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## Turning Over a New Sprout: Promoting Agricultural Health By Fostering the Coexistence of Organic and Genetically Modified Crops in the Wake of *Monsanto Co. v. Geertson Seed Farms* and the Deregulation of Modified Alfalfa

Joseph Kiefer

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**TURNING OVER A NEW SPROUT: PROMOTING  
AGRICULTURAL HEALTH BY FOSTERING THE  
COEXISTENCE OF ORGANIC AND GENETICALLY  
MODIFIED CROPS IN THE WAKE OF MONSANTO CO. V.  
GEERTSON SEED FARMS AND THE DEREGULATION OF  
MODIFIED ALFALFA**

ABSTRACT

*According to the United States Department of Agriculture (USDA), the agricultural health of the United States requires the concurrent feasibility, or coexistence, of organic crops and genetically modified crops. Both types of crops offer separate environmental, economic, and health benefits. Modified crops, or crops infused with beneficial genes to increase yield or decrease the need for chemical applications, are ubiquitous in U.S. farming. Similarly, organic crops, or crops grown without modified genes, are gaining popularity. Unfortunately, the coexistence of organic and modified crops is threatened by the phenomenon of gene flow. Damaging gene flow occurs when modified crops spread their genes and contaminate the genes of nonmodified crops. This contamination threatens the organic status and marketability of organic crops and can thus cause economic damage to organic programs. The current legal and regulatory system is unable to control contamination and thus cannot ensure the vitality of organic-farming operations. To fulfill coexistence goals for the agricultural health of the nation, domestic farm programs must ensure the continued viability of organic farming.*

*The current regulatory system is unable to protect organic farms from the risks of contamination, and its inability deters and undermines organic farming. Recent deregulation decisions confirm this inability. Similarly, recent cases demonstrate that the technical litigation stemming from contamination confuses general courts and leads to inadequate remedies. This Comment argues that the regulatory and adjudicatory systems must protect organic farms from contamination to ensure their economic viability. When organic programs are economically viable, organic farms can beneficially coexist with modified-crop farms.*

*This Comment offers two possible solutions to the current regimes' inability to foster coexistence. The Comment contends that changes in agency*

*policy could better encompass the economic interests of organic programs and therefore encourage coexistence. However, limits on an agency's ability to change policy hinder the efficacy of this solution. This Comment argues that a revised statutory framework is required to protect organic crops from the damaging genetic drift associated with widespread genetically modified crops. The revised framework requires the USDA to consider the economic impacts of contamination when deregulating modified crops. The revision also mandates agency adjudication for contamination disputes to prevent general courts from handing down inadequate remedies. The revisions will ensure the continued viability of organic farms, foster coexistence, and secure the agricultural health of the nation.*

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## INTRODUCTION

The United States enjoys a rich tradition of agricultural prosperity. The country led the world in the development of genetically modified (GM) crops and continues to be a world leader in GM-food production.<sup>1</sup> The domestic planting of GM crops grew at an unprecedented rate from 1996 through 2005.<sup>2</sup> Today, over 80% of the country's corn, cotton, and soybeans contain genetically engineered genes.<sup>3</sup> Modified crops offer benefits, such as increased yields, decreased labor costs, and decreased chemical applications.<sup>4</sup> The United States Department of Agriculture (USDA) advocates GM-crop research because the crops may help solve potential "issues related to global food security, energy security, and climate change."<sup>5</sup>

Like GM-crop farming, organic farming is a growing industry.<sup>6</sup> Organic crops are crops grown without the aid of genetic alterations, pesticides, or herbicides.<sup>7</sup> Organic crops tout benefits, such as the absence of food additives, the absence of pesticides and herbicides, and increased sustainability.<sup>8</sup> Organic crops can also offer an absence of genetically altered elements and resistance to harm stemming from monocropping, or the widespread use of a single

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<sup>1</sup> See Linda Beebe, In re StarLink Corn: *The Link Between Genetically Damaged Crops and an Inadequate Regulatory Framework for Biotechnology*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 511, 535 (2004) (citing George E.C. York, Note, *Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agriculture Trade*, 7 COLUM. J. EUR. L. 423, 426–27 (2001)); Karinne Ludlow & Stuart J. Smyth, *The Quandary of Agricultural Biotechnology, Pure Economic Loss, and Non-Adopters: Comparing Australia, Canada, and the United States*, 52 JURIMETRICS J. 7, 35 (2011).

<sup>2</sup> CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, BRIEF 35: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2006, at 1 (2006), available at <http://www.isaaa.org/resources/publications/briefs/35/download/isaaa-brief-35-2006.pdf>.

<sup>3</sup> See NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., THE IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES 1 (2010).

<sup>4</sup> *Id.* at 3–14.

<sup>5</sup> U.S. DEP'T OF AGRIC., STRATEGIC PLAN FY 2010–2015, at 23 (2010), available at <http://www.ocfo.usda.gov/usdasp/sp2010/sp2010.pdf>.

<sup>6</sup> Jason J. Czarnezki, *The Future of Food Eco-Labeling: Organic, Carbon Footprint, and Environmental Life-Cycle Analysis*, 30 STAN. ENVTL. L.J. 3, 14–15 (2011); *Organic Agriculture*, U.S. DEP'T AGRIC. ECON. RESEARCH SERV., <http://www.ers.usda.gov/Briefing/Organic/> (last updated Nov. 30, 2009).

<sup>7</sup> See Margaret Rosso Grossman, *The Coexistence of GM and Other Crops in the European Union*, 16 KAN. J.L. & PUB. POL'Y 324, 324 (2007); Sara N. Pasquinelli, *One False Move: The History of Organic Agriculture and Consequences of Non-Compliance with the Governing Laws and Regulations*, 3 GOLDEN GATE U. ENVTL. L.J. 365, 368 (2010) (discussing the historic definition of *organic*).

<sup>8</sup> See Grossman, *supra* note 7, at 360–61 (citing Minou Yusefi, *Organic Farming Worldwide 2006: Overview and Main Statistics*, in THE WORLD OF ORGANIC AGRICULTURE: STATISTICS & EMERGING TRENDS 2006, at 23, 23 (Helga Willer & Minou Yusefi eds., 2006)).

variety.<sup>9</sup> The USDA suggests that farmers are changing to organic-crop production at an increasing rate to “lower input costs, conserve nonrenewable resources, capture high-value markets, and boost farm income.”<sup>10</sup>

Because of possible risks associated with GM crops, the interest of organic-farming operations in maintaining the organic status of their crops, and the desire to protect the overall stability of the agricultural sector, Congress has indicated its continued support for organic farming and the USDA has specifically announced its intention to foster coexistence between GM and organic crops.<sup>11</sup> The USDA’s strategic plan and recent legislation emphasize the federal government’s desire to support organic programs. The USDA’s 2010–2015 strategic plan notes that maintaining access to organic markets is a component of ensuring the financial stability of American farms.<sup>12</sup> Indeed, the strategic plan seeks to increase the number of organic-farming operations by approximately 25% by the end of 2015.<sup>13</sup> Similarly, the Organic Foods Production Act’s stated purpose is “to facilitate interstate commerce in . . . food that is organically produced.”<sup>14</sup> The Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) provides specific and ongoing incentives for farmers to engage in organic-crop production.<sup>15</sup> These legislative statements and initiatives indicate a congressional desire to foster organic-crop programs alongside GM-crop programs.

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<sup>9</sup> See Keith Aoki, *Seeds of Dispute: Intellectual-Property Rights and Agricultural Biodiversity*, 3 GOLDEN GATE U. ENVTL. L.J. 79, 124 (2009) (citing CARY FOWLER & PAT MOONEY, SHATTERING: FOOD, POLITICS, AND THE LOSS OF GENETIC DIVERSITY 47 (1990)).

<sup>10</sup> *Organic Production: Documentation*, U.S. DEP’T AGRIC. ECON. RESEARCH SERVICE, <http://www.ers.usda.gov/data-products/organic-production/documentation.aspx> (last updated July 5, 2012).

<sup>11</sup> See Letter from Thomas Vilsack, Sec’y of Agric., U.S. Dep’t of Agric., to Stakeholders (Dec. 2010), available at [http://www.usda.gov/documents/GE\\_Alfa-to\\_stakeholders-2010Dec.pdf](http://www.usda.gov/documents/GE_Alfa-to_stakeholders-2010Dec.pdf) (“[W]e at the USDA are striving to lead an effort to forge a new paradigm based on coexistence and cooperation. If successful, this effort can ensure that all forms of agriculture thrive so that food can remain abundant, affordable, and safe.”).

<sup>12</sup> See U.S. DEP’T OF AGRIC., *supra* note 5, at 9.

<sup>13</sup> *Id.* at 10 (noting the baseline of 16,564 organic farms in 2009 and the target of 20,655 organic farms in 2015).

<sup>14</sup> Organic Foods Production Act of 1990, Pub. L. No. 101-624, tit. XXI, § 2102(3), 104 Stat. 3935, 3935 (codified at 7 U.S.C. § 6501(3) (2006)).

<sup>15</sup> The 2008 Farm Bill created incentives within the Environmental Quality Incentives Program for famers to assist producers in changing to conservation-based organic-production practices. Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-234, 122 Stat. 923 (codified in scattered sections of 7 U.S.C.). The 2008 Farm Bill further charges the Secretary of Agriculture to develop “programs that meet specific needs of producers involved with organic” crop production. *Id.* sec. 2706, § 1242(i)(2)(B)(i), 122 Stat. at 1077. The 2008 Farm Bill also increases funding to the National Organic Program for each year through 2012. See *id.* sec. 10303, § 2123(b), 122 Stat. at 1347.

Unfortunately, there are barriers to the successful coexistence of organic and GM crops. Gene flow, or the spread of genetic materials across plant populations, can contaminate organic crops, causing them to absorb GM genes and lose their organic status.<sup>16</sup> This loss of status can cause considerable economic harm to organic programs that may no longer be able to sell organic crops.<sup>17</sup> Contamination occurs when genetic data is spread from one crop to another by various means, including wind, insect activity, or human intervention.<sup>18</sup> Contamination of organic crops through gene flow is the primary obstacle to the successful coexistence of GM and organic crops.

There is no legal framework directly addressing contamination resulting from gene flow. Responding to the USDA's promotion of coexistence strategies to promote agricultural health, the American Farm Bureau Association implicitly stated that the current legal and regulatory systems are unable to prevent contamination and foster beneficial coexistence.<sup>19</sup> The existing federal system governing the deregulation of GM crops spreads responsibility across the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the USDA.<sup>20</sup> This framework presumes that GM crops are beneficial.<sup>21</sup> The USDA, through the Animal and Plant Health Inspection Service (APHIS), holds the most power over possible contamination through its responsibility to regulate GM crops as pests under the Plant Protection Act.<sup>22</sup> However, APHIS's statutory directives only require it to rely on "sound science" in decisions concerning agricultural products.<sup>23</sup> The agency routinely grants deregulation permits based on general

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<sup>16</sup> See *Gene Flow from GM to Non-GM Populations in the Crop, Forestry, Animal and Fishery Sectors*, FOOD & AGRIC. ORG. UNITED NATIONS, <http://www.fao.org/biotech/C7doc.htm> (last visited Aug. 6, 2012) [hereinafter *Gene Flow from GM to Non-GM Populations*].

<sup>17</sup> See Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 623 (2003).

<sup>18</sup> See *Gene Flow from GM to Non-GM Populations*, *supra* note 16.

<sup>19</sup> Letter from Am. Farm Bureau Fed'n et al. to John P. Holdren, Dir., Office of Sci. & Tech. Policy, Exec. Office of the President (Jan. 5, 2011), available at [http://www.naturalnews.com/files/GMO\\_science\\_letter.pdf](http://www.naturalnews.com/files/GMO_science_letter.pdf).

<sup>20</sup> See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,306 (June 26, 1986) (laying out agency responsibility).

<sup>21</sup> The language of the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) promoted biotechnology and noted that GM crops were not expected to pose any new risks. *Id.* at 23,339.

<sup>22</sup> Pub. L. No. 106-224, tit. IV, 114 Stat. 438 (2000) (codified as amended at 7 U.S.C. §§ 7701-7786 (2006)); 7 C.F.R. § 340.0(a)(2) n.1 (2011).

<sup>23</sup> See 7 U.S.C. §§ 7701-7754.

extrapolations from field tests and without fully considering genetic drift.<sup>24</sup> Further, APHIS presumes GM crops are substantially equivalent to non-GM crops.<sup>25</sup> Thus, APHIS, and therefore the overall regulatory system, does not protect organic-farm systems from contamination and does not support the USDA's goals of coexistence.

