



Spring 3-1-2010

## Statutory Stones and Regulatory Mortar: Using Negligence Per Se to Mend the Wall Between Farmers Growing Genetically Engineered Crops and Their Neighbors

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### Recommended Citation

Joshua B. Cannon, *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 (2010).

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# Statutory Stones and Regulatory Mortar: Using Negligence Per Se to Mend the Wall Between Farmers Growing Genetically Engineered Crops and Their Neighbors

Joshua B. Cannon \*

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### I. Introduction

In his 1914 poem *Mending Wall*, Robert Frost questions the wisdom of the adage "good fences make good neighbors."<sup>1</sup> The speaker in the poem tells the

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1. Robert Frost, *Mending Wall*, in *THE POETRY OF ROBERT FROST: THE COLLECTED POEMS, COMPLETE AND UNABRIDGED* 33, 33 (Edward C. Lathem ed., 1979). The poem states:

Something there is that doesn't love a wall,  
 That sends the frozen-ground-swell under it,  
 And spills the upper boulders in the sun,  
 And makes gaps even two can pass abreast.  
 The work of hunters is another thing:  
 I have come after them and made repair  
 Where they have left not one stone on a stone,  
 But they would have the rabbit out of hiding,  
 To please the yelping dogs. The gaps I mean,  
 No one has seen them made or heard them made,  
 But at spring mending-time we find them there.  
 I let my neighbor know beyond the hill;  
 And on a day we meet to walk the line  
 And set the wall between us once again.  
 We keep the wall between us as we go.  
 To each the boulders that have fallen to each.  
 And some are loaves and some so nearly balls  
 We have to use a spell to make them balance:  
 "Stay where you are until our backs are turned!"  
 We wear our fingers rough with handling them.  
 Oh, just another kind of out-door game,  
 One on a side. It comes to little more:  
 There where it is we do not need the wall:  
 He is all pine and I am apple orchard.  
 My apple trees will never get across  
 And eat the cones under his pines, I tell him.  
 He only says, 'Good fences make good neighbors.'  
 Spring is the mischief in me, and I wonder  
 If I could put a notion in his head:  
 "Why do they make good neighbors? Isn't it  
 Where there are cows?  
 But here there are no cows.  
 Before I built a wall I'd ask to know  
 What I was walling in or walling out,  
 And to whom I was like to give offence.  
 Something there is that doesn't love a wall,

tale of a yearly ritual, performed by him and his neighbor, of restoring a wall between his apple orchard on one side, and the neighbor's pine grove on the other.<sup>2</sup> Questioning the need for the wall, the speaker comments that his apples will not cross to eat the pinecones beneath his neighbor's trees.<sup>3</sup>

But what if one farmer's crops *could* harm those of her neighbor? Would a fence be in order? If so, what would that fence look like? The reality in today's agricultural world is that there are, indeed, situations where crops can cause harm beyond the boundaries of the fields in which they are grown.<sup>4</sup> This Note takes an example of such a harm—gene flow from genetically engineered (GE)<sup>5</sup> crops to organic or conventionally bred crops—and proposes one type of fence that could be employed to help demarcate the limits of the responsibility that growers of GE crops have to their neighbors. This legal fence would assist such growers in keeping their transgenes safely corralled, and facilitate restitution if the transgenes escape and cause harm. Ideally, it would be the type of boundary that does, indeed, good neighbors make.

#### A. The Gene Flow Problem

Increased specialization in crops and reduced tolerances for genetic variation in general, and for transgenic material in particular, have led to a greater need to segregate GE crops from their conventionally bred and organic counterparts.<sup>6</sup> The entire value of a farmer's crop may depend on the ability to

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That wants it down." I could say "Elves" to him,  
 But it's not elves exactly, and I'd rather  
 He said it for himself. I see him there  
 Bringing a stone grasped firmly by the top  
 In each hand, like an old-stone savage armed.  
 He moves in darkness as it seems to me~  
 Not of woods only and the shade of trees.  
 He will not go behind his father's saying,  
 And he likes having thought of it so well  
 He says again, "Good fences make good neighbors."

*Id.*

2. *Id.*

3. *Id.*

4. See *infra* Part I.A. (discussing the potential harms associated with gene movement).

5. The terms "genetically engineered" (GE) and "genetically modified" (GM) are both used to refer to organisms that have been developed through transgenic technology. For consistency in this Note I will use GE when discussing such organisms.

6. See A. Bryan Endres, *Coexistence Strategies, The Common Law of Biotechnology and*

ensure its genetic purity.<sup>7</sup> The adventitious presence of undesirable genetic material, such as DNA derived from GE technology, can result in rejection or destruction of crops or products made from them.<sup>8</sup>

At the same time that tolerances for GE traits have been tightening, GE crop production has been expanding.<sup>9</sup> As GE crop production has increased, it has become clear that the agricultural industry in the United States is not prepared to keep GE crops separate from conventional or organic crops.<sup>10</sup> The statutes and regulations dealing with GE crops have failed to prevent contamination of non-GE crops or to provide adequate remedies for those who have been harmed by such contamination.<sup>11</sup>

### *B. Negligence Per Se as a Possible Solution*

One possible approach to dealing with the problem of GE contamination is to provide civil remedies for harms caused when transgenes end up where they are not supposed to be.<sup>12</sup> A number of traditional tort theories have been

*Economic Liability Risks*, 13 DRAKE J. AGRIC. L. 115, 127–28 (2008) (discussing various sources of the need for crop segregation, including the market-based demands for GE-free foods, regulatory requirements intended to protect health and environment, and segregation of exclusively domestic crops from export crops, necessitated by trade partners' refusal to accept U.S. crops unless segregation standards were enacted).

7. See Richard A. Repp, Comment, *Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift*, 36 IDAHO L. REV. 585, 591 (2000) (giving an example of organic products that were rejected and destroyed after DNA testing revealed that the corn they contained had been contaminated with GE corn, probably through pollination from adjacent GE corn fields).

8. *Id.*

9. See Gregory N. Mandel, *The Future of Biotechnology Litigation and Adjudication*, 23 PACE ENVTL. L. REV. 83, 88–89 (2006) (discussing the rapid acceptance and deployment of GE crops and the coinciding backlash against these technologies).

10. See Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 633 (2003) ("[U]nder the current system co-mingling of these crops, either by design or inadvertence, is inevitable. A crisis is waiting to happen."); Gregory N. Mandel, *History Lessons for a General Theory of Law and Technology*, 8 MINN. J. L. SCI. & TECH. 551, 568 (2007) (stating that anyone with a working knowledge of grain handling and distribution in the United States would know that it was inevitable that GE crops would be mixed with conventional crops).

11. See Bratspies, *supra* note 10, at 615 (describing the "gaping holes in [the] regulatory regime for [GE] crops," which result from trying to force new problems posed by biotechnology into answers provided by statutes and regulations that were written before the advent of GE crops).

12. See Thomas Connor, Comment, *Genetically Modified Torts: Enlisting the Tort System to Regulate Agricultural Contamination by Biotech Crops*, 75 U. CIN. L. REV. 1187, 1214–15 (2007) (suggesting that the civil tort system, in conjunction with proper regulations,

suggested as potential ways to address the problem.<sup>13</sup> The virtues of applying many of these tort theories have been explored fairly extensively in the literature.<sup>14</sup> This Note will examine the use of negligence per se, or statutory negligence, as a theory of tort liability. With appropriately written regulations, negligence per se could provide an effective means to protect farmers whose crops are contaminated with GE material. The predictability of statutory or regulatory standards of care would also benefit GE growers. If the standards are definite enough and GE growers know that the courts will base their evaluations of reasonable conduct on those standards, the growers will be more free to pursue their occupation because they will know more precisely what is expected of them.

Part II of this Note will lay out some background information about GE crops and the phenomenon of gene flow. Part III will then discuss GE regulations and case law involving gene flow, followed by a discussion of negligence per se and why it would be an appropriate theory for recovery in tort for damages caused by wandering genes. Finally, Part IV will consider the allocation of civil remedies between the federal and state governments, and will provide some principles that could make the regulatory framework more amenable to use in establishing duties of care. This discussion will include some examples of crop characteristics and gene traits and how regulations might take into account differing biological and agronomic characteristics.

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might provide the best way to regulate GE growers' activities). Regarding traditional tort causes of action as applied to GE crop-related disputes, Connor says: "These unintentional torts are well-matched to the nature of potential disputes because they provide causes of action specifically developed for disputes over land use and product-related injuries." *Id.* at 1211. Other commentators have suggested different strategies, including strict regulatory compliance oversight and even criminal sanctions. *See* Bratspies, *supra* note 10, at 649 (advocating for a new regulatory structure that would require agencies to monitor compliance in the growing and processing of GE crops); Marcia Ellen Degeer, Comment, *Can Roundup Ready Seeds Ever Be Corralled?: Restraining Genetic Drift Through Criminal Sanctions*, 29 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 255, 261 (2003) ("The lack of a comprehensive regulatory system for GE plants and the lack of legal recourse invites the proposal of a statute that regulates GE farmers and imposes criminal sanctions for the spread of GE plants.").

13. *See* Connor, *supra* note 12, at 1201 ("Several torts could apply to disputes arising when one farmer's crop contaminates another farmer's crop. These include negligence, private nuisance, public nuisance, trespass, and products liability.").

14. *See generally id.*; Mandel, *supra* note 9; Katherine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645 (2004).

## II. Background of Genetically Engineered Crops

People have been genetically modifying crops for thousands of years.<sup>15</sup> This was accomplished first by selection and later by intentionally crossing sexually compatible plants to increase the frequency of desirable traits or to decrease the frequency of undesirable traits.<sup>16</sup> The requirement of natural sexual compatibility limited the pool of available genetic traits to those found in closely related plants.<sup>17</sup> Modern biotechnology allows for the incorporation of genes from disparate organisms.<sup>18</sup> No longer are crop developers limited to the genetic material present in different varieties within the same species; genes can be incorporated from other genera, families, and even kingdoms of living organisms.<sup>19</sup> Plants that have their genetic makeup altered through transgenic biotechnology are often referred to as GE.<sup>20</sup>

Although the technology for producing GE crops was developed in the 1970s, the first commercial GE plant variety was not released until 1994.<sup>21</sup> Despite the relatively recent advent of GE crops in agriculture, farmers have adopted these technologies rapidly and GE crops now comprise a significant portion of crops planted, especially in the United States.<sup>22</sup> The United States Department of Agriculture (USDA) reported that in 2008, GE crops accounted

15. See ROBERT W. ALLARD, *PRINCIPLES OF PLANT BREEDING* 9 (1960) (discussing evidence of early plant breeding, including corn breeding in New Mexico between 2500 BC and 500 AD). See generally DESMOND S. T. NICHOLL, *AN INTRODUCTION TO GENETIC ENGINEERING* (1994) (describing the history of plant breeding).

16. See MAARTEN J. CHRISPEELS & DAVID E. SADAVA, *PLANTS, GENES, AND AGRICULTURE* 273, 280–82 (1994) (discussing the early process of selection and the later advent of intentional crosses to improve crop varieties).

17. See JANE RISSLER & MARGARET MELLON, *THE ECOLOGICAL RISKS OF ENGINEERED CROPS* 4 (1996) (stating that the pool of genetic material available to traditional breeders is limited to that found in species that are sexually compatible with the crop plant).

18. See *id.* at 9–11 (discussing the increased pool of genes available to genetic engineers).

19. See *id.* at 10–11 (giving examples of gene transfers involving different taxonomic kingdoms).

20. 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, 14 (Nigel G. Halford ed., 2006) (defining the terms "genetically engineered" and "genetically modified").

21. See *id.* at 13–15 (explaining the history of genetic engineering technology and the development of the earliest GE crop varieties). The Flavr-Savr tomato was the first commercially available GE variety in the United States. *Id.* at 15. It was deregulated in 1994 and went into commercial production in 1996. *Id.* at 14–15.

