineered seeds."<sup>245</sup> Regardless, the repeated refusal to reconsider the development of more substantive statutory procedures has led to distrust and staunch resistance.<sup>246</sup>

On economic levels, the U.S. minimalist approach to biotechnology regulation has indeed resulted in substantial growth in the industry.<sup>247</sup> The United States dominates the agricultural GM market.<sup>248</sup> In addition, continued growth in the industry has skyrocketed as new developments spread not only to new parts of the world but also to new crops.<sup>249</sup> However, the expansion has not proceeded without cost.<sup>250</sup> The prior controversies of rice and corn contamination, with no known causes for the crop commingling, cost the industry billions.<sup>251</sup>

Yet, this economically driven approach begs the question: Can an agency charged with promoting, rather than impeding, the industry's economic growth objectively evaluate the risk of new products? This question is especially poignant in the case of GM crops, which have indeed proven to stimulate the market.<sup>252</sup> In addition, should the promotion of one part of the industry (GM products) come at the expense of another (organic/conventional products)? Whereas in the past, this concern was expressed but not demonstrable, federal courts emerged as a validating force for the organic and conventional agricultural industry, giving judicial

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242. *See id.* at 734.

243. *See id.* at 735.

244. *See id.* at 734-35 ("U.S. corn farmers alone say they are losing \$200 million a year because of the closed European market, and that millions more are being lost on soy, cotton, potato and other products.").

245. *Id.* at 734.

246. *See id.* at 743-44 (discussing the opposition of various groups to GM products).

247. *See id.* at 735.

248. *See id.*

249. *See generally id.* (noting the United States' dominance in biotechnology and the continued spread of GM products).

250. *See id.* (discussing numerous litigation involving corn and rice cross-contamination with GM seeds).

251. *See id.*

252. *See Mandel, supra* note 122, at 2181-82.

recognition through standing for the conventional farmer to the harm posed by contamination from GM seed.<sup>253</sup>

Up until the recent litigation, the backlash directed toward biotechnology regulation focused on isolated cases and European export resistance.<sup>254</sup> More recently, however, both vocal opposition and judicial intervention have brought to light the myriad of consequences of cross-contamination of GM crops.<sup>255</sup> Although U.S. policy embraced GM technology with the aim of promoting the industry worldwide, such wide-open regulation backfired both overseas and eventually on the plains of America.<sup>256</sup> Not only do concerns for food and chemical safety weigh in the balance, but also the right of conventional and organic farmers to maintain their crop and livelihood without the fear of decimation by contamination from neighboring GM crops.<sup>257</sup> Considering the U.S. policy began with the “presumption against risk” approach, analysis should turn to how this approach resulted in inconsistencies and incomplete risk assessment.<sup>258</sup>

### *B. Procedural Skeletons and Substantive Voids*

For the past two decades, the USDA, through the APHIS, exercised considerable liberties in biotechnology regulation.<sup>259</sup> Rather than developing new, specific regulation geared toward GMOs when the new technology arose, the Coordinated Framework opted to allow agencies to simply use the procedures already in place through NEPA for regulation, and as a result, for deregulation.<sup>260</sup> The end result exposed an incomplete system consisting of bare procedural requirements with little to no substantive guidelines.<sup>261</sup>

Because the Coordinated Framework opted to assign GMO regulation to multiple agencies through various statutory guidelines in place at the time, the resulting structure emerged as a mix of complexities and inconsistencies.<sup>262</sup> A GM product may fall under the authority of the USDA, the FDA, and the EPA.<sup>263</sup> Even within this divided authority, one

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253. See *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2752-56 (2010).

254. See Marden, *supra* note 72, at 743-44.

255. See *id.*

256. See *id.* at 741-44.

257. See Alison Peck, *Leveling the Playing Field in GMO Risk Assessment: Importers, Exporters and the Limits of Science*, 28 B.U. INT'L L.J. 241, 272 & n.150 (2010).

258. See *id.* at 250-51.

259. See generally Marden, *supra* note 72, at 767-76 (discussing the USDA's administrative decisions concerning GM products).