The courts are similarly unable to adequately protect coexistence ideals. Frequent technical litigation in the form of patent infringement suits, tort suits, or regulatory challenges confuses general courts and leads to unsatisfying remedies. The USDA has noted that conflict between GM and non-GM crops, like organic crops, may lead to frequent litigation where the courts ultimately decide "who gets to farm."<sup>26</sup> GM alfalfa was among the crops regulated by APHIS when Monsanto petitioned for deregulation stating that its GM alfalfa should not be considered a pest risk.<sup>27</sup> APHIS granted Monsanto's petition in full and allowed partial deregulation,<sup>28</sup> and then Geertson Seed Farms and other organic groups brought suit against the USDA. The ensuing litigation, which reached the Supreme Court, ultimately led to the deregulation of alfalfa.<sup>29</sup> More recently, APHIS chose to deregulate GM sugar beets in violation of a court order requiring the agency to undertake further environmental assessment.<sup>30</sup> These deregulations demonstrate that the courts are unable to foster coexistence.

The recent disputes over the deregulation and subsequent planting of GM alfalfa and GM sugar beets have highlighted the growing conflict between GM and organic crops. Organic producers argued that the deregulated crops would harm their interests in maintaining organic farms, but GM producers had satisfied the regulatory requirements for deregulation.<sup>31</sup> Both groups have legitimate claims, and the problems for coexistence reside in the legal and regulatory framework governing the farming practices.

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<sup>24</sup> Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 KAN. J.L. & PUB. POL'Y 393, 412 (2007).

<sup>25</sup> *See id.*

<sup>26</sup> Letter from Thomas Vilsack to Stakeholders, *supra* note 11.

<sup>27</sup> *See Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2750 (2010).

<sup>28</sup> *See Monsanto Co. and Forage Genetics International; Availability Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate*, 70 Fed. Reg. 36,917, 36,917-19 (June 27, 2005) (granting deregulation).

<sup>29</sup> Andrew Pollack, *U.S. Approves Genetically Modified Alfalfa*, N.Y. TIMES, Jan. 28, 2011, at B1.

<sup>30</sup> Andrew Pollack, *U.S. Says Farmers May Grow Engineered Sugar Beets*, N.Y. TIMES, Feb. 5, 2011, at B3.

<sup>31</sup> Pollack, *supra* note 29; Pollack, *supra* note 30.



This Comment seeks to explore the current regulatory and legal structures governing GM crops and contamination, and demonstrate how the system does not foster the coexistence of GM and organic crops. Part I discusses the growth of organic- and GM-farming practices. Part I also illustrates how contamination conflicts with the goal of coexistence. Part II explains the current legal issues relating to coexistence. The discussion emphasizes the role of the existing regulatory framework, particularly APHIS's role under the Plant Protection Act. Part II also illustrates the failures of the current legal and regulatory regime in controlling contamination and protecting the economic feasibility of organic farming. Part III explores two court decisions: *Monsanto Co. v. Geertson Seed Farms* and a recent case applying *Monsanto, Center for Food Safety v. Vilsack*. These cases highlight the weaknesses in the federal regulatory program and the inability of the courts to provide adequate remedies. Part IV proposes possible solutions to protect the economic viability of organic programs and therefore foster coexistence. Part IV also addresses the feasibility and costs of the proposed solutions.

## I. GENETICALLY MODIFIED CROPS AND ORGANIC CROPS

The current regulatory system is unable to ensure the beneficial coexistence of GM and organic crops. Similarly, the courts are unable to support coexistence. It is necessary to understand the benefits of both organic crops and GM crops, and the problems of contamination, before exploring the failures in the legal framework. This Part introduces (1) GM-crop farming, (2) organic-crop farming, (3) the goal of coexistence, and (4) the obstacle of genetic contamination in achieving coexistence.

### A. *Genetically-Modified-Crop Farming in U.S. Agriculture*

GM crops emerged in U.S. farming in 1996<sup>32</sup> and were quickly adopted throughout the agricultural sector.<sup>33</sup> Engineered crops are typically infused either with herbicide-resistant genes, pest-resistant genes, or both.<sup>34</sup> Farmers have embraced herbicide-resistant GM soybean and cotton to the greatest

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<sup>32</sup> *Adoption of Genetically Engineered Crops in the U.S.*, U.S. DEP'T AGRIC. ECON. RESEARCH SERVICE, <http://www.ers.usda.gov/Data/BiotechCrops/> (last updated July 12, 2012).

<sup>33</sup> See JAMES, *supra* note 2, at 1 (noting that the period from 1996–2005 had “unprecedented” adoption rates of biotech crops by U.S. farmers).

<sup>34</sup> NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., *supra* note 3, at 30. Some crops are also infused with virus-resistant genes. *Id.* at 29–30.

extent but have also extensively planted GM cotton and corn.<sup>35</sup> In 2009, based on acreage, more than 80% of the corn, cotton, and soybeans grown in the United States contained genetically engineered genes.<sup>36</sup> The United States produces approximately half of the world's biotech crops.<sup>37</sup>

This widespread adoption of GM crops (extending well beyond cotton, soybeans, and corn) has led to undisputed benefits, such as increased yields, decreased labor in weed and pest management, and decreased chemical applications.<sup>38</sup> Additionally, GM crops offer environmental benefits in the form of reduced greenhouse gases.<sup>39</sup> GM crops also have the potential to produce pharmaceutical materials.<sup>40</sup>

The United States has largely encouraged the domestic production and planting of GM crops. To incentivize the development of GM crops, the United States extends patent protection to modified crops.<sup>41</sup> GM producers develop and sell seeds that sprout engineered crops.<sup>42</sup> The patents on these seeds trump farmers' common law rights to replant seeds from a prior harvest.<sup>43</sup> These patents have led to tremendous growth in the United States' GM-crop industry<sup>44</sup> and helped the United States become a world leader in the production of GM crops.<sup>45</sup> The USDA continues to advocate GM-crop research, noting that the technology also "address[es] issues related to global food security, energy security, and climate change."<sup>46</sup>

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<sup>35</sup> *Adoption of Genetically Engineered Crops in the U.S.*, *supra* note 32.

<sup>36</sup> NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., *supra* note 3, at 1.

<sup>37</sup> Alison Peck, *Leveling the Playing Field in GMO Risk Assessment: Importers, Exporters and the Limits of Science*, 28 B.U. INT'L L.J. 241, 265 (2010).

<sup>38</sup> See Andrew Pollack, *Study Finds Benefits in Genetically Modified Crops but Warns of Overuse*, N.Y. TIMES, Apr. 14, 2010, at B3.

<sup>39</sup> See Drew L. Kershen, *Sustainable Intensive Agriculture: High Technology and Environmental Benefits*, 16 KAN. J.L. & PUB. POL'Y 424, 429 (2007) (summarizing and citing numerous studies establishing environmental benefits from biotech farming).

<sup>40</sup> Rebecca M. Bratspies, *Consuming F(ears) of Corn: Public Health and Biopharming*, 30 AM. J.L. & MED. 371, 372 (2004).

<sup>41</sup> See Aoki, *supra* note 9, at 89; Benjamin Ikuta, *Genetically Modified Plants, Patents, and Terminator Technology: The Destruction of the Tradition of Seed Saving*, 35 OHIO N.U. L. REV. 731, 739 (2009); see also discussion *infra* Part II.A.

<sup>42</sup> See Ikuta, *supra* note 41, at 739.

<sup>43</sup> See *id.* at 739–40 (discussing the reduction in a farmer's common law right to save seeds).

<sup>44</sup> See *id.* (noting that use of herbicide-resistant soybeans rose from 17% of total soybean acreage to over 70% from 1997 to 2006).

<sup>45</sup> See Peck, *supra* note 37, at 244–45 (noting the United States' prominent position in producing and exporting GM organisms).

<sup>46</sup> U.S. DEP'T OF AGRIC., *supra* note 5, at 23.

Despite the benefits of GM crops, they have not been unanimously adopted. A small number of countries in the European Union have adopted certain GM crops, but the approval process for such adoption is notably “laborious.”<sup>47</sup> Recent studies in the United States indicate that the benefits of GM crops may come with significant drawbacks, especially in the form of herbicide-resistant weeds.<sup>48</sup> Additionally, excessive monocropping of GM crops can lead to potential drawbacks.<sup>49</sup> Monocropping, or monoculture, describes the homogenous planting of a single genetic strain of a crop.<sup>50</sup> A widespread homogenous crop is more susceptible to disease, weeds, and pests because a single virus or infection capable of hurting the particular strain can damage the entire crop.<sup>51</sup> Diversity within a type of crop prevents a single epidemic from destroying an entire harvest.<sup>52</sup>

### *B. Organic-Crop Farming in U.S. Agriculture*

The establishment of GM crops has coincided with the growth of organic-farming practices in the United States.<sup>53</sup> In 2006, over 623,000 farms in the United States grew organic crops.<sup>54</sup> The organic-product industry is predicted to generate over \$50 billion in revenues in 2025 and expected to continue to grow at a rate of 18% to 20% annually.<sup>55</sup> The growing popularity of organic food in the United States is exemplified by First Lady Michelle Obama’s organic garden on the White House lawn.<sup>56</sup>

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<sup>47</sup> See Elisabeth Rosenthal, *In the Fields of Italy, a Conflict over Corn*, N.Y. TIMES, Aug. 24, 2010, at A4 (noting that there are only two GM crops that have gained approval throughout Europe). There is also controversy in developing countries where leaders refuse to adopt GM crops despite widespread hunger in their nations. See, e.g., *Famine and the GM Debate*, BBC NEWS (Nov. 14, 2002, 9:58 AM), <http://news.bbc.co.uk/2/hi/2459903.stm>.

<sup>48</sup> See Andrew Pollack, *Monsanto’s Fortunes Turn Sour*, N.Y. TIMES, Oct. 5, 2010, at B1 (noting the emergence of Roundup-resistance genes after wide use of the herbicide).

<sup>49</sup> See Aoki, *supra* note 9, at 124 (“Genetic engineering in the context of commercial crops necessarily entails decreased genetic diversity. Because it is essential that GE crops have a uniform genetic structure, genetic engineering encourages monoculture.”).

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* (citing FOWLER & MOONEY, *supra* note 9, at 47).

<sup>52</sup> *Id.* (citing FOWLER & MOONEY, *supra* note 9, at 46–47).

<sup>53</sup> See, e.g., Andrew Martin, *Is a Food Revolution Now in Season?*, N.Y. TIMES, Mar. 22, 2009, at BU1.

<sup>54</sup> See Grossman, *supra* note 7, at 360–61 (citing Yussefi, *supra* note 8, at 23).

<sup>55</sup> Pasquinelli, *supra* note 7, at 366.

<sup>56</sup> Martin, *supra* note 53; see also Marian Burros, *Obamas to Plant Vegetable Garden at White House*, N.Y. TIMES, Mar. 19, 2009, at A1.

Organic products are generally defined as products derived from crops grown without the aid of pesticides, herbicides, or genetic modifications.<sup>57</sup> Although the USDA defines organic food for domestic-labeling purposes, its definition is not as strict, in terms of permissible levels of chemicals or modified genes, as in other organic markets, particularly international markets.<sup>58</sup> Among the benefits attributed to organic products is the absence of genetically altered elements and reduced environmental harm incurred from broad pesticide application.<sup>59</sup> Organic varieties also entail increased diversity to prevent the risks associated with monocropping.<sup>60</sup> As noted, the USDA believes farmers change to organic-crop production “to lower input costs, conserve nonrenewable resources, capture high-value markets, and boost farm income.”<sup>61</sup>

### C. *The Beneficial Coexistence of Modified and Organic Crops*

The benefits associated with both GM crops and organic crops demonstrate that the agricultural health of the United States requires coexistence between the two practices.<sup>62</sup> The Secretary of Agriculture recognized this benefit and announced the USDA’s intention to foster coexistence in December 2010.<sup>63</sup> Similarly, the 2008 Farm Bill included provisions indicating a congressional desire to ensure continued organic farming in the United States.<sup>64</sup> Excessive GM farming is susceptible to the risks of monocropping. Organic farming is not susceptible to the risks of monocropping but does not entail the increased yields or harm resistance of GM crops. Thus, American farming will benefit from enhanced food security resulting from successful coexistence.<sup>65</sup> Unfortunately, coexistence is difficult because genetic drift can cause GM

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<sup>57</sup> See Grossman, *supra* note 7, at 324; Pasquinelli, *supra* note 7, at 368 (discussing the historic definition of *organic* and the origins of the modern organic-agriculture movement).

<sup>58</sup> See William S. Eubanks II, *The Sustainable Farm Bill: A Proposal for Permanent Environmental Change*, 39 ENVTL. L. REP. 10493, 10507–08 (2009).

<sup>59</sup> See Martin, *supra* note 53.

<sup>60</sup> Aoki, *supra* note 9, at 124.

<sup>61</sup> *U.S. Organic Farming*, *supra* note 10.

<sup>62</sup> See A. Bryan Endres, *Coexistence Strategies, the Common Law of Biotechnology and Economic Liability Risks*, 13 DRAKE J. AGRIC. L. 115, 118–19 (2008) (discussing the benefits of coexistence).

<sup>63</sup> See Letter from Thomas Vilsack to Stakeholders, *supra* note 11.

<sup>64</sup> See *supra* note 15 and accompanying text.