22. See Sujatha Sankula, *Crop Biotechnology in the United States: Experiences and Impacts*, in *PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS*, *supra* note 20, at 28, 28–29 (describing the rapid adoption of GE crops in the United States).

for 92% of soybeans, 86% of cotton, and 80% of corn grown in the United States.<sup>23</sup>

Proponents of biotechnology point to the tremendous advantages GE crops can offer over traditionally bred crops.<sup>24</sup> Plant breeders and developers now have a wider range of traits from which to choose to improve the agronomic, processing, and end-use properties of their crop varieties.<sup>25</sup> The genetic engineering of crops can increase crop yields,<sup>26</sup> improve the nutritional value of food,<sup>27</sup> reduce reliance on harmful pesticides,<sup>28</sup> and decrease the need for tillage, which can harm soil health.<sup>29</sup> GE crops also have great potential for use in the development and production of plastics, biofuels,<sup>30</sup> and pharmaceuticals, such as vaccines.<sup>31</sup>

Critics, however, worry that GE crops are insufficiently tested and that there is too much uncertainty about the effects they might have on human health, the environment, and genetic diversity.<sup>32</sup> Opponents of GE crops fear

23. NATIONAL AGRICULTURAL STATISTICS SERVICE, 2008 ACREAGE REPORT 24–25 (2008), available at <http://usda.mannlib.cornell.edu/usda/nass/Acre/2000s/2008/Acre-06-30-2008.pdf> (listing the amounts of biotech crops grown as a percentage of the total of certain crops).

24. See, e.g., Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 47 (2001) ("[B]iotechnology applications have the potential to alleviate some of the most pressing problems facing the global community, as well as to reduce dramatically human suffering and to improve the quality of life, particularly in the developing world.").

25. See NORMAN C. ELLSTRAND, DANGEROUS LIAISONS? WHEN CULTIVATED PLANTS MATE WITH THEIR WILD RELATIVES 175 (2003) (listing three major types of transgenic phenotypes that have been expressed in GE crops: agronomic traits, quality traits, and traits allowing plants to serve as biochemical factories).

26. See *id.* (stating that agronomic traits have been engineered into crops to directly or indirectly increase crop yields).

27. See Dietrich Rein & Karin Herbers, *Enhanced Nutritional Value of Food Crops*, in PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS, *supra* note 20, at 91, 110 ("[I]t can be concluded that GM crops in general offer the opportunity to enrich components with proven health benefits and thereby improve specific food compositions.").

28. See C. NEIL STEWART, JR., GENETICALLY MODIFIED PLANET: ENVIRONMENTAL IMPACTS OF GENETICALLY ENGINEERED PLANTS 195 (2004) (discussing the environmental benefits of GE crop use, including reduced pesticide use).

29. See *id.* (stating that herbicide tolerant crops encourage no-till agriculture, which results in reduced soil erosion).

30. See *id.* at 206–07 (describing the application of GE crops in producing renewable, biodegradable plastics, as well as alternatives to petroleum for energy production).

31. See Liz Nicholson et al., *Production of Vaccines in GM Plants*, in PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS, *supra* note 20, at 164, 164 (discussing the possibilities and advantages of using GE plants to produce proteins used in vaccines).

32. See STEWART, *supra* note 28, at 63–64 (discussing concerns about the potential loss of genetic diversity due to gene flow from GE crops); Daniel Schramm, Note, *The Race to Geneva*:



that GE technology will introduce new allergens into the food chain.<sup>33</sup> Some also point to the inability to segregate GE crops from conventional crops as a possible concern.<sup>34</sup> If GE and conventional crops cannot be separated effectively in transportation and processing, the argument goes, there is no way to ensure that crops producing potentially harmful components, such as pharmaceutical agents, do not end up in the food supply.<sup>35</sup>

GE crops have also garnered considerable opposition due to concerns about their potential environmental impacts.<sup>36</sup> At least one opponent of GE technology has gone so far as to suggest that it will "spell the end of humanity as we know it and the end of the world at large."<sup>37</sup>

Of particular concern is the phenomenon of gene flow.<sup>38</sup> Gene flow is the "successful incorporation of genes from one population into another."<sup>39</sup> Gene

*Resisting the Gravitational Pull of the WTO in the GMO Labeling Controversy*, 9 VT. J. ENVTL. L. 93, 98–99 (2007) ("[T]he very newness of [genetically modified organism] technology has sparked both political and scientific controversies over their use. Environmentalists, farmers' advocates, and others opposed to the use of GMO technology have based their criticism on the potential threats GMOs pose to human health and the environment . . .").

33. See Clare Mills, John A. Jenkins & Peter R. Shewry, *Plant Food Allergens*, in PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS, *supra* note 20, at 243, 254 (mentioning the concern that GE technology will result in introduction of allergens into the food supply, but stating that risk assessment procedures exist that would make this unlikely).

34. See Endres, *supra* note 6, at 123 ("The EPA's current precautionary approach . . . recognizes the impossibility of complete segregation in the existing commodity production/distribution system—an approach unlikely to change until the food supply chain (from farm to fork) improves its segregation capabilities."). The issue of segregation of GE and non-GE crops plays an important role in some of the major cases and will be discussed below. See *infra* Part III.B–C.

35. See Rebecca M. Bratspies, *Consuming (F)ears of Corn: Public Health and Biopharming*, 30 AM. J.L. & MED. 371, 373 (2004) ("Contamination of food crops with non-food, biopharm compounds is a serious threat to human safety and could result in rapid dissemination of non-food pharmaceutical or industrial compounds through the world food supply.").

36. See RISSLER & MELLON, *supra* note 17, at 22–24 (discussing the potential environmental effects of transgenic crops); see also P.J.W. Lutman & K. Berry, *Environmental Impact and Gene Flow*, in PLANT BIOTECHNOLOGY: CURRENT AND FUTURE APPLICATIONS OF GENETICALLY MODIFIED CROPS, *supra* note 20, at 265, 266 (discussing the different types of environmental impacts GE crops can have).

37. See STEWART, *supra* note 28, at 4 (quoting Dr. Mae-Wan Ho, a geneticist and outspoken critic of GE technology, regarding genetic engineering biotechnology). This is, of course, an extreme example, but it illustrates the strong views held by some on the issue.

38. See ELLSTRAND, *supra* note 25, at 171 ("[A]lmost every general treatment of the environmental impacts of plant biotechnology gives some consideration to gene flow." (citations omitted)).

39. *Id.* at 27.

flow can occur through pollen movement, seed dispersal, or movement of vegetative propagules.<sup>40</sup> The result is that genes may end up where they were never intended. As hard as it is to predict the effects transgenes will have in their desired environments, it is extremely difficult, if not impossible, to predict how they will behave in unintended contexts.<sup>41</sup> Furthermore, according to GE skeptics, unlike many pollutants, which have half-lives and eventually dissipate, once genes are introduced into ecosystems, they cannot be recalled.<sup>42</sup>

Gene flow is not unique to GE crops.<sup>43</sup> There is strong evidence supporting the notion that gene flow between crops and other plant populations is the rule and not the exception.<sup>44</sup> A documented example of gene flow between conventionally bred crops and weeds is that of grain sorghum and Johnson grass.<sup>45</sup> Sorghum and Johnson grass are related species that can hybridize fairly easily in normal field conditions.<sup>46</sup> As sorghum genes are introgressed into Johnson grass populations, efforts to improve sorghum indirectly resulted in weedier Johnson grass that was harder to control.<sup>47</sup> Johnson grass is now "considered to be one of the world's worst weeds."<sup>48</sup>

Although gene flow occurs in many conventionally bred crops, GE crops may create some special problems when the genes that move are transgenes.<sup>49</sup> Depending on the trait expressed by the GE crop, it may be more or less likely to hybridize than its conventionally bred counterparts.<sup>50</sup> The specific genes

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40. See *id.* (listing the various media of gene flow in plants).

41. See M.A. Althieri, *The Ecological Impacts of Transgenic Crops on Agroecosystem Health*, 6 ECOSYSTEM HEALTH 13, 16 (2000) (discussing the unpredictability of transgene stability and expression in ecosystems).

42. See STEWART, *supra* note 28, at 7 ("The prevailing belief among skeptics is that once GM plants are released into the environment, the plants or genes can never be recalled.").

43. See Carol Mallory-Smith & Maria Zapiola, *Gene Flow from Glyphosate-Resistant Crops*, 64 PEST MGMT. SCI. 428, 428 (2008) ("Gene flow is a natural phenomenon that is not unique to GE Crops.").

44. See ELLSTRAND, *supra* note 25, at 124 (stating that gene flow is more common than it was once believed to be and presenting evidence to support this claim). One view of gene flow with a sound basis is that crops belong to a crop-weed-wild complex in which hybridization occurs sporadically. *Id.* at 119.

45. See *id.* at 88–89 (discussing the hybridization of sorghum with its wild relatives).

46. See *id.* at 89 (stating that hybridization can occur between the two species, even though sorghum is a diploid and Johnson grass is an allotetraploid).

47. See *id.* ("[I]ntrogression from crop sorghum has been implicated in the evolution of enhanced weediness in [Johnson grass] in North America, South Asia, and elsewhere." (citations omitted)).

48. *Id.* (citations omitted).

49. See *id.* at 171–72 (discussing the possibility that GE crops pose special problems with regard to gene flow that conventional crops do not).

50. See *id.* at 176 (stating that some traits may intentionally or unintentionally affect a GE

present in GE crops may also code for proteins that would themselves present environmental risks.<sup>51</sup>

In addition to the heightened environmental concerns, there are economic concerns that may attend gene flow from GE crops—economic concerns that are not present, or are present only to a lesser extent, with conventional crops.<sup>52</sup> For example, if organic certification allows zero tolerance for the presence of transgenes, regardless of how they found their way into the crop, any amount of transgenic material detected in the crops precludes marketability as organic—and may completely preclude its marketability in some markets.<sup>53</sup> Similarly, a grower of conventional crops who acquires transgenes through gene flow might lose the ability to sell to markets that have limited or no tolerance for GE crops.<sup>54</sup>

### III. Gene Flow and the Law

#### A. Regulation of GE Crops

To understand how negligence per se could be a useful tool in dealing with the problem of damages caused by gene flow, it is helpful to look first at how GE crops and their products are regulated. In the United States, GE crops are regulated primarily by three federal agencies: the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).<sup>55</sup> The Coordinated Framework for the Regulation of Biotechnology<sup>56</sup> sets out the responsibilities

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crop's ability to hybridize).

51. See *id.* at 183–84 (giving the example of moth-resistant GE corn that might emit insecticidal pollen, which could harm insect populations and upset ecosystems).

52. See Repp, *supra* note 7, at 593 ("The U.S. grain industry has lost virtually all of the \$200 million annual export market for sale of corn to the EU . . . as a result of EU regulations restricting the import of GM corn, [and] the inability of the U.S. to prevent intermixing . . .").

53. See Lutman & Berry, *supra* note 36, at 276–77 (discussing the various existing and proposed thresholds for GE crops in organic and unlabeled conventional foods in Europe and the United Kingdom).

54. See Repp, *supra* note 7, at 591 (describing a case where a Texas farmer had an entire shipment of corn chips rejected and destroyed when traces of GE corn DNA were found in the chips).

55. See Wendy Thai, *Transgenic Crops: The Good, the Bad, and the Laws*, 6 MINN. J. L. SCI. & TECH. 877, 885 (2005) (listing the agencies responsible for regulating GE crops).

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

of these three agencies with regard to GE crops.<sup>57</sup> The purpose of the Coordinated Framework was to create a "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products."<sup>58</sup> The drafters of the Coordinated Framework believed that there was a sufficient network of agency control under existing statutes to regulate effectively new organisms created by GE technology.<sup>59</sup>

Under the Coordinated Framework, the FDA regulates food safety aspects of GE crops.<sup>60</sup> The Federal Food, Drug, and Cosmetics Act (FFDCA)<sup>61</sup> gives the FDA the authority to remove unsafe or adulterated foods from the marketplace, and to approve food additives.<sup>62</sup> Adulterated foods are those that contain poisonous or deleterious substances, including pesticides.<sup>63</sup> The term adulterated has been applied to foods that contain material from GE crops that were not approved for human consumption.<sup>64</sup> Any food additive must be approved by the FDA unless it is generally recognized as safe (GRAS).<sup>65</sup> A

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57. See VICTORIA SUTTON, *LAW AND BIOTECHNOLOGY* 35–36 (2007) (discussing the history of the Coordinated Framework).

58. Coordinated Framework for Regulation of Biotechnology, *supra* note 56, at 23,302.

59. See SUTTON, *supra* note 57, at 35 (stating that the belief of the Executive Branch was that no new statutory authority was needed to regulate biotechnology). The White House reaffirmed the position that no new statutory authority was required when the White House Office of Science and Technology Policy issued its Principles of Federal Oversight of Biotechnology in 1991. See Principles of Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. at 31,118 (July 31, 1990) (stating that the Coordinated Framework "determined that existing statutes provide a basic network of agency jurisdiction over both research and products assuring reasonable safeguards for the public").