260. See *id.* at 745.

261. See Mandel, *supra* note 122, at 2228-30.

262. See *id.*

263. See generally Marden, *supra* note 72, at 739 (reviewing the divided purposes of the agencies, including the USDA (safe to grow), the FDA (safe to eat), and the EPA (safe for the environment)).

identifiable need, such as contamination protection for the conventional farmer, could fall under the regulation of divided agencies of the USDA and the EPA.<sup>264</sup> The procedural component under fire in *Geertson Seed Farms* involved the EA and EIS evaluations originally enacted by NEPA.<sup>265</sup>

Congress enacted NEPA in 1969 to provide a general and global consensus in U.S. policy concerning the environment.<sup>266</sup> Although the EA and EIS provide procedures for evaluation, no specific substantive guidelines exist directing which evaluative procedure to use and what constitutes a significant impact on the environment in terms specific to the unique risks presented by GMOs.<sup>267</sup> The *Geertson Farms, Inc.* case exposed these barren guidelines when the district judge ruled that the APHIS violated NEPA requirements by opting to merely complete an EA rather than a full EIS.<sup>268</sup> Some questions remain, however, given that Monsanto and the APHIS failed to appeal the district court's determination, and therefore, the Supreme Court rendered no opinion as to whether the APHIS indeed violated NEPA.<sup>269</sup> Nonetheless, speculation arises that the APHIS conceded the violation by its proposed, and eventually executed, remedy to complete the EIS.<sup>270</sup>

Considering the APHIS operates under the umbrella of the USDA with the primary purpose of protecting and promoting U.S. agriculture, questions arise concerning both the motivation and the expertise of the APHIS to conduct environmental inspections.<sup>271</sup> The focus of the agency, by definition, serves the protection and promotion of the industry, not the environment.<sup>272</sup> In certain cases, such as *Geertson Seed Farms*, these purposes may prove contradictory.<sup>273</sup> With the absence of defined guidelines, the protection of the industry will likely overshadow the concerns for the environment.<sup>274</sup>

Even if the APHIS changes procedures to include an EIS for all new GM crops, a substantive void remains as to what exactly constitutes a significant impact on the environment.<sup>275</sup> Neither NEPA nor EIS

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264. See generally Mandel, *supra* note 122, at 2223-30 (discussing the authority of the EPA and the USDA).

265. See, e.g., *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2750 (2010).

266. See Mark A. Chertok, *Overview of the National Environmental Policy Act: Environmental Impact Assessments and Alternatives*, SR045 ALI-ABA 757, 759 (2010).

267. See *id.* at 759-60, 764-69.

268. See *Geertson Farms, Inc. v. Johanns*, No. C 06-01075, 2007 WL 776146, at \*1 (N.D. Cal. Mar. 12, 2007).

269. See *Geertson Seed Farms*, 130 S. Ct. at 2752.

270. See *id.*; see also *Roundup Ready Alfalfa Documents*, USDA: ANIMAL AND PLANT HEALTH INSPECTION SERVICE, [http://www.aphis.usda.gov/biotechnology/alfalfa\\_documents.shtml](http://www.aphis.usda.gov/biotechnology/alfalfa_documents.shtml) (last modified Mar. 30, 2011) (providing links to the final EIS and press releases regarding the deregulation of alfalfa).

271. See Mandel, *supra* note 122, at 2224-25.

272. See *id.* at 2230-33.

273. See Declaration of Doug Gurian-Sherman, *supra* note 176, ¶ 13.

274. See Mandel, *supra* note 122, at 2230-33.

275. See *id.*

procedures dictate any particular result following the evaluation.<sup>276</sup> NEPA requirements are essentially procedural, providing only a framework to conduct environmental evaluations with no substantive directives.<sup>277</sup> NEPA does dictate that agencies must meet the procedural steps of completing the EIS and providing public notice through the Federal Register prior to proceeding with agency action.<sup>278</sup> Therefore, an agency can conceivably proceed with whatever action regardless of whatever results from an EIS.<sup>279</sup> This is perhaps the most troubling loophole in all of the haphazard regulation of GMOs.