<sup>65</sup> See Susan A. Schneider, *A Reconsideration of Agricultural Law: A Call for the Law of Food, Farming, and Sustainability*, 34 WM. & MARY ENVTL. L. & POL’Y REV. 935, 963 (2010) (noting that the historical aims of food security are fading to special interests).

crops to contaminate organic crops.<sup>66</sup> When organic crops are contaminated, the crops can lose organic status in their desired market, causing substantial economic losses to the organic crop producers.<sup>67</sup>

#### *D. Contamination and Its Frustration of Coexistence*

Gene flow, or the spread of genetic materials across plant populations, can contaminate organic crops by causing them to absorb GM genes and lose their organic status.<sup>68</sup> This loss of status can cause considerable economic harm to organic programs.<sup>69</sup> Contamination results from genetic exposure through cross-pollination, unclean harvesting or storage practices, or improper handling outside the farm.<sup>70</sup> While the USDA often mandates defined boundaries to prevent cross-pollination,<sup>71</sup> such boundaries do not prevent contamination either because of illegal plantings or insufficient boundary distances.<sup>72</sup> Although some contamination is inevitable,<sup>73</sup> the current legal structure is unable to establish a program that can consistently control contamination and support coexistence.<sup>74</sup> Successful coexistence requires the ongoing economic feasibility of organic crops, and contamination threatens such feasibility.

Coexistence troubles were before the USDA when, in 2004, it granted deregulation and then litigated its decision to the Supreme Court.<sup>75</sup> The USDA has now deregulated GM alfalfa despite continuing protests of its potential to contaminate.<sup>76</sup> The ultimate deregulation of GM alfalfa<sup>77</sup> is indicative of the weaknesses of the current framework in fostering coexistence.

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<sup>66</sup> Alison Peck, *The New Imperialism: Toward an Advocacy Strategy for GMO Accountability*, 21 GEO. INT'L ENVTL. L. REV. 37, 38 (2008).

<sup>67</sup> Stephanie M. Bernhardt, *High Plains Drifting: Wind-Blown Seeds and the Intellectual Property Implications of the GMO Revolution*, 4 NW. J. TECH. & INTELL. PROP. 1, 9 (2005). Farmers are unable to insure themselves against the risk of genetic drift. See Roger A. McEowen, *Legal Issues Related to the Use and Ownership of Genetically Modified Organisms*, 43 WASHBURN L.J. 611, 620–21 (2004).

<sup>68</sup> See *Gene Flow from GM to Non-GM Populations*, *supra* note 16.

<sup>69</sup> Bernhardt, *supra* note 67, at 9.

<sup>70</sup> Peck, *supra* note 66, at 43.

<sup>71</sup> See 7 C.F.R. § 205.202(c) (2011) (imposing crop-distance boundaries upon deregulation).

<sup>72</sup> Peck, *supra* note 66, at 47.

<sup>73</sup> *Id.* at 45.

<sup>74</sup> See Schneider, *supra* note 65, at 958 (“[T]he contamination of non-genetically engineered crops through cross pollination represents a significant problem that remains unresolved.”).

<sup>75</sup> *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2750 (2010) (discussing APHIS’s decision to deregulate alfalfa).

<sup>76</sup> See Pollack, *supra* note 29.

<sup>77</sup> *Id.*

## II. THE CURRENT FRAMEWORK AND ITS FAILURES

The current legal structure governing coexistence efforts includes (1) patent protections for GM crops; (2) state and local legal remedies, including tort suits, aiding those harmed by contamination; and (3) a regulatory framework governing the release, or deregulation, of GM crops. GM-crop producers can obtain patents for their products under the Plant Patent Act of 1930, the Plant Variety Protection Act of 1970, and other utility-patent provisions.<sup>78</sup> Producers of patented seed varieties may enforce these patents even in situations where alleged infringers obtained the patented genes via genetic drift.<sup>79</sup> Conversely, farmers have brought suit against GM-crop growers under various tort theories for damage caused by genetic drift.<sup>80</sup> The litigation stemming from contamination (including patent and tort suits) imposes unnecessary costs on U.S. agriculture and may deter organic farming. The Secretary of Agriculture identified consistent litigation as a hurdle for coexistence.<sup>81</sup> He has called for a “better way” to promote coexistence than through the courts.<sup>82</sup>

Outside the courts, the release of GM crops is governed by the patchwork regulatory system established by the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework).<sup>83</sup> While patent protections for GM crops and tort protection for organic farmers offer some protection and relief, the failures of the regulatory system prevent the beneficial coexistence of GM crops and organic crops. Specifically, the Coordinated Framework is unable to satisfactorily account for the risk of contamination under its statutory directives. This part discusses (1) GM-crop patent protection, (2) tort and local remedies, and (3) the Coordinated Framework.

### A. *Patent Protection for Genetically Modified Crops*

A series of patent acts and Supreme Court cases provides incentives for GM producers to develop GM crops.<sup>84</sup> The Plant Patent Act of 1930 granted patents to the developers of asexually reproducing plants.<sup>85</sup> As private-brand

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<sup>78</sup> See Ikuta, *supra* note 41, at 734–39 (discussing the development of patent protections for GM crops).

<sup>79</sup> See Drew L. Kershen, *Of Straying Crops and Patent Rights*, 43 WASHBURN L.J. 575, 578 (2003) (reviewing bases of potential infringement claims).

<sup>80</sup> See McEowen, *supra* note 67, at 618–25 (reviewing potential tort claims).

<sup>81</sup> Letter from Thomas Vilsack to Stakeholders, *supra* note 11.

<sup>82</sup> *Id.*

<sup>83</sup> 51 Fed. Reg. 23,302 (June 26, 1986).

<sup>84</sup> See Ikuta, *supra* note 41, at 734–39.

<sup>85</sup> Plant Patent Act of 1930, ch. 312, 46 Stat. 376 (codified as amended at 35 U.S.C. §§ 161–164 (2006)).

seeds continued to gain market share, Congress passed the 1970 Plant Variety Protection Act<sup>86</sup> (PVPA), extending patent protection to most commercial crops.<sup>87</sup> These legislative protections, combined with Supreme Court decisions favoring biotechnology research,<sup>88</sup> led to the consolidation of large seed companies, particularly Monsanto and DuPont.<sup>89</sup> Monsanto recently acquired “terminator technology” to ensure that farmers who buy GM seeds can only use those seeds for a single harvest.<sup>90</sup>

These patent protections are incapable of fully resolving the issue of genetic drift from modified crops to organic crops.<sup>91</sup> While GM producers risk losing patented products to noncustomer farmers, traditional farmers risk liability when patented-crop genes drift onto their farms.<sup>92</sup> Indeed, as of 2005, Monsanto had filed over one hundred infringement suits against noncustomer farmers.<sup>93</sup> By 2010, the company won fifty-seven judgments and recovered over \$20 million from patent suits.<sup>94</sup> It frequently wins its patent infringement claims.<sup>95</sup> While Monsanto offers to remove patented seeds upon notification by the affected farmer, organic farms risk losing crops in the removal process.<sup>96</sup> Additionally, organic operations may be unaware of contamination until crops are harvested.<sup>97</sup> Recent cases demonstrate that non-GM farmers can be liable

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<sup>86</sup> Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified as amended at 7 U.S.C. §§ 2321–2582).

<sup>87</sup> Haley Stein, *Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World*, 3 NW. J. TECH. & INTELL. PROP. 160, 165 (2005).

<sup>88</sup> See, e.g., *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124 (2001) (extending utility patents to modified seeds and holding that the Plant Patent Act and PVPA cannot limit utility patents); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (interpreting the Plant Patent Act and PVPA broadly, and allowing patents to be issued based on human effort); see also Stein, *supra* note 87, at 166–68 (describing Supreme Court cases as encouraging the development of the agribusiness industry).

<sup>89</sup> Stein, *supra* note 87, at 164, 167. “[T]he Justice Department is investigating Monsanto for possible antitrust violations.” Pollack, *supra* note 48.

<sup>90</sup> See Ikuta, *supra* note 41, at 739. The “terminator technology” and the extension of utility-patent protection to modified seeds effectively eliminate the common law right of farmers to replant seeds purchased in a prior season. *Id.*

<sup>91</sup> See Kershen, *supra* note 79, at 601 (proposing applying the law of stray animals to fix problems with patent rights and genetic drift).

<sup>92</sup> *Id.* at 578.

<sup>93</sup> Bernhardt, *supra* note 67, at 8.

<sup>94</sup> Amanda L. Kool, *Halting Pig in the Parlor Patents: Nuisance Law as a Tool to Redress Crop Contamination*, 50 JURIMETRICS J. 453, 468 (2010).

<sup>95</sup> See Gregory N. Mandel, *The Future of Biotechnology Litigation and Adjudication*, 23 PACE ENVTL. L. REV. 83, 102 (2006).

<sup>96</sup> See Bernhardt, *supra* note 67, at 9 (noting the risk of removal).

<sup>97</sup> See *id.* at 8 (explaining that an organic farmer may have to spray pesticide to determine if a potentially contaminated crop is resistant to the pesticide).

for the inadvertent presence of GM seeds in their crops, even when neighboring farms utilize the patented crops.<sup>98</sup>

The threat of liability from infringement suits or lost profits from crop removals may be enough to deter farmers from growing organically.<sup>99</sup> Similarly, GM producers must invest resources in monitoring and enforcing their patents.<sup>100</sup> Neither GM producers nor organic farmers benefit from lawsuits stemming from the patent framework. The patent system and the ensuing litigation, often stemming from inadvertent contamination, impose costs on both GM producers and organic-farming interests, and frustrate coexistence.

### *B. State and Local Efforts to Promote Coexistence*

State and local efforts at controlling contamination, including tort suits from non-GM farmers, offer some support to coexistence aims. Organic-farming interests can seek relief when their interests are injured by contamination under the traditional tort theories of trespass, nuisance, or negligence.<sup>101</sup> While tort suits on behalf of organic programs may earn them some relief, these options are insufficient to protect the goals of coexistence in U.S. farming. Generally, farmers cannot recover under tort law for purely economic loss.<sup>102</sup> Similarly, organic farmers may not be able to prove damages when contaminated crops still meet the USDA definition of *organic*, despite stricter definitions in foreign markets.<sup>103</sup> Also, organic farmers bringing suit for loss from contamination face countersuits for patent infringement.<sup>104</sup> Farmers who bring specific tort actions face problems in establishing causality or a duty of care.<sup>105</sup> Additionally, local efforts at protecting organic-farming

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<sup>98</sup> See, e.g., *Monsanto Can. Inc. v. Schmeiser*, [2004] 1 S.C.R. 902 (Can.) (imposing liability on a farmer when five neighboring farmers grew Monsanto GM canola and 40% of Canadian farmers used Monsanto canola).

<sup>99</sup> Pasquinelli, *supra* note 7, at 380.

<sup>100</sup> See Bernhardt, *supra* note 67, at 8 (noting that Monsanto has filed over one hundred suits in the United States for patent infringement).

<sup>101</sup> See McEowen, *supra* note 67, at 618–25 (discussing potential tort actions for non-GM farmers). Farmers have been wholly unsuccessful in seeking damages under strict liability theories. *Id.* at 626.

<sup>102</sup> See *id.* at 622.

<sup>103</sup> See Michelle T. Friedland, *You Call That Organic?—The USDA's Misleading Food Regulations*, 13 N.Y.U. ENVTL. L.J. 379, 429 (2005) (discussing labeling and noting that USDA-organic status tolerates the presence of some modified genes).

<sup>104</sup> McEowen, *supra* note 67, at 620.

<sup>105</sup> *Id.* at 618–25.



practices may be frustrated by state and federal preemption.<sup>106</sup> This section discusses (1) trespass, (2) nuisance, (3) negligence, and (4) state and local legislation regarding coexistence.

### 1. *Trespass*

Organic-farming interests can sue under trespass alleging that drifting modified genes interfere with their ownership of land.<sup>107</sup> Trespass is an unauthorized intrusion on a person's land that interferes with that person's ownership of the land.<sup>108</sup> Organic farmers tend to seek negligent trespass because intentional trespass is difficult to prove in the context of contamination, which may occur without intentional human interference.<sup>109</sup> Farmers able to prove invasion face countersuits in terms of patent infringements.<sup>110</sup> Nevertheless, trespass is probably the most promising tort action available to those injured by genetic drift.

### 2. *Nuisance*

Organic programs can also allege that drifting modified genes interfere with the reasonable use of their land.<sup>111</sup> A nuisance, specifically a private nuisance, "is an invasion of an individual's interest in the reasonable use and enjoyment of . . . her land."<sup>112</sup> Proving that genetic drift is a nuisance requires proving that the planting of nearby GM crops was unreasonable.<sup>113</sup> Because of the widespread use of GM crops and the federal imprimatur of GM planting (assuming deregulation), organic programs may have difficulty proving that the planting of GM crops was unreasonable.<sup>114</sup> Further, the widespread use of GM crops would make identifying the culprit of unreasonable behavior nearly impossible.<sup>115</sup> Additionally, many state right-to-farm laws prevent nuisance

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<sup>106</sup> See A. Bryan Endres, *Coexistence Strategies in a Biotech World: Exploring Statutory Grower Protections*, 13 MO. ENVTL. L. & POL'Y REV. 206, 215, 230 (2006).