60. See Coordinated Framework for Regulation of Biotechnology, *supra* note 56, at 23,304 ("Jurisdiction over the varied biotechnology products is determined by their use, as has been the case with traditional products. . . . Foods, food additives, human drugs, biologics and devices, and animal drugs are reviewed or licensed by the FDA.").

61. See Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. (2006) (prohibiting the introduction into interstate commerce of adulterated foods, including foods adulterated with pesticides).

62. 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, 2218 (2004) (stating that, while there is no statutory provision or FDA regulation specifically covering GE crops and their derivatives, FDA regulates GE foods in the same way, and under the same authority, that it regulates conventional food).

63. See 21 U.S.C. § 342 (2006) ("A food shall be deemed to be adulterated . . . [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health . . .").

64. See, e.g., *In re Starlink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d 828, 835 (N.D. Ill. 2002) (stating that the FDA has declared StarLink, a GE variety of corn, to be an adulterant).

65. See 21 U.S.C. § 348 (2006) (setting forth the requirements for non-GRAS food additives to be considered safe).

food additive is a substance "the intended use of which results or may reasonably be expected to result . . . in its becoming a component or otherwise affecting the characteristics of any food."<sup>66</sup> This definition is broad enough to include genes inserted into GE crops and the compounds for which those genes code.<sup>67</sup> However, the FDA has treated most GE food products as GRAS and therefore not subject to regulation as food additives under the FFDCA.<sup>68</sup>

The EPA, in accordance with its authority to regulate pesticides under the Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA)<sup>69</sup> and the FFDCA,<sup>70</sup> is responsible for regulating plant-incorporated protectants (PIPs).<sup>71</sup> The EPA defines a PIP as "a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance."<sup>72</sup> Only PIPs derived from GE technology are subject to regulation under FIFRA.<sup>73</sup> The EPA requires extensive studies, and evaluates potential environmental risks, including those associated with gene flow, when considering the release of GE PIPs.<sup>74</sup>

The USDA regulates GE crops that could be potential plant pests.<sup>75</sup> A plant pest is any living organism "that can directly or indirectly injure, cause damage to,

66. *Id.* § 321(s).

67. *See* Mandel, *supra* note 62, at 2218–19 (discussing the regulation of GE crops as food additives under the FFDCA).

68. *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992) ("In most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food . . .").

69. *See* Federal Insecticide, Rodenticide, and Fungicide Act, 7 U.S.C. § 136 et seq. (2006) (prohibiting the distribution or sale of unregistered pesticides).

70. *See supra* note 61 (defining the FFDCA and providing its citation information).

71. *See* Procedures and Requirements for Plant-Incorporated Protectants, 40 C.F.R. § 174.1 (2009) (stating that plant-incorporated protectants are subject to some different regulations than conventional pesticides, but they are still subject to regulation under FIFRA and FFDCA).

72. Pesticide Registration and Classification Procedures, 4 C.F.R. § 152.3 (2009).

73. *See id.* § 174.25 (stating that PIPs are exempt from regulation if the genetic material that codes for the pesticidal substance came from a sexually compatible plant and was never derived from an organism that is not sexually compatible with the recipient plant).

74. *See* Plant Incorporated Protectants, <http://www.epa.gov/pesticides/biopesticides/pips/index.htm> (last visited Mar. 22, 2010) ("When assessing the potential risks of genetically engineered plant-incorporated protectants, the EPA requires extensive studies examining numerous factors, such as risks to human health, nontarget organisms and the environment, potential for gene flow, and the need for insect resistance management plans.") (on file with the Washington and Lee Law Review).

75. *See* Restrictions on the Introduction of Regulated Articles, 7 C.F.R. § 340 n.1 (2009) ("Part 340 regulates, among other things, the introduction of organisms and products altered or

or cause disease in any plant or plant product."<sup>76</sup> The branch of the USDA that fulfills this regulatory role is the Animal and Plant Health Inspection Service (APHIS).<sup>77</sup> APHIS regulates the introduction of GE crops under the Plant Protection Act (PPA),<sup>78</sup> which gives the USDA a mandate to protect agriculture from pests and diseases.<sup>79</sup> This protection includes preventing harmful gene flow from GE crops.<sup>80</sup> All GE crops are presumed to be plant pests, and thus "regulated articles"<sup>81</sup> until they are proven otherwise.<sup>82</sup> Because of this, APHIS has permitting and notification procedures for field testing of new GE varieties.<sup>83</sup>

Some regulated articles can be released for testing without a permit through a notification procedure.<sup>84</sup> To be eligible for introduction under the notification procedure, a GE crop must meet the following criteria: (1) the plant must not be a noxious weed, (2) the introduced genetic material must be integrated stably, and (3) the function of the introduced genetic material must be known and its

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produced through genetic engineering that are plant pests or are believed to be plant pests.").

76. Plant Protection Act § 403, 7 U.S.C. § 7702 (2006).

77. See Thai, *supra* note 55, at 888 (describing the role of APHIS in the regulation of GE crops).

78. See 7 U.S.C. §§ 7701–7786 et seq. (2006) (authorizing the USDA to undertake action to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests and noxious weeds).

79. See BRS Factsheet, U.S. Dep't of Agric., APHIS Biotechnology: Permitting Progress Into Tomorrow, at 1 (Feb. 2006), [http://www.aphis.usda.gov/publications/biotechnology/content/printable\\_version/BRS\\_FS\\_permitprogress\\_02-06.pdf](http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/BRS_FS_permitprogress_02-06.pdf) [hereinafter BRS Factsheet] (last visited Mar. 22, 2010) (giving the statutory authority for APHIS's regulation of GE crops) (on file with the Washington and Lee Law Review). The Biotechnology Regulatory Services (BRS) is the branch of APHIS that regulated the introduction of GE organisms.

80. See Thai, *supra* note 55, at 888 (discussing the role the USDA plays in regulating GE plants and their products).

81. See 7 C.F.R. § 340.1 (2009) (defining regulated articles). Regulated article is defined as:

Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated [as a plant pest] and meets the definition of plant pest . . . or any other organism or product altered or produced through genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest.

*Id.*

82. See Thai, *supra* note 55, at 888 ("A transgenic plant is assumed to be a plant pest until proven otherwise.").

83. See BRS Factsheet, *supra* note 79, at 2–3 (describing the processes of permitting and notification and the requirements for each).

84. See Notification for the Introduction of Certain Regulated Articles, 7 C.F.R. § 340.3 (2008) (setting forth the conditions under which a regulated article may be introduced without a permit).

expression must not result in plant disease or the production of infectious, toxic, pharmaceutical, or industrial material.<sup>85</sup> If the GE crop meets these criteria and the producer follows certain performance guidelines to prevent the escape and persistence of the crop, the crop may be introduced.<sup>86</sup> The producer is only required to notify APHIS and provide certain information about the crop.<sup>87</sup>

To move, import, or field test a regulated article that does not qualify for, or is denied the notification procedure, a permit is required.<sup>88</sup> Permits are always required and the permitting process is more involved for pharmaceutical-producing plants.<sup>89</sup> The purpose of the permitting process is to prevent the dissemination of the regulated article until it can be evaluated under field conditions.<sup>90</sup>

After a period of field testing, GE crop developers can petition for nonregulatory status.<sup>91</sup> Upon application for deregulation, APHIS conducts an environmental assessment and opens the matter for public comment.<sup>92</sup> If APHIS decides that the crop is not a plant pest, it reaches a "finding of no significant impact" (FONSI), and the crop may be grown under less restrictive conditions.<sup>93</sup> Certain GE traits, such as the production of pharmaceutical agents, are always considered plant pests and are, therefore, subject to more intense regulation.<sup>94</sup> Once a GE crop is deregulated, it can be sold and grown like its conventionally bred counterparts.<sup>95</sup> APHIS may, however, bring any deregulated item back

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85. *Id.* § 340.3(b).

86. *Id.* § 340.3(a).

87. *Id.* § 340.3(d).

88. *See* Permits for the Introduction of a Regulated Article, 7 C.F.R. § 340.4 (2009) (stating the requirements for permitting a regulated article).

89. *See* BRS Factsheet, *supra* note 79, at 2 ("APHIS-BRS conducts a more comprehensive review of permit applications if they are used for GE plants that could have an elevated risk, such as plants that produce pharmaceutical or industrial compounds . . .").

90. *See id.* at 2-3 (providing that the permittee must comply with a list of conditions, and any other conditions deemed by the Administrator to be necessary to prevent dissemination); *see also* Mandel, *supra* note 62, at 2226 ("The primary emphasis of the permitting process is confinement.").

91. *See* BRS Factsheet, *supra* note 79, at 4 (stating that after a GE crop has been shown not to be a plant pest risk, the developer may petition for removal of the product from the list of regulated crops).

92. *See id.* (describing the process of deregulation).

93. *Id.*

94. *See* Thai, *supra* note 55, at 890 (stating that all pharmaceutical producing GE crops are considered by APHIS to be regulated articles and, therefore, subject to confinement procedures regardless of the stage of development).

95. *See* BRS Factsheet, *supra* note 79, at 4 ("Once BRS has granted a product nonregulatory status, the product may be freely moved and planted without the requirement of permits or other regulatory oversight by BRS.").

under regulation at any time if new information becomes available suggesting that it might be a plant pest.<sup>96</sup>

The problem is that, although a crop may pass the FDA's requirements for food safety (assuming it is a food crop), the EPA's environmental standards (assuming it is considered a PIP), and APHIS's requirements for deregulation, it may yet cause harm to other farmers through gene flow.<sup>97</sup> The types of harm that may occur simply are not contemplated by the regulations described above.<sup>98</sup> This was demonstrated clearly in *In re StarLink Corn Products Liability Litigation*,<sup>99</sup> a case discussed in detail below.

### B. *StarLink Corn*

In late 2000, StarLink corn, a GE variety not approved for human consumption, was detected in taco shells.<sup>100</sup> What ensued was one of the most well known GE food scares to date.<sup>101</sup> The incident illustrated many of the things that can go wrong with GE crops and highlighted the shortcomings of the regulatory framework in preventing the commingling of GE and conventional products.

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96. See *id.* (discussing re-listing of deregulated products).

97. See Mandel, *supra* note 62, at 2233–36 (discussing gaps in the regulatory framework of GE crops).

98. See *id.* at 2172 (stating that it is not surprising that there should be lapses in oversight of GE crops, considering that they are regulated pursuant to statutes passed decades before the technologies were developed).

99. See *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d 828, 852 (N.D. Ill. 2002) (granting defendant's motion to dismiss claims for conversion and violation of the North Carolina Unfair Trade Practices Act, but denying defendant's motion to dismiss claims of negligence per se, public nuisance, private nuisance and violations of the Tennessee Consumer Protection Act, and dismissing negligence and strict liability claims). In *StarLink*, corn farmers brought suit against the producer of a GE corn variety not approved for human consumption when that variety was found in food products throughout the country. *Id.* at 835. The plaintiffs claimed that they had been injured by the drop in prices and demand for corn due to contamination, which they alleged was caused by the defendant's failure to comply with the EPA's requirements regarding the distribution and production of the GE crop. *Id.* The plaintiffs brought several causes of action, including negligence, strict liability, nuisance, and conversion. *Id.* at 833. The defendant moved to dismiss the claims, arguing that FIFRA preempted the state law claims, that the economic loss doctrine prevented recovery, and that the plaintiffs failed to state a claim. *Id.* The defendant's motion was granted in part and denied in part. *Id.* at 852.

100. *Id.* at 835.

101. See Mandel, *supra* note 62, at 2203 (commenting on the significant attention garnered by the StarLink incident).



StarLink was a corn variety that carried a gene coding for a protein that is toxic to certain insect pests.<sup>102</sup> The protein, known as Cry9C, possessed some of the attributes of known human allergens, and as a result, StarLink had not been approved for human consumption.<sup>103</sup> The EPA approved StarLink for animal feed and industrial uses in 1998.<sup>104</sup> Despite its best efforts, Aventis CropScience, the company developing StarLink, was unable to obtain approval for StarLink as a human food.<sup>105</sup>

Because of the split approval, special restrictions were placed on the growing of StarLink to prevent it from mixing with corn destined for human consumption.<sup>106</sup> These restrictions included a 660-foot buffer zone that was required between any StarLink corn and conventional corn to prevent cross-pollination.<sup>107</sup> In addition, Aventis CropScience was required to inform growers of the special growing and handling restrictions required by the EPA.<sup>108</sup> The growers were then required to sign agreements stating that they

102. See *StarLink*, 212 F. Supp. 2d at 833–34 (describing the StarLink corn variety and the insecticidal protein it produced).