Specific to GM crops, no statutory mandates exist requiring the APHIS to evaluate impacts specific to the unique concerns about GM crops.<sup>280</sup> Deference is given to agency determination following an EIS unless challenged through judicial review.<sup>281</sup> Even then, considering the lack of concrete requirements, plaintiffs have found difficulty pursuing their cases with such broad statutory guidelines in place.<sup>282</sup> The determination of whether the APHIS acted properly has fallen in the laps of district judges, forced to act as both lawmakers and agency personnel.<sup>283</sup> Shortly after *Geertson Seed Farms*, yet another GM crop deregulation controversy landed in federal court in *Center for Food Safety v. Vilsack*, reinforcing the prime need for a regulatory overhaul.<sup>284</sup>

### C. *Center for Food Safety v. Vilsack: Why Now Is the Time for Revamped Regulation*

After years of voicing concern about the risks presented by GMOs, the Center for Food Safety finally found a stronghold in federal court with the harm posed to the conventional farmer endangered by GM crop contamination.<sup>285</sup> Whereas proponents of GM crops continued to trumpet their declarations that GM crops caused no harm, the risk of decimation of one's entire seed, and therefore livelihood, finally struck a chord in a courtroom.<sup>286</sup> Apparently, GM crop deregulation was proceeding smoothly and quickly up until Judge Breyer brought GM alfalfa to a screeching halt.<sup>287</sup>

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276. See Chertok, *supra* note 266, at 759.

277. See *id.*

278. See *id.*

279. See *id.*

280. See *id.*

281. See *id.* at 762.

282. See *In re Genetically Modified Rice Litig.*, 251 F.R.D. 392, 393-94 (E.D. Mo. 2008).

283. See *supra* Part III.D.

284. See *Ctr. for Food Safety v. Vilsack*, 753 F. Supp. 2d 1051, 1054 (N.D. Cal. 2010), *vacated and remanded by* 636 F.3d 1166 (9th Cir. 2011).

285. See *id.* at 1054-57.

286. See *supra* Part III.D.

287. See *supra* Part III.

In December of 2010, before Monsanto could finish its victory lap after the Supreme Court lifted Judge Breyer's injunction, another California district judge went so far as to order the removal of GM sugar beets from the ground that the APHIS deregulated in violation of NEPA.<sup>288</sup> The Center for Food Safety, one of the plaintiffs in the *Geertson Seed Farms* case, also challenged the APHIS's deregulation of GM sugar beets without the completion of an EIS.<sup>289</sup> In *Center for Food Safety v. Vilsack*, the court addressed the APHIS's decision to consider each of Monsanto's requested permits in isolation, and therefore, allowed more permissive deregulation without full environmental review of the entire project.<sup>290</sup> Judge White reasoned that:

The evidence presented at the evidentiary hearing made clear that, even with the existence of protocols designed to minimize any environmental harm, there is a significant risk that the plantings pursuant to the permits will cause environmental harm. Despite efforts by Defendants to implement effective protocols and efforts by Intervenor-Defendants to minimize any contamination or cross-pollination, there are examples of where such efforts were ineffective, either because the conditions were later determined to be insufficient or the conditions were not followed. In other instances, the causes of the contamination were never discovered. These incidents are too numerous for this Court to declare confidently that these permits provide sufficient containment to protect the environment.<sup>291</sup>

The judge went on to reject Monsanto's and the APHIS's arguments that the removal of any GM plants would, in turn, result in harm to their interests, stating that "[t]o the extent Defendants and Intervenor-Defendants contend that they would suffer any harm, it is only of their own doing. Due to their preemptive conduct, the stecklings have been planted pursuant to the permits at issue and they have created a significant risk of environmental harm."<sup>292</sup> Judge White further noted that the APHIS waited nearly a year after the judge initially determined the deregulation as unlawful before addressing any concerns and then chose to "unlawfully" segment the permits in an attempt to push through the planting of the GM seeds.<sup>293</sup> Judge White's decision is better understood when coupled with the fact that this deregulation occurred shortly after the judge had previously ruled on the matter.<sup>294</sup>

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288. *See Ctr. for Food Safety*, 753 F. Supp. 2d at 1061.

289. *See id.* at 1056.

290. *See id.* at 1058-59.

291. *Id.* at 1055-56.

292. *Id.* at 1056.

293. *See id.* at 1058.