<sup>107</sup> McEowen, *supra* note 67, at 618.

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 619.

<sup>110</sup> See *id.* at 620 (noting the risks of countersuits).

<sup>111</sup> See *id.* at 623.

<sup>112</sup> See *id.* at 623–24.

<sup>113</sup> *Id.* at 624.

<sup>114</sup> See *id.*

<sup>115</sup> See Friedland, *supra* note 103, at 428 n.227.

suits against neighboring farms.<sup>116</sup> Nevertheless, contamination of non-GM crops has formed the basis for nuisance suits against GM growers.<sup>117</sup>

### 3. *Negligence*

To prove negligence, organic programs must establish that a GM producer or grower breached a duty of care in allowing genetic drift from GM crops.<sup>118</sup> There is not a uniform standard for the duty of care owed by GM-crop farmers, but negligence-based suits have had some success.<sup>119</sup> The StarLink litigation, discussed below, included negligence claims.<sup>120</sup> Negligence suits, however, like most tort causes of action, require injured farmers to prove more than just economic damage.<sup>121</sup> Organic programs have been unable to recover under negligence for purely economic loss without evidence of physical damage.<sup>122</sup>

Although organic interests may be able to recover for damages incurred from gene transmission through trespass or nuisance, the theories provide after-the-fact remedies to crop contamination at best and do not seem to offer ex ante deterrence to GM growers. Many organic farmers will be suing their nonorganic neighbors, who have contracted with GM producers and may not have the assets to make the injured organic farmer whole.<sup>123</sup> Farmers injured by drift may also have trouble proving damages when their products can still be labeled organic under domestic standards.<sup>124</sup> While negligence suits have had some success in this arena, they will not be truly valuable until federal law defines a uniform standard of care.<sup>125</sup> Further, adequate federal enforcement of buffer zones between different crops should prevent tort contamination claims.<sup>126</sup> Organic organizations chose not to rely on ex post tort suits in the

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<sup>116</sup> Terence J. Centner, *Governments and Unconstitutional Takings: When Do Right-to-Farm Laws Go Too Far?*, 33 B.C. ENVTL. AFF. L. REV. 87, 87–88 (2006).

<sup>117</sup> Mandel, *supra* note 95, at 100.

<sup>118</sup> See McEowen, *supra* note 67, at 621.

<sup>119</sup> *Id.* at 622.

<sup>120</sup> *Id.* at 622 n.61.

<sup>121</sup> *Id.* at 622.

<sup>122</sup> Thomas P. Redick & A. Bryan Endres, *Litigating the Economic Impacts of Biotech Crops*, NAT. RESOURCES & ENV'T, Spring 2008, at 24, 27.

<sup>123</sup> See Friedland, *supra* note 103, at 428.

<sup>124</sup> *Id.* at 429.

<sup>125</sup> McEowen, *supra* note 67, at 622.

<sup>126</sup> See Bratspies, *supra* note 24, at 414; Emily Gersema, *USDA Survey Shows Biotech Rules Breaches*, IOWA ST. U. EXTENSION & OUTREACH (Sept. 10, 2003), <http://www.extension.iastate.edu/Grain/Topics/BiotechRulesBreaches.htm>.

cases of *Monsanto Co. v. Geertson Seed Farms*<sup>127</sup> and *Center for Food Safety v. Vilsack*,<sup>128</sup> where the organizations challenged deregulation decisions before incurring damage from genetic drift.<sup>129</sup>

#### 4. *State and Local Efforts at Fostering Coexistence*

State and local regulatory efforts at fostering coexistence by controlling contamination have been largely unsuccessful. No state has passed laws shifting the loss incurred from contamination away from the injured farmer.<sup>130</sup> California, Idaho, and Washington impose legislatively enacted buffer zones for specific crops.<sup>131</sup> Although these enactments penalize those who violate the buffer zones,<sup>132</sup> the boundary distances, like those imposed by APHIS, are not necessarily effective. While many localities have taken steps to create “[g]rower[’s] [d]istricts” that prevent the growing of GM crops in certain areas, state laws tend to preempt the local efforts.<sup>133</sup> State laws that preempt local laws tend to promote the planting of GM crops, rather than foster coexistence.<sup>134</sup> Further, state laws are considerably weakened by state deference to the federal government’s scientific determinations.<sup>135</sup> Finally, the Plant Protection Act, under which APHIS regulates GM crops, preempts any inconsistent or excessive state regulations.<sup>136</sup> Because of the weakness of state and local regulations relative to federal regulations, state and local actions are unable to protect the economic feasibility of organic programs and therefore are unable to foster the goals of coexistence.

#### C. *The Existing Regulatory Framework*

There is no regulatory framework directly aimed at fostering coexistence. The relevant regulatory framework addressing coexistence lies in the Coordinated Framework created by the Reagan Administration when

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<sup>127</sup> 130 S. Ct. 2743 (2010).

<sup>128</sup> 734 F. Supp. 2d 948 (N.D. Cal. 2010).

<sup>129</sup> *Monsanto Co.*, 130 S. Ct. at 2749; *Ctr. for Food Safety*, 734 F. Supp. 2d at 950.

<sup>130</sup> Peck, *supra* note 66 at 64.

<sup>131</sup> See Endres, *supra* note 106, at 215–17.

<sup>132</sup> CAL. FOOD & AGRIC. CODE §§ 52971–52976 (West 2001 & Supp. 2012); IDAHO ADMIN. CODE r. 02.06.13.200 (2011); WASH. ADMIN. CODE § 16-302-055(8) (2012).

<sup>133</sup> Endres, *supra* note 106, at 215.

<sup>134</sup> See *id.* at 219 (noting that many of the state laws that preempt local planting restrictions are implemented to encourage biotech crops).

<sup>135</sup> *Id.* at 230.

<sup>136</sup> *Id.* at 231.

engineered crops were first conceived.<sup>137</sup> The system, chartered to control the introduction of GM crops, was devised with a pro-industry,<sup>138</sup> pro-GM crop aim.<sup>139</sup> The program's charter emphasized that GM crops are generally equivalent to non-GM crops.<sup>140</sup> This framework is unable to address the environmental concerns of the introduction of GM crops and has no mechanism to deal with economic harm incurred by neighboring farms.<sup>141</sup>

The Coordinated Framework vested power over the introduction of GM crops in (1) the FDA, (2) the EPA, and (3) the USDA (with the Secretary of Agriculture delegating authority to APHIS).<sup>142</sup> The framework awkwardly delineated limited power to each agency, almost inevitably leading to an incomplete system of protection.<sup>143</sup> None of the three agencies have a clear mandate to regulate GM crops.<sup>144</sup> This section discusses the Coordinated Framework by analyzing (1) the responsibility granted to the FDA, (2) the responsibility granted to the EPA, (3) the responsibility granted to APHIS, (4) the limitations imposed by the National Environmental Policy Act, and (5) the failures of the current framework.

### 1. *The Food and Drug Administration*

Under the Coordinated Framework, the FDA exerts authority under the Federal Food, Drug, and Cosmetics Act (FDCA) and is charged with controlling adulterated foods in the United States food supply.<sup>145</sup> Adulterated

<sup>137</sup> Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302–09 (June 26, 1986).

<sup>138</sup> Peck, *supra* note 66, at 49.

<sup>139</sup> See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302–06 (noting that GM crops will not pose new threats to humans or the environment).

<sup>140</sup> Peck, *supra* note 37, at 251.

<sup>141</sup> 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, 2243 (2004) (calling the deregulation process insufficient).

<sup>142</sup> See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304; see also Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297, 311–12 (2002) (outlining the Coordinated Framework and subsequent delegation). The Coordinated Framework also gave tangential power to the National Institutes of Health and Occupational Safety and Health Administration. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304, 23,306.

<sup>143</sup> Mary Jane Angelo, *Genetically Engineered Plant Pesticides: Recent Developments in the EPA's Regulation of Biotechnology*, 7 U. FLA. J.L. & PUB. POL'Y 257, 269–84 (1996); Bratspies, *supra* note 142, at 310–12.

<sup>144</sup> Bratspies, *supra* note 24, at 404.

<sup>145</sup> See Federal Food, Drug, and Cosmetics Act, ch. 675, § 402, 52 Stat. 1040, 1046–47 (1938) (codified as amended at 21 U.S.C. § 342 (2006)) (outlining FDA responsibilities).

foods include any food that may contain a “deleterious substance which may render it injurious to health.”<sup>146</sup> With power over adulterated foods, the FDA could assert considerable sway over the introduction of engineered crops.<sup>147</sup> The FDA considers GM foods “substantially similar” to conventional foods.<sup>148</sup> This equivalence principle allows the FDA to presume that many GM-food products are “generally regarded as safe.”<sup>149</sup> One commentator suggested that the FDA may have relied on the substantial-equivalence principle as “a convenient vehicle for avoiding its statutory responsibilities under the FDCA.”<sup>150</sup> Relying on this presumptive safe classification, the FDA has declined to impose labeling requirements on GM-food products.<sup>151</sup> This decision hampers the ability of the Coordinated Framework to foster coexistence.<sup>152</sup> In an unequal duality, organic foods face strict labeling requirements in the United States.<sup>153</sup> In essence, the presumption today is that most foods contain GM ingredients. Coexistence principles would be better served by approval and labeling programs that balance incentives between organic farming and GM farming.

## 2. *The Environmental Protection Agency*

Under the Coordinated Framework, the EPA’s influence over GM crops, like the FDA’s, is limited. The EPA’s limited influence is due to its narrow interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act

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<sup>146</sup> 21 U.S.C. § 342(a)(1).

<sup>147</sup> Bratspies, *supra* note 24, at 408. The FDA’s power is necessarily limited because it is only able to regulate products that reach the food (or drug) supply. Bratspies, *supra* note 142, at 312. However, one would think that an FDA indication that a food product would not be marketable would dissuade a producer from planting the crops.

<sup>148</sup> Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 442 (2002) (emphasis omitted) (quoting Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992)). This policy was challenged by groups and individuals seeking stronger scrutiny over GM foods by the FDA. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 170 (D.D.C. 2000). The United States District Court for the District of Columbia concluded that the FDA’s policy choice was not an arbitrary-and-capricious agency decision. *Id.* at 181.

<sup>149</sup> Bratspies, *supra* note 24, at 408 (internal quotation marks omitted).

<sup>150</sup> McGarity, *supra* note 148, at 442.

<sup>151</sup> Bratspies, *supra* note 24, at 408. There have been several legislative initiatives since 2000 to extend the FDA’s oversight of GM crops, but they all died in committee. *Id.* at 410.

<sup>152</sup> See Peck, *supra* note 37, at 254 (claiming that the FDA policy favors biotech products over the vitality of non-GM products).

<sup>153</sup> See Organic Foods Production Act of 1990, Pub. L. No. 101-624, tit. XXI, § 2107, 104 Stat. 3935, 3938 (codified as amended at 7 U.S.C. § 6506 (2006)).

(FIFRA).<sup>154</sup> This power is confined to controlling the amount of pesticides in U.S. food products. The EPA interprets the statute as allowing “no regulatory authority over plants that do not produce pesticides.”<sup>155</sup> While many GM crops produce pesticides and are required to be registered before they can be sold, the EPA issues permits based on a minimal tolerance level and frequently grants exemptions to GM producers.<sup>156</sup> Under the current regime, the EPA generally forgoes a meaningful role in protecting organic farms from contamination.<sup>157</sup> The EPA’s permissive approach limits the protection the Coordinated Framework provides to organic crops and, therefore, frustrates coexistence goals.

### 3. *The United States Department of Agriculture and the Animal and Plant Health Inspection Service*

The Coordinated Framework gave authority to the USDA to control the introduction of GM crops into domestic farms but specifically noted that GM crops should generally be deemed an improvement.<sup>158</sup> The USDA’s authority is derived from the implementing regulations of the Plant Protection Act,<sup>159</sup> which calls for regulation of plants “altered or produced through genetic engineering that are plant pests.”<sup>160</sup> APHIS is an agency within the USDA charged with executing the USDA’s responsibilities under the Plant Protection Act.<sup>161</sup> Because plant pests are defined as any organism capable of injuring or causing disease to any other plant, APHIS’s promulgated regulations presume that genetically engineered plants are regulated as plant pests.<sup>162</sup> GM crops are considered pest risks in part because of their potential to contaminate non-GM crops through genetic drift.<sup>163</sup>

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<sup>154</sup> See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,304, 23,306 (June 26, 1986) (directing the EPA to assert regulatory power over GM plants); McGarity, *supra* note 148, at 466–67 (arguing that the EPA could assert more authority under FIFRA).