103. See *id.* at 834 (stating the reasons why the EPA denied Aventis CropScience's application for registration for human consumption).

104. See *id.* (discussing the EPA's decision to allow StarLink a limited registration for purposes such as animal feed, ethanol production and seed increase).

105. See Mandel, *supra* note 62, at 2203–04 (discussing the history of the EPA's actions regarding StarLink and Aventis CropScience's repeated attempts to acquire registration for human consumption).

106. See *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d 828, 834–35 (N.D. Ill. 2002) (listing the special conditions the EPA required of Aventis CropScience before granting the registration).

107. *Id.* at 834.

108. See *id.* at 834–35 (outlining the information and use requirements placed on Aventis CropScience pursuant to the StarLink registration). In 1999 the EPA agreed to expand the acreage limit of StarLink corn to 2.5 million if Aventis CropScience would do the following:

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

would abide by the EPA's requirements for planting, cultivation, and use of the product before they would be allowed to grow it.<sup>109</sup> In the twenty-nine-month period from May 1998 to October 2000, StarLink corn acreage increased from 10,000 acres to 350,000 acres.<sup>110</sup>

Despite the precautions enacted to prevent StarLink from getting into human food, in September of 2000, StarLink was discovered in Taco Bell taco shells, prompting Kraft Foods, the producer of the shells, to recall more than 2.5 million boxes of taco shells.<sup>111</sup> Taco Bell pulled all taco shells from all of its restaurants.<sup>112</sup> Several major food companies had to cease production at certain facilities because of contamination fears.<sup>113</sup> StarLink corn was eventually detected in a wide range of foods, resulting in the recall of over 300 products.<sup>114</sup>

After investigators detected StarLink in corn bound for Asia, Japan and Korea "terminated or substantially limited" shipments of U.S. corn.<sup>115</sup> These countries' refusal to accept any U.S. corn led to a reduction in exports, costing growers tens of millions of dollars.<sup>116</sup> The depressed demand caused corn prices to drop dramatically.<sup>117</sup>

Due to the widespread contamination, mills and production facilities were required to implement expensive tests to detect the presence of Cry9C.<sup>118</sup> The

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monitor compliance with the Grower Agreement.

*Id.*

109. See Mandel, *supra* note 62, at 2204 (discussing the requirement of signing a grower agreement as part of the registration of StarLink).

110. *StarLink*, 212 F. Supp. 2d at 834-35.

111. See Barnaby J. Feder, *Companies Act to Keep Bioengineered Corn Out of Food*, N.Y. TIMES, Sept. 27, 2000, at C2 (discussing the extent of the efforts in response to the StarLink contamination).

112. See Andrew Pollack, *Kraft Recalls Taco Shells with Bioengineered Corn*, N.Y. TIMES, Sept. 23, 2000, at C1 (stating that Taco Bell pulled all the taco shells from its restaurants even though it had not confirmed that the shells being pulled were contaminated with StarLink corn).

113. See Mandel, *supra* note 62, at 2204 ("Kellogg, ConAgra, and Archer Daniels Midland were all forced to stop production at certain plants because of concerns about StarLink contamination.").

114. See *id.* (describing the widespread nature of the StarLink corn contamination).

115. See *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d 828, 835 (N.D. Ill. 2002) ("South Korea, Japan and other foreign countries have terminated or substantially limited imports of U.S. corn.").

116. See Mandel, *supra* note 62, at 2205 (giving an example of the costs of the contamination borne by the growers of StarLink corn).

117. See *StarLink*, 212 F. Supp. 2d at 833 (stating the reasons the plaintiffs brought the suit against Aventis CropScience, including increased production costs and lower prices allegedly resulting from Aventis CropScience's actions).

118. *Id.* at 835.

FDA issued screening guidelines to help minimize the production of human food with StarLink in it.<sup>119</sup> These guidelines were in effect until 2008, when the FDA finally decided that StarLink had been removed sufficiently from the human food supply, rendering testing no longer necessary.<sup>120</sup>

In an effort to curtail the effects of the crisis, Aventis CropScience voluntarily withdrew its registration for StarLink and bought back all the StarLink corn produced in 2000.<sup>121</sup> The cost of the buyback was nearly \$100 million.<sup>122</sup> Although the exact costs of the StarLink contamination are not known, estimates range from \$100 million to over \$1 billion.<sup>123</sup>

After the contamination became public, there were a number of cases of individuals complaining of adverse reactions resulting from consuming taco shells.<sup>124</sup> However, the Centers for Disease Control (CDC) reported that there were no confirmed incidents of allergic reactions resulting from consumption of food containing Cry9C.<sup>125</sup> Although there were no adverse health effects, the incident demonstrated the inability of the agricultural commodity production and distribution networks to keep GE and conventional products separate.<sup>126</sup>

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119. See Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Availability, 66 Fed. Reg. 6,627, 6,628 (Jan. 22, 2001) (stating that the widespread presence of the Cry9C protein in human food products justified the implementation of screening at milling facilities, and outlining what those screenings should look like).

120. See Guidance for Industry on the Food and Drug Administration Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Withdrawal of Guidance, 73 Fed. Reg. 22,716, 22,717 (Apr. 25, 2008) (stating that the FDA was withdrawing its guidelines for the industry because of the release of the EPA's findings that the Cry9C protein no longer posed a threat to human health).

121. See Mandel, *supra* note 62, at 2205 (describing the steps that Aventis CropScience took to try to mitigate the harm caused by the contamination).

122. *Id.*

123. See Sheryl Lawrence, Comment, *What Would You Do with a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 *ECOLOGY L.Q.* 201, 273 (2007) (discussing estimates of the costs associated with the StarLink contamination).

124. See *id.* at 274 ("[T]here were mass reports of allergic reactions to the StarLink products following publication of the contamination . . .").

125. See Press Release, CDC Division of Media Relations, CDC Involvement in Investigating Adverse Health Effects Associated with Eating Corn Products Potentially Contaminated with the Cry9C Protein in StarLink Corn (June 13, 2001), <http://www.cdc.gov/media/pressrel/r010613a.htm> (last visited Mar. 22, 2010) (describing the CDC's investigation of possible adverse health effects among people who claimed to have had allergic reactions to potentially contaminated corn products) (on file with the Washington and Lee Law Review).

126. See D.L. Uchtmann, *StarLink: A Case Study of Agricultural Biotechnology Regulation*, 7 *DRAKE J. AGRIC. L.* 159, 209 (2002) ("The current U.S. grain marketing system

As a result of the contamination and the subsequent drop in demand for U.S. corn, numerous class action suits were brought against Aventis CropScience.<sup>127</sup> Classes included farmers whose crops had been contaminated with StarLink by commingling with StarLink corn and by cross-pollination.<sup>128</sup> There were also attempts to sue Aventis CropScience on behalf of all corn growers because of the depressed corn prices that occurred as a result of the incident.<sup>129</sup> These class action lawsuits eventually were combined into one multidistrict case.<sup>130</sup>

The plaintiffs in *StarLink* brought causes of action against Aventis CropScience for negligence, public and private nuisance, strict liability, and conversion.<sup>131</sup> Aventis CropScience moved to dismiss, claiming that FIFRA preempted the plaintiffs' state law claims, that the economic loss rule barred recovery, and that the plaintiffs failed to state a claim under any of the legal theories presented in their complaint.<sup>132</sup> Aventis CropScience's motion was granted in part and denied in part.<sup>133</sup> Aventis CropScience settled some of the claims for a reported \$110 million.<sup>134</sup>

Although the case was not ultimately decided by the court, the *StarLink* opinion provides some guidance for how cases of harm caused by gene flow or

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has difficulty keeping a particular crop variety in 'feed only' marketing channels, at least when the crop is planted on a rather large scale."); see also Bratspies, *supra* note 10, at 645 ("The CDC may have concluded that there is too little StarLink contamination to pose a human health risk, but the dangers the crisis revealed about an inadequate regulatory climate remain significant and unaddressed.").

127. See Charles A. Deacon & Emilie K. Paterson, *Emerging Trends in Biotechnology Litigation*, 20 REV. LITIG. 589, 614–15 (2001) (describing the lawsuits filed against Aventis CropScience in the aftermath of the StarLink contamination).

128. See *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d 828, 841–42 (N.D. Ill. 2002) (describing the various ways that non-StarLink corn could have become contaminated with StarLink corn).

129. See *Dupraz v. Aventis CropScience USA Holding, Inc.*, 153 F. Supp. 2d 1102, 1103 (D.S.D. 2001) (stating that the plaintiff sought to certify a class including "all persons and entities who cultivated and harvested non-StarLink corn in the State of South Dakota for commercial purposes from 1998 to the present").

130. See *StarLink*, 212 F. Supp. 2d at 833 (stating that the fifteen separately filed cases were consolidated for pretrial purposes by the Panel for Multidistrict Litigation).

131. *Id.*

132. *Id.*

133. *Id.*

134. See Thomas P. Redick & Donald L. Uchtmann, *Coexistence Through Contracts: Export-Oriented Stewardship in Agricultural Biotechnology vs. California's Precautionary Containment*, 13 DRAKE J. AGRIC. L. 207, 213–14 (2008) (commenting on the settlement between Aventis CropScience and growers of contaminated corn). Aventis also settled a class action suit with consumers for over \$9 million. *Id.* at 214.

commingling will be handled. Significantly for this discussion, the court said that negligence per se was an appropriate claim under the circumstances.<sup>135</sup> The court also said that only farmers whose crops were physically harmed by contamination, either through cross-pollination or post-harvest commingling, were eligible for recovery of damages.<sup>136</sup> Those who acquired StarLink unknowingly before planting and those who sued based solely on the drop in corn prices were barred from recovery.<sup>137</sup>

### C. LibertyLink Rice

In a more recent case, similar to *StarLink*, traces of two lines of GE rice not approved for human consumption were found in several places in the food supply chain.<sup>138</sup> The two lines, LLRICE601 and LLRICE604, were part of a family of LibertyLink crops that express a protein conferring resistance to the herbicide glufosinate.<sup>139</sup> Two other related rice lines, LLRICE06 and LLRICE62, containing the same protein, had already been approved by the USDA for commercial use, although they had not been put into production.<sup>140</sup>

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135. See *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d 828, 852 (N.D. Ill. 2002) (denying Aventis CropScience's motion to dismiss the negligence per se-based claims).

136. See *id.* at 841 ("Non-StarLink corn crops are damaged when they are pollinated by StarLink corn. . . . Non-StarLink corn is also damaged when it is commingled with StarLink corn. Once mixed, there is no way to resegregate the corn . . . [t]he entire batch is considered tainted.").

137. See *id.* at 841–42 (stating that farmers who purchase contaminated seed are barred from recovery because they could have bargained with their suppliers for pure seed and did not, and those whose seed was commingled by food manufacturers during processing were also barred because the harm occurred after they relinquished their ownership rights). The court said: "Absent a physical injury, plaintiffs cannot recover for drops in market prices. Nor can they recover for additional costs, such as testing procedures, imposed by the marketplace." *Id.* at 842.

138. See A. Bryan Endres & Justin G. Gardner, *Genetically Engineered Rice: A Summary of the LL Rice 601 Incident*, AGRIC. L. & TAXATION BRIEFS 2 (2006), available at [http://www.farmdoc.uiuc.edu/legal/articles/ALTBs/ALTB\\_06-04/ALTB\\_06-04.pdf](http://www.farmdoc.uiuc.edu/legal/articles/ALTBs/ALTB_06-04/ALTB_06-04.pdf) (discussing the discovery of LibertyLink Rice in conventional rice planted in 2005).

139. See USDA, Report of LibertyLink Rice Incidents, at 3 (2007), available at [www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf](http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf) [hereinafter USDA Rice Report] (stating that the 35SBar gene, which is common to all of the lines and conferred resistance to glufosinate, has a long history of safe use, is present in many deregulated products, and had undergone and passed rigorous safety testing at the time the contamination occurred).