294. *See id.*

In August 2010, Judge White vacated the APHIS's decision to grant permits to Monsanto for GM sugar beets.<sup>295</sup> Only weeks after that decision, on September 1, 2010, the APHIS announced it had received permit requests for GM sugar beet stecklings (seedlings) and intended to grant those permits shortly.<sup>296</sup> The APHIS followed through, granting the permits in question on September 6, 2010, only five days after the announcement.<sup>297</sup> In an apparent disregard for the plaintiffs' concerns of permit and deregulation abuse, Monsanto and the APHIS proceeded to deregulate and plant GM sugar beets despite the district court's ruling.<sup>298</sup>

Judge White went on to conclude that pursuant to Monsanto's own claims it would destroy already planted sugar beets if the APHIS declined its permit, Monsanto must remove all stecklings already planted because "the legality of Defendants' conduct does not even appear to be a close question. It appears clear that Defendants and Intervenor-Defendants were merely seeking to avoid the impact of the Court's prior order."<sup>299</sup> White punctuated his decision with the conclusion that Monsanto and the APHIS were "merely seeking to avoid the impact of the Court's prior order."<sup>300</sup> Although the decision only stood for two months, Judge White's scathing ruling pinnacled the last several years of mounting controversy surrounding the deregulation of GM crops.<sup>301</sup>

#### V. HOW TO REGULATE GENETICALLY MODIFIED CROPS WITH BOTH THE INDUSTRY AND ENVIRONMENT IN MIND

Critics have called for change in biotechnology regulation since it emerged in the 1980s.<sup>302</sup> Early concern focused on the uncertainty of the science in such an early stage of its development and called for more deliberate evaluation procedures.<sup>303</sup> Even then, critics expressed doubt that the structure and inherent bias in the policy would allow meaningful inspection of new biotechnology products.<sup>304</sup> Concerns intensified when the George H.W. Bush Administration shifted the entire review power of new biotechnology products out from under the EPA to the USDA, later

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295. *Id.*

296. *Id.*

297. *Id.*

298. *See id.*

299. *Id.* at 1061.

300. *Id.*

301. *See* Ctr. for Food Safety v. Vilsack, 636 F.3d 1166, 1174 (9th Cir. 2011) (affirming that organic farmers had standing to challenge the partial deregulation, but rejecting Judge White's conclusion that the plaintiffs met their burden of proving the risk of harm warranting an injunction).

302. *See* Ruth E. Harlow, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 563-64 (1986) (criticizing the lack of attention to the unknown aspects of biotechnology in the early stages of release on the market).

303. *See id.* at 570-71.

304. *See id.* at 560-63.



developing the division of the APHIS.<sup>305</sup> With that change in agency oversight, the policy expanded the liberties in the review process handing the right of approval to the agency responsible for promoting the industry.<sup>306</sup>

#### *A. Agency Centrality and Accountability*

Judge White's exasperation with the APHIS had good cause. He worked with the agency for over a year to come into compliance with NEPA requirements for the deregulation of GM sugar beets.<sup>307</sup> Yet, days after he vacated the agency's deregulation decision in August 2010, the APHIS announced its intent to continue with deregulation by circumventing the court's ruling and segmenting the permit to stecklings, without any further compliance with the court's directive to abide by NEPA requirements.<sup>308</sup> The APHIS has repeatedly shown a disregard for NEPA guidelines and environmental concerns by organic growers and public interest groups.<sup>309</sup> Indeed, environmental compliance is not a primary purpose of the APHIS under the USDA—its primary purpose is to promote the U.S. agricultural industry.<sup>310</sup>

Tracing back to when biotechnology regulation went astray with the assignment to the USDA reveals that the intent to promote the U.S. biotechnology industry came at the expense of environmental interests.<sup>311</sup> In light of the recent actions of the APHIS attempting to circumvent Judge White's vacatur decision, it is unlikely that any meaningful changes in regulation are possible under the supervision of the USDA. Therefore, to truly address the deficiency in environmental inspection of GM crops, Congress must involve the EPA.

Considering that the EPA's primary purpose is to protect health and the environment, its expertise and experience fit best within the needs of biotechnology regulation.<sup>312</sup> EPA evaluators specialize in risk assessment to the environment both in the immediate area in question and on a grander scale.<sup>313</sup> In fact, given the other areas of the EPA's oversight, it appears the White House specially carved out the duty for the USDA from traditionally EPA-supervised activities.<sup>314</sup> The EPA already holds control of

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305. See Marden, *supra* note 72, at 739, 742-43.