<sup>155</sup> Bratspies, *supra* note 24, at 411.

<sup>156</sup> *Id.* at 410–11.

<sup>157</sup> See McGarity, *supra* note 148, at 467, 469–72 (noting the extensive exemptions issued by the EPA under FIFRA).

<sup>158</sup> Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,339; see also Bratspies, *supra* note 24, at 411–12 (noting that the Coordinated Framework indicated that GM crops will not pose threats).

<sup>159</sup> Pub. L. No. 106-224, tit. IV, 114 Stat. 438 (2000) (codified as amended at 7 U.S.C. §§ 7701–7786 (2006)).

<sup>160</sup> 7 C.F.R. § 340(a)(2) n.1 (2011).

<sup>161</sup> *Id.* §§ 2.80(a)(36), 340.1.

<sup>162</sup> See *id.* §§ 340.0(a)(2), 340.1–2, 340.6.

<sup>163</sup> See Angelo, *supra* note 143, at 271.

Modified crops must be cleared by APHIS before they can be planted.<sup>164</sup> Pursuant to the Coordinated Framework, APHIS presumes that modified organisms are not unlike their nonmodified counterparts.<sup>165</sup> Indeed, APHIS considers modified plants “substantially equivalent” to nonmodified plants of the same variety.<sup>166</sup> APHIS has considerable discretion when considering deregulation because Congress only directs the agency to follow sound science.<sup>167</sup> APHIS may grant a permit when the party seeking deregulation presents scientific information showing that the GM crop causes no more environmental harm than the nonmodified variety.<sup>168</sup> Typically, APHIS will authorize a permit for the planting of a new GM crop after field tests demonstrate that the organism will not pose a pest risk to other plants.<sup>169</sup> APHIS does not necessarily fully deregulate a strain and may instead impose boundary distances between partially deregulated crops and non-GM crops.<sup>170</sup> Once permitted for planting or deregulated, a crop is no longer considered a pest and therefore is no longer subject to APHIS’s oversight.<sup>171</sup> However, APHIS has a duty to monitor partially deregulated crops to ensure that boundary distances and handling instructions are adhered to.<sup>172</sup>

#### 4. *The National Environmental Policy Act*

The Coordinated Framework is supplemented by the restrictions imposed on all agencies by the National Environmental Policy Act of 1969 (NEPA).<sup>173</sup>

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<sup>164</sup> See 7 C.F.R. § 340.4. Any individual can request deregulated status. *Id.* § 340.6.

<sup>165</sup> Bratspies, *supra* note 24, at 412.

<sup>166</sup> *Id.* The substantial-equivalence approach is at odds with the “precautionary regulatory approach,” which advocates restraint in the face of scientific uncertainty relating to a proposed course of action’s possible environmental damage. Bratspies, *supra* note 142, at 317–18.

<sup>167</sup> 7 U.S.C. § 7711(b) (2006). Producers may petition APHIS for deregulation pursuant to 7 C.F.R. § 340.6, and APHIS is entitled to deny the petition, grant the petition, or grant the petition in part. *Id.* § 340.6(d)(3).

<sup>168</sup> *Permits, Notifications, and Petitions*, U.S. DEP’T AGRIC. ANIMAL & PLANT HEALTH INSPECTION SERVICE, <http://www.aphis.usda.gov/biotechnology/submissions.shtml> (last modified Feb. 17, 2012).

<sup>169</sup> See Angelo, *supra* note 143, at 271 (describing field-testing procedures).

<sup>170</sup> *Biotechnology Regulatory Service*, U.S. DEP’T AGRIC. ANIMAL & PLANT HEALTH INSPECTION SERVICE, [http://www.aphis.usda.gov/biotechnology/brs\\_main.shtml](http://www.aphis.usda.gov/biotechnology/brs_main.shtml) (last modified Apr. 3, 2012); *Permits, Notifications, and Petitions*, *supra* note 168; *Regulatory Operations Programs: Compliance and Inspections*, U.S. DEP’T AGRIC. ANIMAL & PLANT HEALTH INSPECTION SERVICE, [http://www.aphis.usda.gov/biotechnology/compliance\\_main.shtml](http://www.aphis.usda.gov/biotechnology/compliance_main.shtml) (last modified Apr. 11, 2012).

<sup>171</sup> Bratspies, *supra* note 24, at 412; *Permits, Notifications, and Petitions*, *supra* note 168.

<sup>172</sup> *Permits, Notifications, and Petitions*, *supra* note 168; *Regulatory Operations Programs: Compliance and Inspections*, *supra* note 170.

<sup>173</sup> Pub. L. No. 91-190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. §§ 4321–4375 (2006 & Supp. IV 2010)).

NEPA imposes environmental-consideration requirements on agencies deregulating GM crops.<sup>174</sup> NEPA requires all agencies, before taking any major action, to assess the environmental impacts of the proposed action.<sup>175</sup> NEPA charges agencies to prepare an Environmental Impact Statement (EIS) before any major federal action.<sup>176</sup> The EIS must include a detailed account of the environmental impacts of the action, the adverse environmental impacts that cannot be avoided, and any possible alternatives to the action.<sup>177</sup> An agency can, however, avoid issuing an EIS if it determines through an Environmental Assessment (EA) that there will be no significant environmental impact relating to the agency action.<sup>178</sup> Agency determinations under NEPA are subject to judicial review.<sup>179</sup> While APHIS plays a major role in the deregulation of modified crops (indeed, a more significant role than either the FDA or the EPA), NEPA remains a check on the environmental impacts of APHIS actions because APHIS will have to justify a decision on an action under an EIS or EA before a court.<sup>180</sup> Such a justification entails proving that environmental impacts were sufficiently considered.<sup>181</sup>

The litigation against APHIS in both *Monsanto*<sup>182</sup> and *Center for Food Safety v. Vilsack*<sup>183</sup> involved allegations that the agency did not adhere to NEPA requirements. The decisions show that APHIS has disregarded significant NEPA requirements when deregulating GM crops.<sup>184</sup> Indeed,

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<sup>174</sup> See 42 U.S.C. § 4332 (requiring all agencies, in their decision making, to take certain actions to ensure that environmental impacts are considered).

<sup>175</sup> *Id.* § 4332(2)(C).

<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

<sup>178</sup> 40 C.F.R. §§ 1508.9, 1508.13 (2011). The inquiry into whether an impact is significant includes determining the context, intensity, and public health effects of the proposed impact. See *id.* § 1508.27. *But see* *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2751 (2010) (noting that APHIS erred in issuing only an EA and should have issued an EIS before deregulating alfalfa).

<sup>179</sup> See Administrative Procedure Act, Pub. L. No. 79-404, § 10(e), 60 Stat. 237, 243-44 (1946) (codified as amended at 5 U.S.C. § 706); *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1211 (9th Cir. 1998).

<sup>180</sup> See, e.g., *Monsanto*, 130 S. Ct. at 2751 (confirming that NEPA applies to APHIS actions).

<sup>181</sup> See *id.* (noting that APHIS erred in issuing only an EA when additional environmental impacts should have been considered).

<sup>182</sup> See *id.* (stating that plaintiffs' complaint alleged violations of NEPA).

<sup>183</sup> See No. C 10-04038 JSW, 2010 WL 3835699, at \*1 (N.D. Cal. Sept. 28, 2010) (alleging that APHIS violated NEPA in its decision to issue permits without conducting any environmental review).

<sup>184</sup> See *Monsanto*, 130 S. Ct. at 2751 (noting APHIS's failure to conduct sufficient environmental review under NEPA); *Ctr. for Food Safety*, 2010 WL 3835699, at \*7 (“[T]he Court finds that Plaintiffs are likely to succeed on the merits that APHIS unlawfully relied on a categorical exclusion to avoid conducting any environmental review.”).



despite a court order to consider GM sugar beets regulated pests until an EIS was completed, APHIS partially deregulated the strain before completing an EIS.<sup>185</sup> The *Monsanto* and *Center for Food Safety* cases also demonstrate that courts are uncertain about the scope of NEPA protections and whether the environmental impacts that must be considered include economic impacts.<sup>186</sup> Further, the lack of significant judicial review after APHIS violated NEPA (where the courts either vacated an injunction against deregulation or allowed partial deregulation)<sup>187</sup> may not deter APHIS from continuing to forego sufficient environmental assessments before deregulating modified crops.<sup>188</sup>

### 5. *Failures in the Current Regulatory System*

Gaps in the regulatory structure and incomplete implementation of existing policies pose substantial problems for the coexistence of organic and GM crops. The primary failure of the current system is its inability or refusal to sufficiently consider the impact of genetic drift before approving new GM crops.<sup>189</sup> Although the FDA's substantial-equivalence approach and the EPA's narrow interpretation of FIFRA prevent either agency from playing a role in fostering coexistence, the primary hurdles for coexistence rest in APHIS's deregulation procedures. This subsection discusses (1) APHIS's failure to consider the potential contamination of non-GM crops, (2) pre-deregulation field-testing procedures that only require notification and general scientific explanations, (3) APHIS's lack of oversight after deregulation, (4) APHIS's current inability to consider the economic effects of contamination on organic programs, and (5) APHIS's problems in implementing partial-deregulation conditions. This subsection concludes with a discussion of the StarLink corn deregulation as an example of insufficient regulatory oversight.

First, "APHIS does not consider . . . the possible contamination that might result from pollen drift from GM plants to unmodified plants."<sup>190</sup> By not considering the potential contamination, APHIS is deregulating GM crops without considering a primary hurdle to coexistence efforts. *Monsanto* and

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<sup>185</sup> Pollack, *supra* note 30.

<sup>186</sup> *Monsanto*, 130 S. Ct. at 2751; *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 953 (N.D. Cal. 2010).

<sup>187</sup> See *infra* Part III.

<sup>188</sup> See Pollack, *supra* note 30 (noting that the USDA chose to deregulate GM sugar beets without completing an EIS).

<sup>189</sup> See Bratspies, *supra* note 24, at 412 (discussing APHIS's failure to account for potential contamination).

<sup>190</sup> *Id.*

*Center for Food Safety* demonstrate that APHIS may have to revise this approach.<sup>191</sup> To avoid a NEPA violation, APHIS should have to demonstrate that the environmental impact of genetic drift resulting from deregulation of the petitioned crop is not sufficiently adverse to warrant maintaining regulated status. However, after the decisions in both cases, APHIS deregulated the disputed crops.<sup>192</sup> APHIS itself should have substantive requirements to consider the potential impacts of genetic drift on the economic feasibility of organic operations. As discussed, protecting the economic feasibility of organic operations promotes coexistence. APHIS is narrowly construing the Plant Protection Act when it does not sufficiently consider genetic drift.

Second, APHIS only requires notifications before a GM producer commences field-testing of a new GM crop.<sup>193</sup> The permissive approach may lead to contamination from crops that have not been addressed by the regulatory regime.<sup>194</sup> While APHIS requires companies to complete a field test before granting deregulation, the tests need only “evaluate risks wholly by extrapolating from general, published scientific literature.”<sup>195</sup> Producers only need to submit discussions of scientific literature after loose field-testing.<sup>196</sup> Under this approach, APHIS has allowed over ten thousand field tests and has deregulated over sixty GM crops since 1987.<sup>197</sup> APHIS’s permissive testing procedures increase opportunities for contamination, thereby threatening organic operations and frustrating coexistence.

Third, APHIS loses oversight capability once crops are fully deregulated,<sup>198</sup> and the lack of continuing oversight threatens coexistence aims. As discussed, excessive monocropping of GM crops can potentially lead to catastrophic effects.<sup>199</sup> Additionally, a deregulated crop may cause more contamination than

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<sup>191</sup> See *infra* Part III.

<sup>192</sup> Pollack, *supra* note 30.

<sup>193</sup> 7 C.F.R. §§ 340.3(a), 340.3(d)(1) (2011). A GM producer can use the notification system as long as the new GM crop meets six standard requirements. *Id.* § 340.3(b); see also Bratspies, *supra* note 24, at 412–13.

<sup>194</sup> In *International Center for Technology Assessment v. Johanns*, organizations and individuals sued APHIS for allowing field tests (after only notification) for a GM-grass variety. 473 F. Supp. 2d 9, 12–13 (D.D.C. 2007). The court held that APHIS had erred in allowing the field tests without first considering the environmental impacts under NEPA. *Id.* at 29–30. Because of the weaknesses with NEPA, this holding has not had a significant impact on testing procedures.

<sup>195</sup> Bratspies, *supra* note 142, at 323.

<sup>196</sup> See *id.*

<sup>197</sup> Bratspies, *supra* note 24, at 412–13.

<sup>198</sup> *Permits, Notifications, and Petitions*, *supra* note 168.