140. See Endres & Gardner, *supra* note 138, at 1 (stating that, although Bayer CropScience had approval for LLRICE06 and LLRICE62, it "chose not to market these genetically engineered varieties . . . because growers were not interested in producing rice not yet approved for sale in major importing nations such as Japan and the European Union").

However, Bayer CropScience, the company developing the product, had only sought an experimental use permit for LLRICE601.<sup>141</sup>

In January 2006, traces of the LLRICE601 were discovered in Midwestern long-grain rice by Riceland, the nation's largest rice cooperative.<sup>142</sup> Bayer CropScience confirmed that the rice was indeed LLRICE601 and reported the problem to the USDA, which promptly initiated an investigation.<sup>143</sup> In 2007, low levels of GE rice, later identified as LLRICE604, were found in rice samples, prompting further inquiry by the USDA.<sup>144</sup>

After an investigation that required 8,500 staff hours in eleven states and Puerto Rico, the USDA finally reported on February 20, 2007 that it did not know how the regulated rice ended up in the food supply and that it would pursue no enforcement action against any entities as a result of the incident.<sup>145</sup> The investigation did reveal, however, that the LLRICE604 contamination was not likely the result of cross-pollination.<sup>146</sup> The USDA decided that LLRICE601 did not pose any health risks and deregulated it in November 2006, but in many ways the damage was already done.<sup>147</sup>

As soon as news of the contamination got out, Japan stopped importation of any U.S. long-grain rice and the European Union required purity testing of

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141. *Id.*

142. *See* Endres, *supra* note 6, at 134 (discussing the discovery of GE material in conventional rice from the 2005 season). Riceland originally thought that the GE material was contamination from residue of GE corn or soybeans that may have been transported in the same equipment. *Id.* After a significant number of samples tested positive, Riceland contacted Bayer CropScience, which confirmed that it was LLRICE601. *Id.*

143. *See* USDA Rice Report, *supra* note 139, at 3–4 (stating that Bayer CropScience orally informed the USDA of the possibility of low levels of GE contamination in rice on July 31, 2006 and that the USDA began its investigation on August 1, 2006).

144. *See id.* at 5–6 (stating that, because of the LLRICE601 incident, rice grower associations implemented testing procedures to ensure that U.S. rice did not contain GE material, and describing the subsequent discovery and identification of LLRICE604 in up to thirty percent of certain rice varieties).

145. *See id.* at 1–2 (describing the extensive nature of the investigation and stating that, given the lack of definitive evidence, APHIS would not be able to take any action against Bayer CropScience).

146. *See id.* at 6–7 (stating that, based on records kept at the research facilities where the varieties were grown, the variety containing LLRICE604 was not ever grown at the same time as the CL131 variety, which ended up being contaminated with LLRICE604, thus ruling out the possibility of pollen-mediated gene flow).

147. *See id.* at 3 (stating that "[f]ederal authorities have concluded that LibertyLink rice poses no threat to food safety, human health, or the environment, and after thorough safety evaluations, APHIS extended deregulation to include LLRICE601 in November 2006"); Redick & Uchtman, *supra* note 134, at 212 (pointing out that the "plaintiffs [in the LibertyLink litigation] argue that economic harm had already occurred because of Bayer's delay in detecting and reporting the commingling").

every shipment of rice from the United States.<sup>148</sup> Russia, Canada, Taiwan, the Philippines, and Iraq also restricted the importation of U.S. rice because of the contamination.<sup>149</sup> The announcement caused an immediate decline in rice futures and products made with U.S. rice were pulled off the shelves of grocery stores throughout the European Union.<sup>150</sup> As occurred with the StarLink contamination, many farmers filed lawsuits claiming damages resulting from the drop in demand due to the contamination.<sup>151</sup> Many of these lawsuits were joined into one, which is pending in the Eastern District of Missouri.<sup>152</sup> Regardless of the outcome of the litigation, these events revealed that many of the regulatory problems that led to the StarLink incident have yet to be remedied.<sup>153</sup>

### *D. Negligence Per Se*

#### *1. Overview*

Negligence per se, or statutory negligence, is a legal doctrine that presumes an act to be negligent if it is in violation of a statute.<sup>154</sup> This doctrine only applies to statutes that are enacted to protect a particular group of people

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148. See Endres & Gardner, *supra* note 138, at 3 (describing the international reaction to the discovery of GE rice in conventional rice in the United States).

149. See *In re Genetically Modified Rice Litig.*, 251 F.R.D. 392, 393 (E.D. Mo. 2008) (listing the nations that placed import restrictions on U.S. rice).

150. See Redick & Uchtmann, *supra* note 134, at 211 (summarizing the aftermath of the discovery of LibertyLink contamination).

151. See *In re Genetically Modified Rice Litig.*, 251 F.R.D. at 394 ("Plaintiffs' primary claim for damages, however, is that the defendants' activities caused a market loss injury to the U.S. rice market.").

152. See Transfer Order at 1–2, *In re LLRice601 Contamination Litigation*, No. 1811 (E.D. Mo. Dec. 19, 2006), available at [http://www.bayerricelitigation.com/pdfs/12.19.06%20MDL\\_Transfer\\_Order.PDF](http://www.bayerricelitigation.com/pdfs/12.19.06%20MDL_Transfer_Order.PDF) (transferring thirteen cases to the Eastern District of Missouri and noting the existence of a number of tag along cases, which, although not consolidated, were based on the same causes of action). Regarding the cases, the Judicial Panel on Multidistrict Litigation said that "[c]entralization . . . is necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings (especially with respect to questions of class certification), and conserve the resources of the parties, their counsel and the judiciary." *Id.* at 2.

153. See Endres, *supra* note 6, at 138 (stating that the LibertyLink incident demonstrates the "lingering post-StarLink coexistence concerns").

154. See, e.g., *Reed v. Molnar*, 423 N.E.2d 140, 144 (Ohio 1981) ("Where there exists a legislative enactment commanding or prohibiting for the safety of others the doing of a specific act and there is a violation of such enactment solely by one whose duty it is to obey it, such violation constitutes negligence per se . . . ." (internal quotations omitted)).

and prevent particular types of harm.<sup>155</sup> To prevail on a claim of negligence per se, the plaintiff must prove that the defendant violated the statute.<sup>156</sup> Additionally, the plaintiff must be in the class of people the statute was designed to protect.<sup>157</sup> If the above conditions are met, the plaintiff must then prove that the defendant's violation of the statute was the proximate cause of harm to the plaintiff.<sup>158</sup>

In contrast with common law negligence, where the existence of a duty of care is a question left to the finder of fact, in cases of negligence per se, the duty of care is established by statute.<sup>159</sup> However, not all statutes create duties of care.<sup>160</sup> A statute that does not define a standard of care, but merely imposes an administrative requirement, cannot be used as a basis for negligence per se claims.<sup>161</sup> Even statutory requirements, such as licensing and reporting, that are enacted to promote public safety do not necessarily create duties.<sup>162</sup> For a statute to establish a duty of care upon which a civil action can be brought, the

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155. See *OMI Holdings, Inc. v. Howell*, 918 P.2d 1274, 1296 (Kan. 1996) ("In order for the violation of a statute or ordinance to constitute negligence per se, the statute must be designed to protect a specific group of people, not just designed to protect the general public with incidental consideration given to the protection of a certain group.").

156. See *Moody v. Boston & Me. Corp.*, 921 F.2d 1, 4 (1st Cir. 1990) ("Under a traditional negligence per se analysis, proof of defendant's violation of a safety statute designed to protect the party who was injured against the type of injury which occurred, relieves the plaintiff from pleading the negligence elements of foreseeability, duty and breach."); *Cannon v. Jones*, 377 So. 2d 1055, 1058 (Miss. 1979) ("Although violation of a statute is negligence per se, in order to rely on it, there must be a showing . . . that the statute was indeed violated.").

157. See *Talley v. Danek Med., Inc.*, 179 F.3d 154, 158 (4th Cir. 1999) (stating that under Virginia law, in order to establish the duty element of negligence per se, "the plaintiff must show that the injured person is a member of a class for whose benefit the legislation was enacted" (internal quotations omitted)).

158. See *id.* ("The plaintiff must also show that the breach of duty was a proximate cause of the plaintiff's injury.").

159. See *Taft v. Derricks*, 613 N.W.2d 190, 194 (Wis. Ct. App. 2000) ("When a statute provides that under certain circumstances particular acts shall or shall not be done, it may be interpreted as fixing a standard for all members of the community, from which it is negligence to deviate." (internal quotations omitted)).

160. See *OMI Holdings*, 918 P.2d at 1296 ("A statute which is clearly promulgated to provide safety and welfare for the public at large does not impose a duty on the statute violator which is owed to the person injured; thus, negligence per se is inapplicable.").

161. See *Talley*, 179 F.3d at 159 ("Where a statutory provision does not define a standard of care but merely imposes an administrative requirement, such as the requirement to obtain a license or to file a report to support a regulatory scheme, violation of such requirement will not support a negligence per se claim.").

162. See *id.* (stating that "[e]ven if the regulatory scheme as a whole is designed to protect the public or promote safety, the licensing duty itself is not a standard of care, but an administrative requirement" (citations omitted)).



intent of the legislature to establish such a duty must be clear.<sup>163</sup> If the legislation either explicitly or by necessary implication provides that its violation will result in civil liability, then courts must apply it.<sup>164</sup> Depending on the jurisdiction, violation of such statutes can be considered negligence per se, create a rebuttable presumption of negligence, or may only be considered as evidence of negligence.<sup>165</sup> In addition to statutes, administrative regulations can also create duties of care.<sup>166</sup>

## 2. *The Johnson Grass Statute*

One historical example of the use of negligence per se in the agricultural context, and one that is somewhat analogous to the gene flow situation, is the Johnson Grass Statute enacted by the Texas Legislature in 1901.<sup>167</sup> This law was enacted to protect farmers from having their fields infested with Johnson grass from railroad rights of way abutting their property.<sup>168</sup>

Railroad cars traveling all around the country provide an effective means of distributing weed seed, including Johnson grass, which is a particularly noxious weed.<sup>169</sup> Although Johnson grass presents a serious threat to farmers,

163. See *Antwaun A. ex rel. Muwonge v. Heritage Mut. Ins. Co.*, 596 N.W.2d 456, 466 (Wis. 1999) ("[A] statute will not be interpreted to impose a greater duty than that imposed by the common law unless it clearly and beyond any reasonable doubt expresses such purpose by language that is clear, unambiguous, and peremptory." (internal quotations omitted)).

164. See RESTATEMENT (SECOND) OF TORTS § 286 cmt. c (1965) (discussing the circumstances under which courts are required to apply negligence per se to violations of statutes). The Restatement also says that in the absence of a provision for civil liability, courts are free to decide whether or not to adopt statutory requirements as standards of care. *Id.* cmt. d.

165. Compare *Rogers v. Stillman*, 268 S.W.2d 614, 616 (Ark. 1954) (stating that in Arkansas, violation of a statute is only considered evidence of negligence, to be taken into account with the other facts and circumstances of the case), with *Ramirez v. Nelson*, 188 P.3d 659, 665 (Cal. 2008) (stating that, according to the California Evidence Code, "violation of a statute gives rise to a presumption of negligence" (internal quotations omitted)), and *Ray v. Goldsmith*, 400 N.E.2d 176, 178 (Ind. Ct. App. 1980) ("In Indiana a non-excused or non-justified violation of a duty prescribed by statute or ordinance is negligence per se.").

166. See *Karle v. Nat'l Fuel Gas Distrib. Corp.*, 448 F. Supp. 753, 767 (W.D. Pa. 1978) ("It is well established that federal regulations have the same force as the federal statute under which they are promulgated." (citations omitted)).

167. See Johnson Grass Statute, 1901 Tex. Gen. Laws 283 (repealed 2007) (prohibiting railway companies operating in the state from allowing Johnson grass to go to seed on their rights of way).

168. See *San Antonio & A.P. Ry. Co. v. Burns*, 87 S.W. 1144, 1146 (Tex. 1905) ("The policy of the state in enacting the [Johnson grass] law was to prevent the spread of Johnson grass . . .").