306. See *supra* Part III.A.

307. See *id.*

308. *USDA Announces Next Steps on Sugar Beets*, USDA (Sept. 1, 2010), <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2010/09/0437.xml>.

309. See *supra* Parts III, IV.

310. See *supra* Part IV.

311. See *supra* Part IV.

312. See Mandel, *supra* note 122, at 2216-17, 2221-24.

313. See *id.*

314. See *id.* at 2231-46.

pesticide–herbicide application on plants.<sup>315</sup> In addition, with the evaluated deficiencies in the APHIS’s environmental assessments, the EPA could better assess the relevant risks posed specifically by GM plants.<sup>316</sup> The experts and practiced evaluators of the EPA could better address the numerous concerns associated with GM plants, including cross-contamination, human consumption, and ecological impacts.<sup>317</sup> Some have argued that the APHIS has held the position since the explosion of GMOs in the 1990s and, therefore, should continue to maintain the supervision.<sup>318</sup> In perspective, however, the introduction of biotechnology is still in its infancy, and the vast majority of GM crops are yet to arrive to the public.<sup>319</sup>

Further, the EPA could provide the detached outlook needed for an unbiased review of the risks.<sup>320</sup> The USDA’s purpose to promote the industry presents an obstructive bias, preventing the inspectors from taking the hard look necessary to fully evaluate the risks. Although the USDA should continue its involvement with released GM crops, this should only come once the EPA has determined the seed is safe for the public and developed guidelines for its use.<sup>321</sup> Considering the world growth challenges emerging over the next several decades, the biotechnology industry should continue to maintain its drive to best develop products that could meet the mushrooming global-feeding needs.<sup>322</sup> Through meaningful agency cooperation, the EPA could complete environmental review and provide guidelines that could better account for the concerns by farmers, such as Geertson, for the risks of contamination associated with GM crops.<sup>323</sup>

### B. Procedure with Substance

The procedural guidelines for environmental review of GM crops severely lack substantive guidance.<sup>324</sup> Considering the size and scope of the biotechnology industry, Congress can no longer ignore the need to structure a statutory scheme with real substance.<sup>325</sup> Specific statutory guidelines should equip evaluators with the tools necessary to address the unique risks inherent in GM crops. Further, statutory guidelines must dictate action to

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315. *See id.* at 2229.

316. *See id.* at 2232.

317. *See id.*

318. *See Marden, supra* note 72, at 743-44.

319. *See supra* Part I.C.

320. *See Mandel, supra* note 122, at 2235-46.

321. *See infra* Part V.B.

322. *See infra* Part V.B-C.

323. *See supra* Parts IV, V.A.

324. *See infra* Part V.B.

325. *See supra* Part III.

accompany the outcome determinations to set what levels of risk are tolerable and what levels require action.<sup>326</sup>

In the past ten years, proposals have urged legislation to develop concrete guidelines that account for the risks inherent in introducing a crop into the environment that, due to genetic modification, contains genes and traits like none other in existence.<sup>327</sup> Even though critics have generally insisted on an improved evaluation structure, recent litigation highlighted the specific potential harms that GM crops present.<sup>328</sup>

The *Geertson Seed Farms* and *Center for Food Safety* cases support a judicial interpretation of NEPA to require unequivocal compliance with a full EIS, rather than the shortened EA, as the APHIS has freely employed.<sup>329</sup> Although the EIS is simply a procedural model, it provides at a minimum a hard look at potential effects and risks presented by the new crop.<sup>330</sup> In addition to the EIS prerequisite, EPA experts must provide Congress with more specific parameters as to what results generated from the EIS require action. Specific risk assessment should target the distinctive risks associated with GM crops such as cross-contamination.<sup>331</sup> When the EPA determines that contamination risks are inherent in the GM crop, Congress must dictate in the statutory structure what should happen next.<sup>332</sup> As discussed, the APHIS currently has no required action in place regardless of the EA or the EIS results.<sup>333</sup> When the EIS conclusions indicate that cross-contamination risks are present, statutory guidelines should deny market release until mitigation techniques, such as isolation distances, can reduce those risks.<sup>334</sup> If the United States desires improved trade relations with Europe, then Congress must consider contamination tolerance levels consistent with the EU's requirement of deterring any risks through isolation.<sup>335</sup> Scientists tend to agree that isolation distances,

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326. See generally Mandel, *supra* note 122, at 2239 (describing the *StarLink* incident when an agency did not have the knowledge or statutory guidance to prevent a transgenic food scare).