<sup>199</sup> See Aoki, *supra* note 9, at 124 (citing FOWLER & MOONEY, *supra* note 9, at 47).

expected.<sup>200</sup> Once a crop has been partially deregulated, APHIS's primary strategy for controlling contamination is through containment measures.<sup>201</sup> Unfortunately, containment is rarely successful.<sup>202</sup> The failure is either because planting-distance requirements are not adhered to<sup>203</sup> or because the requirements themselves are insufficient.<sup>204</sup> The USDA itself found in 2003 that roughly 20% of farms growing modified crops did not comply with physical-planting requirements.<sup>205</sup> To protect coexistence, APHIS must fulfill its monitoring responsibility over partially deregulated crops. Additionally, APHIS should be able to determine, after granting deregulation, that a modified crop takes too strong a toll on the underlying resources or disrupts neighboring farming practices too much and thus deserves to return to regulated status.

Fourth, APHIS does not have an explicit avenue to consider the potential economic impacts of deregulation. While APHIS must consider the impact of contamination under NEPA, it does not consider the potential economic harm to adjacent non-GM farms.<sup>206</sup> Without considering economic impacts on non-GM farms resulting from deregulation, APHIS is not ensuring the continued feasibility of organic farms and is not fostering the goals of coexistence. The organic farmers in both *Monsanto* and *Center for Food Safety* incurred economic harm but were only successful in suits relating to NEPA violations.<sup>207</sup> Although the Supreme Court, when discussing the standing challenges in *Monsanto*, concluded that economic harms do not disqualify a NEPA claim,<sup>208</sup> the district court in *Center for Food Safety* specifically noted that it was unclear whether economic harms contribute to NEPA claims.<sup>209</sup> Organic programs should not have to resort to nebulous NEPA claims when an APHIS deregulation has threatened their economic rights.

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<sup>200</sup> See Bratspies, *supra* note 17, at 622.

<sup>201</sup> Bratspies, *supra* note 24, at 414.

<sup>202</sup> See Peck, *supra* note 66, at 43 (noting several potential sources of contamination).

<sup>203</sup> Organic farmers are able to sue under regulatory causes of action when GM growers do not comply with substantive regulatory directives. See Mandel, *supra* note 95, at 97. This Comment argues that economic damage to organic farmers caused by GM growers acting within regulatory directives harms the goals of coexistence.

<sup>204</sup> See Peck, *supra* note 66, at 43 (noting failures in containment measures).

<sup>205</sup> Bratspies, *supra* note 24, at 414.

<sup>206</sup> *Id.* at 412.

<sup>207</sup> See *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2749 (2010); *Ctr. for Food Safety v. Vilsack*, No. C 10-04038 JSW, 2010 WL 3835699, at \*1, \*7 (N.D. Cal. Sept. 28, 2010).

<sup>208</sup> *Monsanto*, 130 S. Ct. at 2756.

<sup>209</sup> *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 953 (N.D. Cal. 2010).

Finally, APHIS has erred in not satisfying its explicit responsibilities under the Coordinated Framework. The USDA Office of Inspector General found in a 2005 audit that the USDA had failed significantly in several responsibilities, including the “failure to monitor whether GM crops were segregated, failure to test for contamination during and after field trials, [and] failure to comply with shipping requirements designed to prevent inadvertent dispersal of unapproved crops.”<sup>210</sup> The report “concluded that APHIS ‘is relinquishing its regulatory responsibilities in favor of self-certification’ by GM[-crop] purveyors.”<sup>211</sup> APHIS’s inability to fulfill its own responsibilities further frustrates the goals of coexistence.

The StarLink corn litigation highlights the potential repercussions of the insufficient regulatory system. StarLink corn was developed by Aventis as an herbicide- and pesticide-resistant strain of corn for use as animal feed.<sup>212</sup> After obtaining nonregulated status from APHIS and registration for nonfood use from the EPA, Aventis began planting StarLink corn.<sup>213</sup> The agencies imposed a buffer zone between areas where StarLink corn was planted and areas where nonmodified corn was planted, but the boundaries were ineffective.<sup>214</sup> StarLink corn genes were discovered in a variety of food products, and the FDA recalled millions of dollars of corn because the StarLink genes had not been cleared for human consumption.<sup>215</sup> StarLink genes were also discovered in exported corn, and Japan subsequently cut its corn imports from the United States nearly in half.<sup>216</sup> The slash injured the organic interests selling to international markets. The resulting lawsuits cost Aventis a multimillion-dollar indemnity to sellers of consumer goods, settlement agreements with the attorneys general of seventeen states, and the defense of a multidistrict litigation of individual suits.<sup>217</sup> Aventis was subject to millions of dollars in liability despite its regulatory clearance.<sup>218</sup> The StarLink episode demonstrates that the regulatory

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<sup>210</sup> Bratspies, *supra* note 24, at 415 (citing OFFICE OF INSPECTOR GEN., U.S. DEP’T OF AGRIC., AUDIT REPORT: ANIMAL AND PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS (2005) [hereinafter AUDIT REPORT], available at <http://www.usda.gov/oig/webdocs/50601-08-TE.pdf>).

<sup>211</sup> *Id.* at 416–17 (footnote omitted) (quoting AUDIT REPORT, *supra* note 210, at v–vi).

<sup>212</sup> Bratspies, *supra* note 17, at 593, 598.

<sup>213</sup> *Id.* at 617–18.

<sup>214</sup> *Id.* at 622.

<sup>215</sup> *Id.* at 623.

<sup>216</sup> *Id.* Several other countries, including South Korea and Thailand, also canceled orders. *Id.*

<sup>217</sup> *Id.* at 627.

<sup>218</sup> *See id.*

failures at fostering coexistence can also impose substantial costs on GM producers.

The StarLink corn incident emphasizes the overall weakness of the regulatory system. The FDA could control the spread of GM crops if it abandoned its substantial-equivalence principle and seriously considered the human health effects of modified food products. The EPA considers itself statutorily constrained to only consider pesticide-producing plants.<sup>219</sup> NEPA forces agencies to consider environmental impacts, but its protection is limited by its inability to encompass economic harms and courts' hesitation to provide sufficient remedies after violations. APHIS's coverage of GM crops is similarly constrained by the substantial-equivalence principle. APHIS oversight is also lacking in that it does not fully appreciate the consequences of genetic drift, it allows permissive field-testing, it abrogates oversight after full deregulation, and it does not consider economic consequences of deregulated GM crops.

The regulatory regime established by the Coordinated Framework was not designed to protect the interests of organic farming but rather to control and monitor the introduction of GM crops.<sup>220</sup> To protect coexistence, the Coordinated Framework must ensure the economic feasibility of organic operations. Ideally, considering recent developments in agricultural research showing possible deleterious effects of mass GM-crop farming, the USDA and congressional goals of fostering coexistence, and the growing desire among American consumers for organically produced products, the regulatory structure should accommodate coexistence of organic and GM crops.

### III. *MONSANTO CO. V. GEERTSON SEED FARMS AND CENTER FOR FOOD SAFETY V. VILSACK*

Two recent cases demonstrate the current regulatory regime's failure to protect the aims of coexistence. This part discusses (1) *Monsanto Co. v. Geertson Seed Farms*, where the Supreme Court struck down a broad injunction after APHIS improperly deregulated GM alfalfa,<sup>221</sup> and (2) *Center for Food Safety v. Vilsack*, where a district court in California restrained itself

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<sup>219</sup> See McGarity, *supra* note 148, at 466–67 (arguing that the EPA could assert more authority under FIFRA).

<sup>220</sup> Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,306 (June 26, 1986).

<sup>221</sup> 130 S. Ct. 2743, 2761–62 (2010).

from issuing a broad injunction following the premature deregulation of GM sugar beets.<sup>222</sup> These cases display current regulatory weaknesses and the failure of the courts to protect coexistence.

#### A. *Monsanto Co. v. Geertson Seed Farms*

*Monsanto Co. v. Geertson Seed Farms* began when APHIS granted a petition to deregulate modified alfalfa, and organizations of organic farmers brought suit challenging the decision.<sup>223</sup> Although the organizations advanced several theories, the district court determined that APHIS erred in failing to comply with NEPA procedures.<sup>224</sup> Specifically, the court held that APHIS was required to issue an EIS prior to granting deregulation and that the determination of no significant impact under a preliminary EA was insufficient.<sup>225</sup> The EA was insufficient in part because APHIS did not consider the extent of gene transmission from engineered alfalfa to organic alfalfa.<sup>226</sup> The court noted that gene transmission could tarnish the organic quality of organic crops.<sup>227</sup> The district court proceeded to the remedy phase and allowed Monsanto to intervene.<sup>228</sup>

The court requested proposals on the appropriate remedy.<sup>229</sup> APHIS and Monsanto submitted a proposed judgment whereby the court would require APHIS to complete an EIS but continue to allow the planting of GM alfalfa in specific regions.<sup>230</sup> APHIS contended that modified alfalfa could be planted with several restrictions, including an isolation distance to protect from gene flow; tailored cleaning, handling, identification, and harvesting practices; and a requirement that all GM-alfalfa farmers have contracts with Monsanto that comply with the restrictions.<sup>231</sup> The district court declined to adopt the proposed judgment.<sup>232</sup>

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<sup>222</sup> 734 F. Supp. 2d 948, 949 (N.D. Cal. 2010).

<sup>223</sup> *Monsanto*, 130 S. Ct. at 2743, 2750.

<sup>224</sup> *Id.* at 2751.

<sup>225</sup> *Id.*

<sup>226</sup> *Id.*

<sup>227</sup> *See Monsanto*, 130 S. Ct. at 2755; *see also Redick & Endres, supra* note 122, at 25 (reviewing the *Monsanto* litigation before the lower courts).

<sup>228</sup> *Monsanto*, 130 S. Ct. at 2751.

<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> *Id.*

<sup>232</sup> *Id.*

The court instead fashioned its own injunction imposing a near blanket ban on all GM-alfalfa planting.<sup>233</sup> In determining the scope of the injunction, the court noted the technical difficulty in trying to “fine-tune a particular remedy” and concluded that a simpler remedy is more attractive “from the Court’s point of view.”<sup>234</sup> The court allowed farmers who had already purchased modified alfalfa seeds to plant their crops until a certain date.<sup>235</sup> Later, the court issued a permanent injunction vacating the deregulation, requiring APHIS to issue an EIS before deregulating, enjoining all planting until the completion of the EIS,<sup>236</sup> and imposing other handling and identification restrictions.<sup>237</sup> The Ninth Circuit upheld the injunction after APHIS and Monsanto appealed its scope.<sup>238</sup>

When the case reached the Supreme Court, the challengers to the deregulation had been forced to pursue the case as a NEPA violation.<sup>239</sup> The Court held that the organic organizations had standing because they had demonstrated environmental harm through the NEPA violation and that the presence of additional economic harm did not remove that standing.<sup>240</sup> However, the Court ultimately rejected the injunction because the plaintiffs failed to satisfy the traditional four-factor test for injunctive relief.<sup>241</sup> The Court’s decision rested primarily on the plaintiffs’ failure to demonstrate that they would suffer irreparable injury from the proposed remedy allowing partial deregulation.<sup>242</sup>

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<sup>233</sup> *Id.*

<sup>234</sup> *Id.* at 2760 n.6.

<sup>235</sup> *Id.* at 2751.

<sup>236</sup> *Id.* In December 2009, APHIS did complete an EIS and concluded that complete deregulation will not interfere with organic-alfalfa farmers and that the two “could co-exist peacefully.” See *Supreme Court Rules Ban on Deregulation of Genetically Modified Crops Was Too Broad*, 78 U.S.L.W. 1839 (June 22, 2010).

<sup>237</sup> *Monsanto*, 130 S. Ct. at 2751–52.

<sup>238</sup> *Geertson Seed Farms v. Johanns*, 570 F.3d 1130, 1140–41 (9th Cir. 2009), *rev’d sub nom.* *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010).

<sup>239</sup> *Monsanto*, 130 S. Ct. at 2750–51.

<sup>240</sup> *Id.* at 2756.

<sup>241</sup> *Id.* at 2756–59. The four-factor test for obtaining permanent injunctive relief requires a plaintiff to demonstrate the following:

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

*Id.* at 2756 (quoting *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)) (internal quotation mark omitted).

<sup>242</sup> *Id.* at 2759–60.

This rebuke of the district-court-fashioned injunction demonstrates courts' difficulties in their efforts to adhere to coexistence goals. The lower court could not comprehend the technical aspects of the issue. APHIS, Monsanto, and the organic interests had all submitted evidence supporting or refuting the appropriateness of allowing partial deregulation.<sup>243</sup> The district judge noted the difficulties in establishing the requisite facts to determine the extent of the injunction and acknowledged that a blanket ban may be overreaching.<sup>244</sup> But the judge nevertheless imposed a broad injunction.

Based on the language used in *Monsanto*, district courts will now be very hesitant to issue broad injunctions when APHIS has failed to consider the implications of a deregulation decision.<sup>245</sup> APHIS ultimately concluded to deregulate GM alfalfa in January 2011, and organic interests announced their intention to challenge the deregulation.<sup>246</sup> The inability of courts to understand scientific issues and provide a sufficient remedy, as the district court was unable to do in *Monsanto*, illustrates the inability of courts to support coexistence goals.