169. See Robert J. Hill, Pa. Dep't Agric., *Weed Circular No. 4: Johnsongrass, Sorghum*

it does not impact the operation of the trains, so the railroads have little incentive to implement costly control measures along their lines.<sup>170</sup> As a result, Johnson grass on railroad lands was often allowed to head and produce seed, which was disbursed onto the agricultural fields adjacent to the tracks.<sup>171</sup>

The Johnson Grass Statute prohibited railway companies operating in the state from allowing Johnson grass or Russian thistle to go to seed on their rights of way.<sup>172</sup> The statute also provided for a penalty and damages in favor of farmers whose lands were adjacent to railways where Johnson grass had been allowed to go to seed as long as the farmers had not let the weed go to seed on their own lands.<sup>173</sup> Because of the clearly expressed provision for a civil remedy, the courts were obliged to apply negligence per se analysis to lawsuits brought by farmers against the railroad companies.<sup>174</sup>

There are at least three characteristics of the Johnson Grass Statute that make it a good example of what a statute or regulation should look like if it is to be used as a basis for claims of negligence per se. First, it identified the particular group of persons it was designed to protect.<sup>175</sup> Although it did not state explicitly the harm it intended to prevent, the desire to limit the spread of Johnson grass onto farmers' fields was implicit. Second, it identified the group for whom the statute created a new duty.<sup>176</sup> The statute singled out the railroads and imposed exclusively on them a new duty.<sup>177</sup> This element was

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halepense (L.) Pers. and Shattercane, *Sorghum bicolor* (L.) Moench ssp. *drummondii* (Steud.) de Wet, 9 REGULATORY HORTICULTURE 1, 2 (1983), available at <http://www.agriculture.state.pa.us> (follow "Publications" hyperlink; then select "Control Weed Article Johnson Grass" under "Select by Publication Name") (stating that railroads are a major means of distributing Johnson grass seed, and that it continues to be a major weed problem).

170. See *Mo., Kan. & Tex. Ry. Co. v. May*, 194 U.S. 267, 270 (1904) (giving as one possible justification for the Johnson Grass Statute that "whereas self-interest leads the owners of farms to keep down pests, the railroad companies have done nothing in a matter which concerns their neighbors only").

171. See *Wichita Falls, Ranger & Fort Worth Ry. Co. v. Sparks*, 12 S.W.2d 1082, 1083 (Tex. Civ. App. 1928) (citing several circumstances in which railroads allowed Johnson grass and other weeds to go to seed on lands they controlled).

172. Johnson Grass Statute, 1901 Tex. Gen. Laws 283 § 1 (repealed 2007).

173. *Id.* § 2.

174. See *Wichita Falls*, 12 S.W.2d at 1084 (stating that because the purpose of the statute was to prevent railroad companies from letting Johnson grass go to seed, any who did so would be considered negligent per se and adjacent farmers would need to prove no other negligence).

175. See Johnson Grass Statute, 1901 Tex. Gen. Laws 283 (repealed 2007) (extending a legal right exclusively to any person owning, leasing or controlling land contiguous to railroad rights of way).

176. See *id.* § 1 (making the prohibited act unlawful only for "any railroad or railway company or corporation doing business in [Texas]").

177. *Id.*

controversial and was challenged under the Equal Protection Clause of the Fourteenth Amendment<sup>178</sup> to the United States Constitution.<sup>179</sup> The United States Supreme Court upheld the law, saying that singling out the railroads was justified sufficiently.<sup>180</sup> Third, the law was clear in creating a civil remedy and the conditions under which that remedy could be had.<sup>181</sup> There could be no question from the plain language of the statute that it was intended to create a private right that could be enforced through the civil court system. These three characteristics are important to keep in mind when considering potential statutory or regulatory solutions to the problem of gene flow.

### 3. *Negligence Per Se in Cases of Gene Flow*

With appropriate regulations, negligence per se could be an effective means of establishing liability for damages resulting from gene flow. Without a duty there can be no negligence.<sup>182</sup> The problem with common law negligence in the context of GE crops is that there are no recognized duties or standards of care.<sup>183</sup> GE crops are so new that no one really knows how the reasonable grower of GE crops should behave.<sup>184</sup> Negligence per se removes ambiguity about who owes what duties to whom.

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178. U.S. CONST. amend. XIV, § 1 ("No state shall . . . deny to any person within its jurisdiction the equal protection of the laws.").

179. *See* *Mo., Kan. & Tex. Ry. Co. v. May*, 194 U.S. 267, 269–70 (1904) (upholding the Johnson Grass Statute).

180. *See id.* (stating that there was insufficient evidence that the discrimination against railroads was unfair enough to justify disturbing the law). Justice Holmes, who delivered the opinion of the court, stated:

When a state legislature has declared that in its opinion policy requires a certain measure, its action should not be disturbed by the courts under the Fourteenth Amendment, unless they can see clearly that there is no fair reason for the law that would not require with equal force its extension to others whom it leaves untouched.

*Id.* at 269.

181. *See* Johnson Grass Statute, 1901 Tex. Gen. Laws 283–84, § 2 (repealed 2007) (providing for a twenty-five dollar penalty and damages for farmers adjacent to railroad rights of way where Johnson grass had gone to seed, but restricting this remedy to farmers who had not allowed the weed to go to seed on their own land).

182. *See, e.g.,* *District of Columbia v. Harris*, 770 A.2d 82, 87 (D.C. 2001) ("[T]o establish negligence a plaintiff must prove a duty of care owed by the defendant to the plaintiff, . . .").

183. *See* Celeste Marie Steen, Note, *FIFRA's Preemption of Common Law Tort Actions Involving Genetically Engineered Pesticides*, 38 ARIZ. L. REV. 763, 791 (1996) ("[T]he ever-changing nature of genetic engineering leaves the courts with no standard of care. Therefore, it is unreasonable to think the plaintiff could prove negligence." (internal quotations omitted)).

184. *Id.*

In a field where experts disagree about what the appropriate standards should be, it may be unwise to allow the courts to decide what care is due.<sup>185</sup> Such decisions should be made by legislatures with greater fact-finding capacity than courts.<sup>186</sup> Legislative or administrative pronouncements of standards of care would reflect the overall policy preferences of the community at large.<sup>187</sup> An appropriate statutory and regulatory regime enacted with the purpose of establishing standards of care for growers of GE crops would place the important policy questions presented by gene flow squarely in the hands of the political branches of government.

#### 4. *Shortcomings of Negligence Per Se*

Despite its potential utility in establishing liability in cases of gene flow, negligence per se is not without its problems. Some have criticized the use of regulatory standards because they tend to establish only minimum requirements.<sup>188</sup> Many courts, subscribing to this view, have therefore held that a violation of a statute is sufficient to establish negligence, but compliance is not necessarily sufficient to satisfy due care.<sup>189</sup> This being the case, a grower of GE crops would not necessarily be fulfilling his duty simply by complying with the regulations. Different states give different effect to the fact of regulatory compliance.<sup>190</sup>

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185. See Richard C. Ausness et al., *Providing a Safe Harbor for Those Who Play by the Rules: The Case for a Strong Regulatory Compliance Defense*, 2008 UTAH L. REV. 115, 133–34 (stating that the courts are not well suited to evaluate safety regulations because they are not experts, are limited to the information presented to them by litigants, and only focus on the narrow issues before them).

186. See *id.* at 132–33 (arguing that legislatures are better equipped than the courts to formulate effective safety standards).

187. See Joan M. Ferretti, *Looking for the Big Picture—Developing a Jurisprudence for a Biotechnological Age*, 10 PACE ENVTL. L. REV. 711, 722 (1993) (“Courts . . . are ill-equipped to create a jurisprudence embodying social value considerations which, in a democracy, are primarily the province of the legislature. Legislation is supposed to represent collective wisdom, borne of the full and public explication of the many facets of an issue.”).

188. See *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1543 (D.C. Cir. 1984) (noting that “federal legislation has traditionally occupied a limited role as the floor of safe conduct” (emphasis omitted)).

189. See Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003, 1014–15 (2008) (describing the role regulatory compliance plays in establishing liability and defenses in claims of negligence).

190. See *Berkebile v. Brantly Helicopter Corp.*, 281 A.2d 707, 710 (Pa. 1971) (“Compliance with a law or administrative regulation . . . does not establish as a matter of law that due care was exercised.”); *Phillips v. Roux Lab.*, 145 N.Y.S.2d 449, 451 (App. Div. 1955) (“Just as failure to comply with a statute and regulations promulgated thereunder is evidence of

It has been suggested, however, that the courts' reluctance to allow for a compliance defense in negligence cases is an artifact from an era when cases involved standards of care in highly context-specific circumstances.<sup>191</sup> The argument is that "[m]odern regulatory systems typically represent legislative or administrative efforts to set optimal—not minimal—safety standards."<sup>192</sup> Those who argue for the adoption of a strong compliance defense contend that more deference should be given to safety regulations because they "often represent important policy choices by the legislative and executive branches of government that should be respected by the courts."<sup>193</sup>

Another way that negligence per se, by itself, is not completely adequate for dealing with gene flow is that, although an action may be negligent per se, the plaintiff still needs to prove that the violation was the proximate cause of the harm of which he complained.<sup>194</sup> This could be nearly impossible or relatively easy, depending on the circumstances. For example, if the only farmer growing a wind-pollinated GE crop is directly upwind and adjacent to a conventional seed producer's crops, and the conventionally grown seed expresses the GE trait, it would not be difficult to establish causation. However, in a more realistic scenario, where there are numerous growers of GE crops in an area, pinpointing the exact farm from whence genes escaped may not be possible. A solution to this could be to enact regulations that, like the Johnson Grass Statute, provide a remedy against neighbors who violate the statute, regardless of causation or actual harm.<sup>195</sup> The possibility of a penalty for violation of the statute, even without actual damages, could serve to deter conduct that could result in harm. It is also important to note that the problem of proving causation is not unique to negligence per se. The need to prove

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negligence, full compliance therewith is some evidence of the exercise of due care . . .").

191. See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2152 (2000) ("In the century since the development of the common-law rule against recognizing a regulatory compliance defense, the focus of tort litigation has shifted from heavily context-dependent collision cases to recurring situations such as defects in mass-produced consumer goods, which are more readily subject to nationally uniform requirements for safeguards . . .").

192. *Id.*

193. Ausness et al., *supra* note 185, at 157.

194. See *Talley v. Danek Med., Inc.*, 179 F.3d 154, 159 (4th Cir. 1999) ("[E]ven when a statutory provision does specify a standard of care, a plaintiff must still prove . . . proximate causation . . .").

195. See Johnson Grass Statute, 1901 Tex. Gen. Laws 283 § 2 (repealed 2007) (providing a penalty of twenty-five dollars to be paid to neighbors by railroads that allow Johnson grass to go to seed). The statute requires that damages be proved, but makes no such qualification about the right to recover the penalty. *Id.*

causation is common to all applicable theories of recovery and is equally difficult to satisfy under any of them.<sup>196</sup>

#### *IV. Possibilities for Future Regulation*

The first question to ask, when considering the regulation of GE crops, is who should be entrusted with the task? This question must be answered as to the allocation of responsibility among the branches of government, between the federal government and the states, and among the various regulatory agencies. As discussed above, the problems presented by GE farming in general, and gene flow in particular, are well suited to being solved by legislative and administrative action.<sup>197</sup> Standards set by legislative or regulatory action and applied in negligence per se claims would allow for more uniform outcomes and provide greater predictability to growers of both GE and non-GE crops than the reasonableness standards that would be applied by juries in common law negligence claims.<sup>198</sup> The questions of whether civil claims for gene flow damages should be based on state or federal regulation, and the question of which administrative agency, if any, should bear this responsibility are addressed below.

##### *A. State Versus Federal Regulation of GE Crops*

As described above, under the current regime, GE crops are regulated primarily by the federal government, but there is nothing stopping a state from enacting its own statutes or regulations governing the growing of GE crops. Several states have chosen to enact more stringent standards than those required

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196. See Repp, *supra* note 7, at 602–03 (discussing the application of trespass in gene flow cases and stating that “[w]hile the technology currently exists to prove that plaintiffs’ land has been invaded and contaminated by GMOs, it may still be difficult to meet the ‘causation’ element and show that the contamination came from a particular defendant”); *id.* at 607 (stating that plaintiffs bringing nuisance claims for gene flow harms “will still be required to meet the difficult causation element—to show that a defendant’s conduct caused the interference with their use and enjoyment of their property”); *id.* at 619–20 (stating that under a strict liability theory, if plaintiffs could convince the court that growing of GE crops is an abnormally dangerous activity, GE growers could be required “to pay the consequences of the production activities that cause damage to neighboring farmers” (emphasis added)).