327. See *id.* at 2249-59 (calling for improved agency coordination and statutory guidelines); see also Marden, *supra* note 72, at 735 (accounting how the regulatory framework should continue to evolve as products themselves evolve); Peck, *supra* note 257, at 277-78 (addressing that "sound science" and adequate risk assessment could restore biotechnology trade flow with the World Trade Organization); Allison M. Straka, Casenote, *Geertson Seed Farms v. Johanns: Why Alfalfa Is Not the Only Little Rascal for Bio-Agriculture Law*, 21 VILL. ENVTL. L.J. 383, 400-02 (2010) (discussing that the increased litigation indicates that "something more needs to be done").

328. See Straka, *supra* note 327, at 401.

329. See *supra* Parts III.D., IV.C.

330. See *supra* Part III.B.

331. See *supra* Part III; Mandel, *supra* note 122, at 2248-59.

332. See *supra* Part III.B.

333. See *supra* Part IV.B.

334. Jun Rong et al., *Modeling Pollen-Mediated Gene Flow in Rice: Risk Assessment and Management of Transgene Escape*, 8 PLANT BIOTECHNOLOGY 452, 459 (2010).

335. See A. Artuso, *Risk Perceptions, Endogenous Demand and Regulation of Agricultural Biotechnology*, 28 FOOD POL'Y, No. 2, 131, 131-32 (2003).

coupled with responsible management, can greatly reduce cross-contamination.<sup>336</sup>

The *Geertson Seed Farms* case, for example, illustrates the need for reliable guidance for isolation techniques to prevent cross-contamination from GM crops to organic, conventional crops.<sup>337</sup> Alfalfa, which is insect-pollinated, requires increased isolation distances than crops that are not insect-pollinated.<sup>338</sup> In addition, the risks associated with GM crop-contamination of weeds developing “super weeds” resistant to herbicides such as Roundup require the development of environmental policy and guidance to farmers on the best manner to contain the risks of such ecological damage.<sup>339</sup> As experts testified in *Geertson Seed Farms*, scientists have studied and compiled cross-contamination data worldwide.<sup>340</sup> While the statutory scheme may not provide specific guidance on what specific distance is required, Congress should mandate that the EPA assess the distance required depending on the unique attributes of the crop and set guidelines for GM growers to abide by when adding the new crop to the environment. In *Geertson Seed Farms*, the APHIS proposed a distance of a mere 1,500 feet while opposing experts advised anywhere from two to five miles between conventional and GM alfalfa crops to adequately deter cross-contamination.<sup>341</sup> The EPA must balance the diverse interests and maintain the objective ability to determine the best distance requirements for each individual crop to minimize cross-contamination and protect the environment. If 1,500 feet provides no meaningful contamination reduction, and yet five miles proves unrealistic, the answer must lie somewhere in between.<sup>342</sup>

Finally, GM crops present highly diverse risks contingent on a variety of factors.<sup>343</sup> Depending on the region and crop variety, risk assessment must account for variables such as wind trends, insect habits, and prevalence of the variety. Whereas some crops, such as alfalfa, contaminate others through insect pollination, other crops contaminate in different ways.<sup>344</sup> Oversight must account for an ever-changing and emerging

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336. See Rong et al., *supra* note 334, at 459, 462.

337. See *supra* Part III.D.

338. See Declaration of Doug Gurian-Sherman, *supra* note 176, ¶¶ 64-65.

339. See generally Peck, *supra* note 257, at 265-67 (discussing the potential for GM resistant weeds).

340. See Artuso, *supra* note 335, at 131-32; Jonathan Gressel, *Needs for and Environmental Risks from Transgenic Crops in the Developing World*, 27 NEW BIOTECHNOLOGY J., No. 5, 522, 523 (2010); Rong et al., *supra* note 334, at 455; Takayoshi Shimazaki et al., *Establishment of a Homogenized Method for Environmental Biosafety Assessments of Transgenic Plants*, 26 PLANT BIOTECHNOLOGY 143, 143-44 (2009).