#### B. Center for Food Safety v. Vilsack

Shortly after the *Monsanto* decision, organic-farming associations and a Washington organization against biotech products sought vacation of an APHIS decision deregulating GM sugar beets.<sup>247</sup> APHIS had permitted the planting of GM sugar beets after Monsanto petitioned for deregulation.<sup>248</sup> The organizations brought suit claiming that APHIS erred in failing to conduct an EIS before allowing deregulation.<sup>249</sup> While the district court vacated the deregulation, it noted that *Monsanto* counseled against issuing an injunction and chose to not enjoin planting, at least in part because planting for the season was already completed.<sup>250</sup> The district court also noted, when discussing the

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<sup>243</sup> *Id.* at 2758.

<sup>244</sup> *See id.* at 2760 n.6.

<sup>245</sup> *See id.* at 2760–61 (“[T]he courts have no cause to intervene. Indeed, the broad injunction entered here essentially pre-empts the very procedure by which the agency could determine, independently of the pending EIS process for assessing the effects of a *complete* deregulation, that a *limited* deregulation would not pose any appreciable risk of environmental harm.”).

<sup>246</sup> Pollack, *supra* note 29.

<sup>247</sup> *Ctr. for Food Safety v. Vilsack*, No. C 10-04038 JSW, 2010 WL 3835699, at \*1 (N.D. Cal. Sept. 28, 2010).

<sup>248</sup> *Id.* at \*1, \*6.

<sup>249</sup> *Id.* at \*1.

<sup>250</sup> *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 954–55 (N.D. Cal. 2010).



NEPA violation, that “it is not clear that economic consequences is a factor the Court may consider in environmental cases.”<sup>251</sup> This statement evidences the need to clarify the regulatory options protecting the economic interests of organic farm programs.

While the district judge did not fully enjoin the planting of distributed sugar beets, he emphasized that the vacatur returned GM sugar beets to regulated status under the Plant Protection Act.<sup>252</sup> The decision thus required APHIS to issue an EIS before deregulating GM sugar beets.<sup>253</sup> However, the USDA announced in February 2011 that it would deregulate sugar beets for the upcoming season without completing an EIS, which it did not complete until June 1, 2012.<sup>254</sup> APHIS’s choice to defy the court illustrates the weak role that courts play in fostering coexistence.

These cases demonstrate that APHIS and the courts are unable to protect the economic interests of organic operations from the potential harms of GM crops. The cases also demonstrate that organic programs have limited and incomplete avenues for relief once they have been harmed by APHIS or nearby GM crops. The limited relief deters farmers from adopting organic practices. APHIS is unable to foster the goals of coexistence because its deregulation decisions do not capture the economic interests of organic farmers. Legal and regulatory reform is required to adequately foster coexistence in the United States.

#### IV. POSSIBLE SOLUTIONS

To adequately foster coexistence, the legal and regulatory structures must be able to control contamination. Possible solutions to the current inability to control contamination include unilateral agency reform and statutory reform. The agencies with authority under the Coordinated Framework can change their policies to enhance protections toward organic-farming interests and, therefore, coexistence efforts. While the EPA and FDA can implement changes to advance coexistence efforts, APHIS can effect the most change. APHIS can

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<sup>251</sup> *Id.* at 953.

<sup>252</sup> *Id.* at 955.

<sup>253</sup> *See id.* at 950, 955.

<sup>254</sup> Pollack, *supra* note 30; *USDA Announces Final Environmental Impact Statement and Plant Pest Risk Assessment for Genetically Engineered Sugar Beets*, U.S. DEP’T AGRIC. ANIMAL & PLANT HEALTH INSPECTION SERVICE, [http://www.aphis.usda.gov/newsroom/2012/06/sugar\\_beets.shtml](http://www.aphis.usda.gov/newsroom/2012/06/sugar_beets.shtml) (last visited Aug. 6, 2012).

(1) give more weight to the genetic-drift impact on organic farming when considering deregulation under the Plant Protection Act, (2) discontinue its permissive field-testing practices and demand specific scientific evidence before granting deregulations, and (3) ensure that its boundary impositions are adhered to. However, limitations on agencies' abilities to change policies within their statutory directives may prevent the agencies from fully accounting for contamination problems. Coexistence will be best served by statutory reform (1) requiring APHIS, the FDA, and the EPA to abandon or temper the substantial-equivalence doctrine and consider economic impacts on organic-farming interests when reviewing deregulation petitions and (2) granting adjudicatory power to APHIS.<sup>255</sup> This Part discusses agency reform and statutory reform, respectively, as avenues to advance the aims of coexistence.

#### A. *New Course from Within APHIS, the FDA, and the EPA*

Generally, APHIS, the FDA, and the EPA could change their interpretations of their governing statutes and earn judicial deference for their interpretation of ambiguous statutes.<sup>256</sup> However, there can be limitations on agencies' abilities to modify their interpretations of statutes or modify their practices. When agencies change positions, they must account for reliance interests.<sup>257</sup> Such reliance interests might not be as strong when an agency reinterprets a statute but may pose difficulties when the agency changes positions from guidance documents or regular practice.<sup>258</sup> Similarly, APHIS, the EPA, and the FDA will be constrained by their long adherence to the equivalence principles in the Coordinated Framework.<sup>259</sup>

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<sup>255</sup> This proposed solution is offered within the confines of the Coordinated Framework. A more thorough overhaul of agency responsibility may be more effective. *See* Mandel, *supra* note 141, at 2249–50 (proposing, for regulating GM crops, to scrap the Coordinated Framework's existing allocations and spread power to agencies under more direct mandates). This Comment argues that coexistence can be advanced when the current framework accounts for the economic interests of organic farming.

<sup>256</sup> *See* *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843, 863–64 (1984) (extending controlling weight to agencies' interpretations of ambiguous statutes and noting that agencies can change such interpretations).

<sup>257</sup> *See* *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009) (noting that changes in position do not require more justification but that more detail may be required when the agency's "prior policy has engendered serious reliance interests that must be taken into account").

<sup>258</sup> *Compare id.* (noting a possible requirement for increased justification of an agency's change in relied-upon policy), *with* *Chevron*, 467 U.S. at 865 (noting that agencies must have space to change statutory interpretations under a new administration).

<sup>259</sup> *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,306 (June 26, 1986).

The nation's coexistence interests can be protected if APHIS takes steps to revise its interpretation of the Plant Protection Act. Similarly, if the FDA and the EPA revise their interpretations of the FDCA and FIFRA, respectively, then the agencies would be better able to protect the interests of organic farming and, therefore, the aims of coexistence. This subsection analyzes (1) changes within the FDA and the EPA, (2) changes in APHIS's interpretation of the Plant Protection Act, and (3) policy changes within APHIS relating to the deregulation of GM crops.

### *1. EPA and FDA: Interpretive Changes of FIFRA and the FDCA*

As discussed, there may be valid reasons for directing the FDA to reconsider its substantial-equivalence approach to GM-food products. If the FDA were to abandon the substantial-equivalence principle and begin strictly assessing the safety of GM products, the resulting changes in approval and labeling may decrease the demand for GM food and increase the demand for organic food. The FDA's statutory mandate does not require it to adhere to the substantial-equivalence principle.<sup>260</sup> While an FDA change may not directly foster coexistence, limitations on the approval of GM crops may reduce instances of contamination.

The EPA's regulatory authority under FIFRA is not directly contrary to the interests of organic farming. The EPA's statutory mandate could allow the EPA to impose stricter standards when permitting GM crops.<sup>261</sup> Organic interests could benefit from a reinterpretation of FIFRA whereby the EPA revokes its minimum tolerance levels and more strictly reviews GM crops and their ultimate impact on pesticide levels.<sup>262</sup> However, such a reinterpretation is not necessarily conducive to promoting the goals of coexistence. The agency that can effect the most significant change toward coexistence is APHIS.

### *2. APHIS Interpretive Changes of the Plant Protection Act*

APHIS could announce its intention to consider new deregulation petitions on the basis of gene-flow effects on organic crops. The Plant Protection Act

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<sup>260</sup> See Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399d (2006)) (laying out FDA responsibilities under the FDCA and not mentioning any required analysis). The FDA's interpretation withstood an arbitrary-and-capricious challenge. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 181 (D.D.C. 2000).

<sup>261</sup> See McGarity, *supra* note 148, at 466–67 (arguing that the EPA could assert more power over GM crops through FIFRA).

<sup>262</sup> See *id.*

largely leaves the ability to APHIS to determine what a pest is; it only requires the agency to obey sound science.<sup>263</sup> APHIS could announce its intention to consider new petitions for deregulation of modified crops as pests under a standard naming any pest as an organism capable of contamination causing a certain level of economic harm to farms within a certain distance.<sup>264</sup> This change would force APHIS to consider ongoing marketability of non-GM crops and potential liabilities for patent infringement. Although this approach would not allow APHIS to fully consider economic impacts on organic crops, it would implicitly encompass the economic interests by protecting more organic crops from genetic drift. If APHIS were able to overcome the administrative hurdles and begin to reinterpret the Plant Protection Act to provide more protection to organic crops, coexistence efforts would be better served. This approach would be difficult because the current statute says nothing about economic interests and because the approach would entail a divergence from the long-followed equivalence principles in the Coordinated Framework.<sup>265</sup>

### 3. Policy Changes Within APHIS and the USDA

APHIS could also take less drastic approaches, without reinterpreting the Plant Protection Act, to better account for the interests of organic operations and, therefore, coexistence. The agency could change its permissive field-testing procedures and begin engaging in environmental studies before allowing tests that could lead to harmful gene flow.<sup>266</sup> *International Center for Technology Assessment v. Johanns* suggests that APHIS may soon be required to conduct assessments before permitting field-testing.<sup>267</sup> If APHIS restrains

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<sup>263</sup> See 7 U.S.C. §§ 7702, 7711; 7 C.F.R. § 340.1 (2011).

<sup>264</sup> The Plant Protection Act states:

[N]o person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and is in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.

7 U.S.C. § 7711(a). Clearly, the congressional grant of power can be considered an express grant providing a great deal of deference to USDA interpretations. See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–44 (1984). The *Chevron* decision even noted that agencies should be encouraged to change their interpretations of ambiguous statutes. *Id.* at 865.

<sup>265</sup> See *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41–43 (1983) (articulating the standard for review of agency decisions pursuant to statutes).

<sup>266</sup> Cf. Bratspies, *supra* note 24, at 412 (explaining that, under the current regime, APHIS typically does not require permits for field-testing).

<sup>267</sup> 473 F. Supp. 2d 9, 30 (D.D.C. 2007).

field-testing, organic crops will not be exposed to gene flow from modified crops before the crops are deregulated. Similarly, APHIS could begin to require more stringent scientific evidence that potentially deregulated crops will not harm the environment, as opposed to the general evidence it currently requires.<sup>268</sup> This more stringent standard could prevent the contamination problems seen in *Monsanto*.

Finally, the USDA as a whole could upgrade its monitoring of boundary limitations imposed on GM crops. Even if APHIS takes into account the interests of organic farmers, if the planters of GM crops do not adhere to the ensuing boundary limitations,<sup>269</sup> organic operations may still lose their harvest to GM-crop drift. If the USDA is not ensuring compliance with boundary limitations, GM farmers have no incentive to constrain the planting of modified crops, and organic farms will continue to be injured. The USDA could foster coexistence by enforcing existing programs without changing policy.

There are several limitations in unilateral agency efforts to foster coexistence. APHIS may not be able to adequately encompass economic interests in its determinations of what is a plant pest under the current statute. APHIS may not be able to review existing deregulations without additional statutory mandates.<sup>270</sup> Further, any agency action may be constrained by existing reliance interests.<sup>271</sup> APHIS, the EPA, and the FDA have followed the Coordinated Framework since 1986. Additionally, agency-initiated change will not be able to overcome the problem of general courts deciding who gets to farm.<sup>272</sup>

Without substantive changes to the underlying statutes, specifically the Plant Protection Act, the regulatory system is unable to adequately foster the goals of coexistence. Generally, the possible administrative changes would be

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<sup>268</sup> See Bratspies, *supra* note 24, at 412 (noting APHIS's current practice of allowing general scientific extrapolations).

<sup>269</sup> See *id.* at 414 (discussing the USDA's failure to ensure compliance with physical-planting requirements).

<sup>270</sup> See Bratspies, *supra* note 142, at 325–26 (noting that the USDA does not retain control over deregulated crops).

<sup>271</sup> See *FCC v. Fox Television Stations, Inc.*, 129 S. Ct. 1800, 1811 (2009) (noting that an agency may require a heightened justification to change a relied-upon policy).

<sup>272</sup> See Letter from Thomas Vilsack to Stakeholders, *supra* note 11 (lamenting that the current wealth of litigation relating to contamination is leading judges to decide who gets to farm).

helpful to coexistence but not as effective as the implementation of statutory revisions.