197. See *supra* notes 185–87 and accompanying text (discussing why standards of care for negligence actions in certain circumstances should be set by legislatures or administrative agencies and not by courts).

198. *Supra* notes 185–87.

by federal regulators.<sup>199</sup> In fact, in California, several individual counties have promulgated rules restricting the growing of GE crops.<sup>200</sup> The result is a veritable patchwork of rules and regulations.<sup>201</sup> This, combined with the variation in courts' application of regulations as standards of care in civil cases, leaves uncertainty about what is required of GE crop growers. Furthermore, as federal preemption of regulatory issues becomes more prevalent, the question of what role state regulations will play in the civil cases is left open.<sup>202</sup>

Some would argue that this diversity is healthy—that under our federalist Constitution, the states should be allowed to "experiment with policies and adopt laws that reflect local concerns."<sup>203</sup> The very fact that states have chosen to deal with the same biotechnology issues in different ways indicates that they have different policy concerns.<sup>204</sup> Some states have chosen to enact voluntary or mandatory labeling requirements for GE crops and products.<sup>205</sup> Over twenty states offer tax credits, funding, or other support for development of biotechnology.<sup>206</sup> One state might be very concerned about protecting the genetic identity of its seed crops, and therefore would wish to exclude GE crops from areas where seed is produced. Another state's economy might rely heavily on certain GE varieties, and that state's policy choices would reflect a preference for GE crops. States may also point to episodes, such as StarLink and LibertyLink, which show the inadequacy of federal regulations in protecting growers of non-GE crops, as justification for state regulation.

199. See Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439, 459 (2007) (discussing the various actions states have taken regarding biotechnology).

200. See A. Bryan Endres, *Coexistence Strategies in a Biotech World: Exploring Statutory Grower Protections*, 13 MO. ENVTL. L. & POL'Y REV. 206, 218 (2006) (discussing bans in Mendocino, Marin, and Trinity Counties, in California, which make it unlawful to "propagate, raise, or grow genetically modified organisms" (quotations omitted)).

201. See *id.* at 219–20 (describing the complexity and variation among regulations regarding GE crops throughout the country).

202. See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 242 (2007) (discussing the "discernable trend, if not a dominant position, towards deference to agency preemption determinations," and its effect on tort claims).

203. See Farquhar & Meyer, *supra* note 199, at 458 (stating that the Framers of the United States Constitution intended for states to be able to adopt policies to address local concerns).

204. See *id.* at 458–59 (giving an example of five states that each have specific regulations regarding GE fish species, and stating that each handled the issue in a unique way).

205. See *id.* at 459 (describing the somewhat restrictive approach some states have taken in regulating biotechnology).

206. See *id.* (describing the more biotechnology-friendly tack several states have taken regarding biotech regulation).

On the other hand, the fragmentation of regulation may have undesirable effects. For one thing, most agricultural products are stored and transported in interstate systems. Because purchasers of agricultural products are most often not in the areas where the crops are produced, it makes sense to have nationally uniform standards and enforcement. The federal government has preempted many causes of action that traditionally have been governed by state law.<sup>207</sup> Because there is a presumption that federal laws do not preempt state causes of action, unless accompanied by a congressional statement authorizing the agency to promulgate such a regulation, any regulatory basis for civil negligence per se claims requires such a statement.<sup>208</sup>

*B. Which Agency Should Establish the Standards of Care to Prevent Gene Flow?*

Many of the problems that have arisen in the regulation of biotechnology have occurred because the agency administering the regulations was operating out of its area of expertise.<sup>209</sup> An example of this is the fact that if the EPA had been more aware of agricultural production and processing, it would have known that keeping StarLink corn out of the food supply was virtually impossible.<sup>210</sup> With this in mind, the USDA seems to be a natural choice to regulate gene flow among cultivated crops. The definition of plant pest under the PPA is broad enough to include all GE crops, regardless of what GE trait they carry.<sup>211</sup> The USDA, acting pursuant to its authority under the PPA, could promulgate regulations that would prevent gene flow and serve as standards of

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207. See Sharkey, *supra* note 202, at 227 (describing the trend towards federal preemption).

208. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.").

209. See Mandel, *supra* note 62, at 2239 (stating that examples of failures in biotechnology regulation coincide with agencies acting out of their areas of expertise). Mandel gives some examples of agencies regulating outside of their areas of expertise, including the USDA and the FDA's regulating environmental impacts of GE plants other than those modified to produce PIPs and the FDA's regulating the environmental impact of GE fish and animals. *Id.*

210. See *id.* ("[H]ad the EPA . . . been familiar with the nation's agricultural system, it would have recognized that it was impossible for StarLink corn to be kept fully segregated from corn used for human food.").

211. See *supra* notes 75–76 and accompanying text (discussing the USDA's authority to regulate any living organism "that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product").



care for negligence per se claims. The regulations must clearly define the duty and state that they create a civil cause of action.<sup>212</sup>

### *C. Regulations Reflecting Biological Realities*

In the aftermath of the LibertyLink investigation, USDA-APHIS released a paper stating the lessons it learned from the experience.<sup>213</sup> Among the lessons learned was the need to ensure the use of the latest science for isolation as a confinement tool.<sup>214</sup> The paper says:

As breeding techniques and GE technology continue to advance, it will be essential to incorporate the latest scientific information into APHIS' regulatory requirements to maximize confinement of regulated articles. For example, APHIS will need to use the latest scientific information on factors such as pollen flow to ensure that regulated GE material is sufficiently isolated from conventional breeding and seed production fields.<sup>215</sup>

In order to serve as effective standards of care for GE farmers, regulations need to take into account the biological characteristics of the particular GE crop. A good example of what can happen when this is not done is the USDA-APHIS decision to allow field testing of GE creeping bentgrass.<sup>216</sup> "Creeping bentgrass is a fast-growing perennial species which is biologically and ecologically very variable, adaptable, and robust."<sup>217</sup> It spreads rapidly via runners, wind-pollinated flowers, and tiny seeds, and its pollen can travel up to thirteen miles.<sup>218</sup> The GE creeping bentgrass variety being tested contained a gene that

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212. See Andre E. Costa, *Negligence Per Se Theories in Pharmaceutical & Medical Device Litigation*, 57 ME. L. REV. 51, 76 (2005) ("[I]f a statute or regulation does not clearly define what conduct is required . . . it will not support a negligence per se claim.").

213. See USDA, *Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework*, at 1–4 (2007), available at <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/LessonsLearned10-2007.pdf>. (setting out the conclusions to the internal review of the USDA investigation of LibertyLink rice).

214. *Id.* at 3.

215. *Id.*

216. See *Int'l Ctr. for Tech. Assessment v. Johanns*, 473 F. Supp. 2d 9, 26 (D.D.C. 2007) (finding that USDA-APHIS acted arbitrarily and capriciously by denying a petition to list glyphosate resistant creeping bentgrass as a noxious weed under the PPA).

217. *Id.* at 13 (quotations omitted).

218. See Margaret Rosso Grossman, *Anticipatory Nuisance and the Prevention of Environmental Harm and Economic Loss from GMOs in the United States*, 18 J. ENVTL. L. PRAC. 107, 148 (2008) (describing the characteristics of creeping bentgrass that made it likely to spread).

made the plants tolerant to the herbicide glyphosate.<sup>219</sup> Between 2002 and 2005, large field trials were conducted in an 11,000-acre control area in central Oregon.<sup>220</sup> In 2004, a study conducted by the EPA documented significant gene flow from the GE creeping bentgrass into areas surrounding the test plots.<sup>221</sup> Given the outcrossing nature and easy vegetative reproduction of creeping bentgrass, it is hard to imagine that gene flow would not occur.

The rate of outcrossing exhibited by a plant is an important characteristic to consider when contemplating regulations to address the issue of gene flow.<sup>222</sup> Plants with high rates of outcrossing tend to pollinate or be pollinated by other plants. By contrast, in self-pollinated plants, ovules are pollinated from anthers of the same flower or plant.<sup>223</sup> An example of a primarily self-pollinated crop is soybean, which has outcrossing rates of less than one percent, and maximum outcrossing distances of less than ten meters.<sup>224</sup> Canola, on the other hand, is a high outcrosser, with outcrossing rates as high as eighty-one percent.<sup>225</sup> Canola is also capable of cross-pollinating at great distances.<sup>226</sup> GE traits are most likely to move among crops that have high rates of outcrossing.<sup>227</sup> The high rates of outcrossing in canola mean that genes can move easily among canola populations.<sup>228</sup> Thus, growers of canola would have to take greater precautions

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219. See *Int'l Ctr. for Tech. Assessment*, 473 F. Supp. 2d at 13 (describing the glyphosate resistance exhibited by this variety of creeping bentgrass).

220. *Id.* at 15.

221. *Id.*

222. See Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the E.U. Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775, 779 (2008) (defining outcrossing as the "the spread of transgenes in the natural environment through cross-pollination").

223. See MAARTEN J. CHRISPEELS & DAVID E. SADAVA, PLANTS, GENES, AND CROP BIOTECHNOLOGY 368 (2003) (stating that self-pollinated plants have perfect flowers, meaning that the flowers have both male and female reproductive structures and are thus able to inbreed).

224. See Y. Yoshimura et al., *Gene Flow from GM Glyphosate-Tolerant to Conventional Soybeans Under Field Conditions in Japan*, 5 ENVTL. BIOSAFETY RES. 169, 171 (2006) (stating that in a four-year study, the average outcrossing rate in adjacent rows of soybeans was 0.2%, and that the farthest distance at which outcrossing was measured was seven meters).

225. See Alexis L. Knispel et al., *Gene Flow and Multiple Herbicide Resistance in Escaped Canola Populations*, 56 WEED SCI. 72, 72 (2008) (stating that outcrossing rates in canola can be as high as eighty-one percent).

226. See Mary A. Rieger et al., *Pollen-Mediated Movement of Herbicide Resistance Between Commercial Canola Fields*, 296 SCI. 2386, 2387 (2002) (describing a study in which outcrossing in canola was found up to three kilometers from the pollen source).

227. See Knispel et al., *supra* note 225, at 72 (stating that high levels of outcrossing can result in rapid pollen-mediated gene flow).

228. See *id.* at 72-73 (stating that because of the high rate of outcrossing, pollen-mediated gene flow has led to rapid and widespread escape of herbicide resistance genes from GE canola fields in Canada).

to prevent gene flow than growers of a generally self-pollinated crop, such as soybeans.<sup>229</sup>

Another characteristic to consider when establishing regulations to prevent gene flow from GE crops is the ability of the crop to hybridize with other species, including weeds.<sup>230</sup> This is related to the overall rate of outcrossing, but also depends on the presence of compatible species within the area of deployment.<sup>231</sup> Some crop species, such as creeping bentgrass, can hybridize with several native and introduced species in the areas where it is grown.<sup>232</sup> At the opposite end of the spectrum are soybeans, which do not cross with any native or introduced species in North America.<sup>233</sup> If a crop can hybridize with weeds or other plants outside the cultivated field, the recipient plants could become a source of genetic contamination long after the GE crop is gone.<sup>234</sup> For this reason, GE crops that can easily hybridize should be more carefully controlled than those that do not.

A further consideration is the invasiveness of the crop species and its wild relatives. Invasiveness is the ability to "readily increase in numbers and aggressively spread, outcompeting other species for resources."<sup>235</sup> GE crops that have invasive qualities present a high risk for gene flow because if crop plants escape from fields by seed or vegetative propagule movement, or emerge in subsequent seasons as volunteers, they can act as sources of GE

229. See M. Alejandra Martinez-Ghersa et al., *Concerns a Weed Scientist Might Have About Herbicide-Tolerant Crops: A Revisitation*, 17 WEED TECH. 202, 206 (2003) (noting that the risk for gene flow is higher with canola than with soybeans).

230. See James F. Hancock, *A Framework for Assessing the Risk of Transgenic Crops*, 53 BIOSCIENCE 512, 513 (2003) (stating that the presence of sexually compatible relatives increases the risk of gene flow from GE crops).