341. See Declaration of Doug Gurian-Sherman, *supra* note 176, ¶¶ 64-65.

342. See generally *id.* (comparing the effects of increasing distance between planted GM crops and non-GM crops).

343. See *id.*

344. See Peck, *supra* note 257, at 272.

science that will undoubtedly present novel challenges on a regular basis.<sup>345</sup> Therefore, regulatory reform must continue beyond the initial evaluation.

### C. Regulatory Reform in Practice

While statutory guidelines, such as the categorical requirement of a full EIS evaluation for all GM crops, would better equip evaluators in safely releasing new GM crops, regulatory reform must also include meaningful regulation in practice.<sup>346</sup> Once released on the market, the APHIS has deregulated products without any continued supervision to address risks such as cross-contamination.<sup>347</sup> The APHIS must ensure that it not only protects both the interests of the agriculture biotechnology industry but also the interests of the organic and conventional agriculture industry. In order to effectively protect organic seed, the APHIS must enforce isolation between GM crops that could potentially contaminate a conventional or organic crop. As experts testified in the *Geertson Seed Farms* case that a scientifically agreed distance between crops to prevent contamination lies around two to five miles, the unique concerns of each new GM crop should dictate the required isolation distance.<sup>348</sup> For instance, bees pollinate and cross contaminate alfalfa, requiring the crop-specific assessment of bee traveling tendencies for the possibility of cross-contamination through pollination.<sup>349</sup>

In Texas, however, where cotton covers more fields than any other crop, cross pollination is likely less of a concern than mishandling.<sup>350</sup> Recent studies confirm that the greatest culprit of cotton cross-contamination is indeed human error in handling seed.<sup>351</sup> The APHIS's responsibility to protect conventional cotton growers would lie in closer supervision and testing requirements in seed distribution. This duty proves especially relevant considering Monsanto's history of filing patent infringement lawsuits against farmers who find themselves with GM contaminated crops for unknown reasons.<sup>352</sup> Therefore, when the APHIS assumes regulatory supervision of GM crops, its duty lies not only with GM growers, but also with organic and conventional growers. Continued

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345. *See id.* at 265.

346. *See supra* notes 180-82.

347. *See supra* Part III.C.

348. *See* Declaration of Doug Gurian-Sherman, *supra* note 176, ¶¶ 13, 64-65.

349. *See id.*

350. *See* Shannon Heuberger et al., *Pollen- and Seed-Mediated Transgene Flow in Commercial Cotton Seed Production Fields*, 5 PLOS ONE, No. 11, 7, 7-8 (2010), available at <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0014128> (finding that mishandling accounts for far more cross-contamination from GM cotton to conventional cotton than pollination).

351. *See id.* (discussing that while some pollination-caused cross-contamination occurs, its prevalence is only one percent at field edges).

352. *See supra* Part II.D.

supervision of GM crops must ensure that the unique concerns of contamination potential, as diverse as seed handling and isolation, are both addressed.

## VI. CONCLUSION

The United States has voluntarily assumed the role of world biotechnology leader.<sup>353</sup> The reported justifications of biotechnology growth in meeting the growing population needs are real and quickly approaching.<sup>354</sup> It is, therefore, even more urgent that the United States no longer skirt the issue the rest of the world has identified: meaningful biotechnology regulation.<sup>355</sup> Realistically, it is unlikely the booming biotechnology industry would meet more structured regulation with little resistance. Monsanto, for one, has proven itself as a mighty force in Washington, lobbying heavily against regulation and successfully planting its own employees in federal positions of power.<sup>356</sup> Regardless, the industry as a whole should step up for its less powerful constituents, the conventional and organic growers, and demand that GM crops only arrive on the market after sufficient environmental evaluation.<sup>357</sup> By sacrificing the cost of the time and expense needed to better assess the risks of GM crops, the industry as a whole can move toward the future with sound confidence and security that it is equipped to deal with the risks while still enjoying the benefits of genetic modification.

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353. See *supra* Part II.

354. See *supra* Parts I, II.

355. See *supra* Part II.C-D.

356. *Monsanto, A Corporate Profile*, CORPORATE WATCH, <http://www.corporatewatch.org/?lid=209> (last visited Feb. 1, 2012) (documenting the “revolving door” between Monsanto employees and officials from U.S. government regulatory bodies, such as the former lobbyist for Monsanto, Michael Taylor, who was appointed as the FDA administrator).

357. See *supra* Part IV.