231. See *id.* ("[I]f compatible relatives are within the cloud of crop pollen, genes will escape.").

232. See Lidia S. Watrud et al., *Evidence for Landscape-Level, Pollen-Mediated Gene Flow from Genetically Modified Creeping Bentgrass with CP4 EPSPS as a Marker*, 101 PROC. OF THE NAT'L ACAD. OF SCI. OF THE U. S. 14533, 14534 (2003) ("Natural hybrids of *A. stolonifera* have been reported with six other native species."); see also F.C. Belanger et al., *Interspecific Hybridization Between *Agrostis stolonifera* and Related *Agrostis* Species under Field Conditions*, 43 CROP SCI. 240, 245 (2003) (finding interspecific hybridization between creeping bentgrass and *Agrostis capillaris* and *Agrostis castellana*).

233. See Martinez-Ghersa et al., *supra* note 229, at 206 (providing the fact that closely related wild relatives of soybeans are not present in North America as a reason for the lack of gene flow from GE soybeans).

234. See Knispel et al., *supra* note 225, at 78–79 (stating that escaped canola populations and other *Brassica* species receive gene flow from cultivated canola fields and in turn transfer those genes to other wild cultivated populations).

235. Hancock, *supra* note 230, at 513.

contamination.<sup>236</sup> Most crops do not persist long in natural environments, but some, like canola, can thrive outside of cultivated areas.<sup>237</sup> Escaped canola populations do not persist long, and are therefore not a concern from a management perspective.<sup>238</sup> However, if the escaped canola plants are GE, they can contribute to gene flow.<sup>239</sup>

Plants that are invasive often share certain characteristics, including discontinuous germination, vigorous vegetative reproduction, rapid growth to flowering, brittle propagules, continuous seed production, and vigorous competition.<sup>240</sup> Release of GE crops with these traits should be considered carefully. Some have argued that invasiveness cannot be reliably predicted.<sup>241</sup> Even if this is true, in situations where crop plants are known to have invasive potential, regulators should be particularly cautious when considering field testing or commercial release of GE varieties of these crops.

Regulations should also take into account the function of the gene being expressed in the GE crop. The current regulations do this to some degree.<sup>242</sup> As discussed above, GE crops producing pharmaceutical agents are always considered plant pests and subject to regulation as such.<sup>243</sup> Different GE traits are likely to have different environmental or health impacts.<sup>244</sup> Although it is

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236. See Linda Hall et al., *Pollen Flow Between Herbicide-Resistant Brassica napus is the Cause of Multiple-Resistant B. napus Volunteers*, 48 WEED SCI. 688, 694 (2000) (stating that GE canola volunteers have the potential to transfer GE traits to conventional canola crops for up to four years).

237. See Knispel et al., *supra* note 225, at 72 ("[E]scaped canola populations have become ubiquitous in rural landscapes throughout western Canada.").

238. See *id.* ("[E]scaped canola populations are believed to be transient and thus of little management concern.").

239. See *id.* (stating that although escaped GE canola populations are transient, they can still contribute to movement of GE traits in a single generation).

240. See Hancock, *supra* note 230, at 513–14 (listing the traits common to the most successful weeds and stating that "the invasive potential of a species can often be characterized by evaluating the number of weediness traits it contains").

241. See RÜDIGER WITTENBERG & MATTHEW J.W. COCK, GLOBAL INVASIVE SPECIES PROGRAMME, INVASIVE ALIEN SPECIES: A TOOLKIT OF BEST PREVENTION AND MANAGEMENT PRACTICES 99 (2001) (describing case studies that illustrate the shortcomings of efforts to predict invasiveness based on plant characteristics, and that relying on such predictions can lead to a false sense of security for managers and policymakers).

242. See Thai, *supra* note 55, at 885 (discussing the USDA's categorical treatment of pharmaceutical producing GE crops as plant pests).

243. *Id.*

244. See Steven H. Straus, *Regulating Biotechnology as though Gene Function Mattered*, 53 BIOSCI. 453, 453 (2003) ("[S]ome kinds of genes in some kinds of crops need to be highly restricted or even forbidden. But . . . large classes of genes have a high level of environmental safety.").

impossible to predict with absolute certainty what effect an escaped gene might have, certain categories of genes present greater risks than others.<sup>245</sup> For example, genes that are general domestication traits are not likely to cause harm in the environment.<sup>246</sup> Such traits are likely to reduce the fitness of plants outside of the agricultural context and therefore can be expected to diminish in frequency after escape.<sup>247</sup> Other traits, such as cold tolerance or improved nutrient uptake, could be beneficial to recipients of those genes, improving the plants' fitness and increasing the frequency of the gene in the environment.<sup>248</sup> GE crops expressing such traits should be regulated more restrictively to avoid potential environmental harm.

Although GE traits may have varying environmental effects, and may require different regulatory restrictions based on those variations, adventitious presence of GE material can have a serious impact on a non-GE crop's value, regardless of gene function. For example, the USDA's organic certification does not allow for any GE material, no matter what GE gene is present.<sup>249</sup> The European Union has a 0.9% threshold for GE contamination in foods not labeled as containing GE products.<sup>250</sup> As is the case with the USDA's organic certification, this restriction does not differentiate based on gene function.<sup>251</sup>

Experts have proposed a number of strategies to keep GE genes from escaping. These can be divided into two main categories: ecological containment methods and genetically-based containment methods.<sup>252</sup> Ecological containment focuses on manipulation of the growing environment to prevent gene flow and is undertaken by the grower of the plant, rather than the

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245. See Hancock, *supra* note 230, at 514 (describing five categories of risk for GE traits, including: (1) traits that are selectively neutral in the natural environment; (2) traits that have negative impacts on fitness; (3) herbicide resistance traits; (4) pest resistance traits; and (5) traits that alter environmental tolerance or development).

246. See *id.* ("Genes with detrimental effects will be selected against in the natural environment and will not spread. Many of the traits associated with crop domestication fall into this category.").

247. *Id.*

248. See *id.* at 514–15 (giving examples of GE traits that could positively impact fitness of weeds if the genes coding for those traits escaped to weed species).

249. See National Organic Program, 7 C.F.R. § 205.2 (2008) (stating that GE crops are excluded from what can be considered organic).

250. See Alison Peck, *The New Imperialism: Toward an Advocacy Strategy for GMO Accountability*, 21 GEO. INT'L ENVTL. L. REV. 37, 46 (2008) (stating, according to the 2004 European Union labeling legislation, the maximum allowable level of GE contamination in non-GE labeled products).

251. *Id.*

252. See ELLSTRAND, *supra* note 25, at 192 (describing the various methods of gene containment that are in use or have been proposed for use with GE crops).

scientist who releases it.<sup>253</sup> A common form of ecological containment is physical isolation of the GE crop from its sexually compatible counterparts.<sup>254</sup> Depending on the crop and the desired level of genetic purity, this could mean buffer zones ranging from zero to over 1,000 meters.<sup>255</sup> Because of the variation among crop species and even among crop varieties, regulation of individual GE crops will have to be specifically tailored to the crop and the conditions under which it is grown.<sup>256</sup>

Genetic containment strategies are based on genetic manipulation of the crop prior to its release.<sup>257</sup> One example of a possible genetic containment strategy is to insert genes into crop genomes that are not shared by the species with which the crop can hybridize.<sup>258</sup> Another possibility is to insert genes into organelles, which are maternally inherited.<sup>259</sup> At present, these methods of gene containment are theoretical and have yet to be effectively reduced to practice.<sup>260</sup>

Because this Note focuses on the duties farmers owe their neighbors, the types of regulations contemplated do not include genetic containment, which is generally undertaken by breeders and manufacturers of seed. Instead, the regulations proposed would involve ecological or cultural containment methods, which could be used to establish duties of care for growers of GE crops. The following hypothetical situation examines one restrictive measure—a buffer zone between GE and conventional crops—and explores how this measure could be adapted to address different policy concerns and remain viable as a basis for civil liability.

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253. *Id.*

254. *Id.*

255. *Id.*

256. See Watrud et al., *supra* note 232, at 14,533 (discussing the disparity in outcrossing rates and distances among crops); see also B.L. Ma et al., *Extent of Cross-Fertilization in Maize by Pollen from Neighboring Transgenic Hybrids*, 44 CROP SCI. 1273, 1273 (2004) (stating that environmental conditions, such as temperature, humidity, and atmospheric water potential affect pollen viability and outcrossing potential).

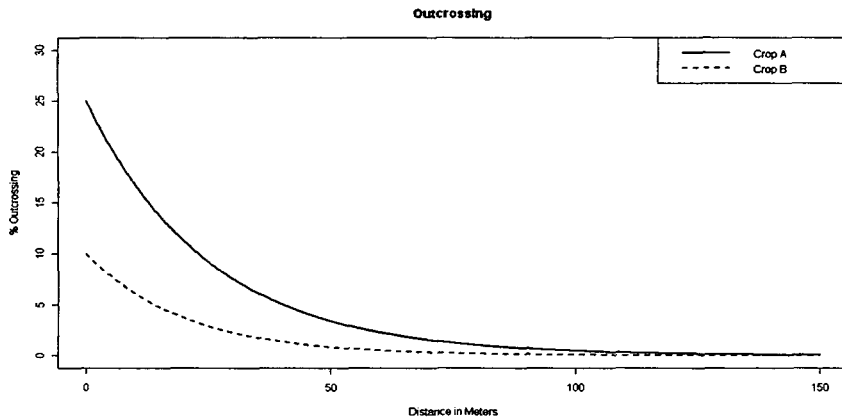
257. See ELLSTRAND, *supra* note 25, at 192 (discussing the ways in which genetic containment differs from ecological containment).

258. See Jeremy R. Snyder et al., *Seed Production on Triticum aestivum by Aegilops cylindrica Hybrids in the Field*, 48 WEED SCI. 588, 592 (2000) (suggesting placement of herbicide resistance genes in wheat on a genome that is not shared by jointed goatgrass, a weed species with which wheat can hybridize, to reduce the risk of gene flow).

259. See ELLSTRAND, *supra* note 25, at 198 (stating that engineering genes into the DNA of mitochondria or chloroplasts would eliminate pollen-mediated gene flow).

260. See *id.* at 200 ("[T]he efficacy of any of these proposed [genetic containment] systems must be tested under field conditions. Presently, not one of the options provides a general panacea for . . . containment of domesticated alleles.").

The graph below represents the outcrossing rates for two hypothetical crops, Crop A and Crop B, over distance. Crop A is a highly outcrossing species with 25% outcrossing at 0 meters and 0% outcrossing at about 110 meters. Crop B is less of an outcrosser and has 10% outcrossing at 0 meters and 0% outcrossing at about 85 meters.



In order to achieve a threshold of 5% outcrossing, buffer zones would need to be approximately forty-five feet and fifteen feet for Crops A and B, respectively. If a lower threshold is required, for example, to protect crops grown for export to the European Union, and no more than 0.9% is allowed, then the buffer zones would be around 100 feet for Crop A and sixty-five feet for Crop B.

It is important to remember that regulatory agencies do not have to ensure complete gene containment. If the regulations are to serve as standards of care in civil litigation, they need only impose restrictions to keep gene flow below the desired threshold. What that threshold is will depend on the policy preferences of those promulgating the restriction. The problem with the regulations in *StarLink* was that the restrictions did not match the policies that were driving them. In other words, by denying Aventis CropScience's application for registration of *StarLink* for food uses, the EPA essentially set the threshold for *StarLink* contamination at zero, but only required a buffer zone of 660 feet, which was inadequate to achieve that goal. This misalignment of policy and administrative requirements rendered the regulations useless as standards of care.

If the goal is to keep contamination under a certain percentage (whatever that percentage may be), then regulations should reflect the biological and ecological characteristics of the crops involved. If they do so, a conventional

farmer whose crops have been contaminated by his neighbor's GE crops can point to the GE grower's failure to follow the prescribed growing practices as proof that the GE grower's conduct fell short of the standard of care set by the regulation.

### *V. Conclusion*

We live in an age of biotechnology. For better or worse, biotechnologies, including GE crops, are a part of life and cannot be ignored. Society is faced with the dilemma of balancing the advantages and costs of GE crops. More concrete federal regulations that create a civil cause of action for negligence per se and preempt state regulation of GE crops will provide safety for growers of non-GE crops, should they adventitiously acquire GE material. To serve as effective standards of care, these regulations must recognize and deal adequately with biological realities of gene flow and the difficulties involved in segregating GE from non-GE crops after harvest. Such a system, combined with a regulatory compliance defense, would provide growers of GE crops with predictable standards of care. When GE growers know what is required of them, and their neighbors know that they will be protected in the event of gene flow, all parties are better off than they are under the current, ambiguous system.