## *B. Statutory Reform*

Congress can revise the governing statutes to force the agencies under the Coordinated Framework to protect the feasibility of organic crops and, therefore, foster coexistence. Congress should (1) revise the Plant Protection Act to change the inquiry undertaken by APHIS when reviewing deregulation petitions by abandoning the substantial-equivalence principle and considering economic impacts caused by genetic drift, (2) direct APHIS to retain oversight after deregulation and monitor scientific developments on the impacts of deregulated crops, and (3) add a mandatory adjudicative arm to APHIS. The proposed revisions should also require APHIS to change field-testing and monitoring procedures, as discussed in the previous section. This section analyzes the proposed changes and implements them using the facts in *Monsanto*. This section also discusses the feasibility and costs of the proposed revisions.

### *1. Revising the Plant Protection Act to Account for Economic Impacts*

Congress should direct APHIS to abandon the substantial-equivalence principle and begin exploring the economic impacts of deregulation on organic-farming programs. Although organic-farming interests and the U.S. agricultural system as a whole would benefit from changes in labeling and permitting procedures from the FDA and the EPA,<sup>273</sup> Congress does not need to revamp the FDA or the EPA to protect organic-farming interests sufficiently. However, revising the Plant Protection Act to impose a requirement on APHIS to temper the equivalence principle and consider the economic feasibility of organic crops when considering deregulation will significantly enhance coexistence efforts.

The necessary revisions should prevent APHIS from continuing to grant permits permissively for the release of GM crops without fully considering the economic interests of organic farming.<sup>274</sup> The revised statute must include language requiring APHIS to consider and protect the economic interests of

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<sup>273</sup> See, e.g., Friedland, *supra* note 103, at 403–05, 414–16 (discussing the failures in the current labeling system).

<sup>274</sup> Agencies are constrained to follow their statutory directives, to withstand judicial review. See *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41–44 (1983).

organic farming.<sup>275</sup> These interests, as discussed, benefit U.S. agriculture generally and are not necessarily exclusive of GM planting.<sup>276</sup> The revision should maintain the presumption that GM crops should not be introduced until permitted by APHIS and should further require that deregulation involves a searching review of contamination and its potential economic impact on organic crops.<sup>277</sup> APHIS's eventual deregulation decisions will be subject to an exacting statutory standard protecting organic economic interests.<sup>278</sup> Congress should ensure that statutory revisions prohibit continued permissive field-testing, which exposes organic farms to contamination from crops that have not been adequately analyzed.

While Congress does not need to modify the current organic-labeling system,<sup>279</sup> Congress should ensure that APHIS deregulation procedures recognize that organic-farming interests may adopt stricter definitions of *organic* than the USDA definition. Many organic operations sell to the European community, which imposes stricter standards than the USDA promulgates domestically.<sup>280</sup> Similarly, many organic organizations require their own standards in addition to USDA standards.<sup>281</sup> Therefore, APHIS should defer to organic farmers' reasonable determinations of organic status.

## 2. *Revising the Plant Protection Act to Require Continuing Oversight After Deregulation*

Congress should also modify the Plant Protection Act to include a mandate for APHIS to monitor technological and scientific developments within the

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<sup>275</sup> Supreme Court precedent requires agencies to provide a rational explanation for a decision that relates the found facts to the statutory requirements. *Id.*

<sup>276</sup> See Endres, *supra* note 62, at 117 (noting the benefits of GM and non-GM crops growing simultaneously).

<sup>277</sup> As discussed in Part II.B, *supra*, organic farmers cannot necessarily recover for economic loss under tort-recovery theories. See Redick & Endres, *supra* note 122, at 27. This Comment argues that sufficient economic protection can only be attained at the federal regulatory level.

<sup>278</sup> The heightened standard, hard look review, requires agencies to provide a rational explanation for a decision that relates the found facts to the statutory requirements. See *State Farm*, 463 U.S. at 42–44.

<sup>279</sup> See Organic Foods Production Act of 1990, Pub. L. No. 101-624, tit. XXI, 104 Stat. 3935 (codified as amended at 7 U.S.C. §§ 6501–6523 (2006)) (imposing national standards on the production, handling, and labeling of organic foods).

<sup>280</sup> 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, 145 (2008) (noting European organic standards).

<sup>281</sup> See *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2755 (2010) (discussing organic farmers' affidavits wherein farmers described steps taken to continue marketing non-GM alfalfa to their consumers).

GM-crop arena.<sup>282</sup> Congress can align this mandate with existing programs aimed at sustainability and conservation.<sup>283</sup> As noted, there are potential risks associated with extensive monocropping and the repeated planting of GM crops leading to potentially deleterious effects on overall agricultural health.<sup>284</sup> With a focus on monitoring developments, APHIS will be obligated to recognize new scientific studies that quantify the risks of new and existing GM crops. While the USDA has been unsuccessful at implementing prior conservation and sustainability programs,<sup>285</sup> a focus on deregulated GM crops' subsequent environmental impact may make such programs more effective. Parties should be able to submit data to the agency on scientific developments. APHIS will be obliged to acknowledge the data, and when data shows that a deregulated crop exacts too hard a cost on the environment or neighboring farms, APHIS should return the crop to regulated status.

### 3. *Creating an Adjudicative Arm Within APHIS*

Congress should also direct APHIS to create an adjudicatory arm capable of deciding disputes between GM and non-GM crop farms.<sup>286</sup> An adjudicatory arm will prevent the confused remedies entered by general courts, such as the injunction issued by the district court in *Monsanto*.<sup>287</sup> Similarly, an adjudicatory arm could utilize agency expertise and experience in hearing patent and tort suits, saving parties the cost of educating a general court. An educated adjudicative arm within APHIS could help promote the coexistence policies that the USDA advocates for agricultural health.<sup>288</sup> The arm will

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<sup>282</sup> See Mandel, *supra* note 141, at 2247–48 (noting that APHIS should have the capability of postmarket monitoring).

<sup>283</sup> See David E. Adelman & John H. Barton, *Environmental Regulation for Agriculture: Towards a Framework to Promote Sustainable Intensive Agriculture*, 21 STAN. ENVTL. L.J. 3, 37–38 (2002) (noting that the USDA has not implemented prior sustainability programs).

<sup>284</sup> See Aoki, *supra* note 9, at 124 (“Genetic engineering in the context of commercial crops necessarily entails decreased genetic diversity. Because it is essential that GE crops have a uniform genetic structure, genetic engineering encourages monoculture.”).

<sup>285</sup> See Adelman & Barton, *supra* note 283, at 37–38.

<sup>286</sup> The Administrative Procedure Act allows agencies to adjudicate disputes relating to an administrative program. See 5 U.S.C. § 557(a) (2006). Currently, the Plant Protection Act provides federal courts with jurisdiction over disputes arising under the Act. 7 U.S.C. § 7736(a).

<sup>287</sup> See *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2760 n.6 (2010) (quoting the district court’s decision, which noted both that it was difficult to “fine-tune a particular remedy” and that “the simpler the remedy, the more attractive it is from the Court’s point of view”).

<sup>288</sup> See Letter from Thomas Vilsack to Stakeholders, *supra* note 11 (contending that the USDA wants to foster coexistence).



prevent “the courts [from] deciding who gets to farm their way and who will be prevented from doing so,” as the Secretary of Agriculture fears.<sup>289</sup>

While ideally statutory reform will reduce contamination, it is unlikely that such determinations will preclude disputes between GM farms and organic farms. The adjudicative arm should be vested with power to decide factual disputes between parties—for instance, whether each party is adhering to distance requirements imposed by a partial deregulation of GM crops.<sup>290</sup> The adjudicatory arm will also be in an excellent position to hear patent disputes<sup>291</sup> stemming from gene flow.<sup>292</sup> Disputes involving GM crops are fraught with scientific and technical information.<sup>293</sup> The district court dealing with the dispute in *Monsanto* specifically noted its difficulty in discerning the science involved in genetic-drift disputes,<sup>294</sup> and the ensuing broad injunction earned heavy criticism from the Supreme Court.<sup>295</sup> Remedies often involve discerning adequate boundary distances and outlining handling and shipping restrictions.<sup>296</sup> Therefore, adjudicatory outcomes will benefit from a forum that is able to draw on accrued agency expertise, a common justification for agency adjudication.<sup>297</sup> Indeed, in both the deregulation and adjudicative arenas, organic and GM interests will benefit from agency expertise.<sup>298</sup> Additionally, the adjudicative arm can serve as a venue for organic- and modified-crop

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<sup>289</sup> *See id.*

<sup>290</sup> The Supreme Court has allowed Congress to vest Article I courts with decision-making power traditionally left to Article III courts when the decision making is part of and necessary to a broad program, such as efforts to promote coexistence. *See Commodity Futures Trading Comm’n v. Schor*, 478 U.S. 833, 857 (1986) (allowing adjudication as part of the commodity futures trading program and noting that the Court’s “prior precedents . . . have not intimated that principles of federalism impose limits on Congress’ ability to delegate adjudicated functions to non-Article III tribunals”).

<sup>291</sup> The agency expertise in this area should not be on the validity of patents, traditionally left to the patent specialty agencies. *See Aoki*, *supra* note 9, at 102 (noting the role of specialized patent courts).

<sup>292</sup> *See Bernhardt*, *supra* note 67, at 24 (noting the wealth of patent infringement cases filed by GM producers).

<sup>293</sup> Some commentators question the current level of scientific expertise possessed by APHIS. *See Mandel*, *supra* note 141, at 2248–49. Such criticisms are beyond the scope of this Comment.

<sup>294</sup> *See Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2760 n.6 (2010).

<sup>295</sup> *See id.* at 2758.

<sup>296</sup> *See, e.g., id.* at 2751–52 (noting that the lower court imposed handling requirements for extant GM alfalfa as part of the injunction).

<sup>297</sup> *See Richard H. Fallon, Jr., Of Legislative Courts, Administrative Agencies, and Article III*, 101 HARV. L. REV. 915, 935 (1988) (“The first important interest supporting congressional flexibility to employ non-article III adjudicators is the interest in making the best use of expertise to implement a substantive regulatory agenda.”).

<sup>298</sup> *See Endres*, *supra* note 106, at 233 (noting that technically competent licensing committees could guide coexistence efforts).

interests to petition for a change in classification pending the discovery of additional information.<sup>299</sup>

#### 4. *Genetically Modified Alfalfa Under a Revised Regime*

The situation in *Monsanto* is illustrative of the potential efficacy of a revised statutory scheme in promoting coexistence. The dispute began when APHIS granted a permit to Monsanto allowing it to plant GM alfalfa.<sup>300</sup> Organic programs argued that subsequent GM-alfalfa planting would lead to contamination causing several organic farms to lose organic status.<sup>301</sup> The organic programs brought suit against APHIS alleging failures in its determination that the modified alfalfa could be fully deregulated.<sup>302</sup> Their allegations against the agency involved a hodgepodge of inadequacies, including a violation of NEPA.<sup>303</sup> Because the district court adopted the NEPA-violation angle,<sup>304</sup> APHIS's violation of NEPA was reviewed at the higher levels, including at the Supreme Court.<sup>305</sup> Organic interests struggled to establish their case, especially in terms of economic harm, because of the lack of avenues available to protect their economic interests. While a later case discussed the ambiguity regarding whether NEPA violations should include an analysis of economic harm,<sup>306</sup> organic operations should not need to utilize roundabout methods to protect their interests. With a more concrete avenue for protecting organic interests, the dispute in *Monsanto* would have taken a different form.

Had a revised Plant Protection Act been in effect during the deregulation process, APHIS would have been forced to consider the economic impacts of genetic drift. In *Monsanto*, the district court specifically noted that APHIS insufficiently considered the scientific aspects of genetic drift,<sup>307</sup> whereas under the new regime, APHIS would have to consider the scientific genetic

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<sup>299</sup> Congress should mandate an agency response to such petitions so as to avoid deference to agency inaction. See *Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (expressing strong deference to an agency's determination of whether an action should be taken).

<sup>300</sup> *Monsanto*, 130 S. Ct. at 2751.

<sup>301</sup> *Id.* at 2754. The organic farmers complained that their crops could not meet their organization's definition of *organic food*, independent of the USDA's definition. *Id.* at 2755.

<sup>302</sup> *Id.* at 2750–51.

<sup>303</sup> *Id.*

<sup>304</sup> *Id.* at 2751 (discussing the district court's determinations).

<sup>305</sup> *Id.* at 2756–57.

<sup>306</sup> *See* *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 953 (N.D. Cal. 2010) (“[I]t is not clear that economic consequences is a factor the Court may consider in environmental cases.”).

<sup>307</sup> *Monsanto*, 130 S. Ct. at 2751.

drift and its economic impact, and also explain it in a manner sufficient to withstand strict hard look judicial review.<sup>308</sup>

It is of course unclear whether a revision would lead to a different outcome regarding the deregulation of modified alfalfa.<sup>309</sup> Organic interests could only be sure that their economic interests be taken into consideration. Presumably, any deregulation decision with sufficiently high stakes will face pre-enforcement review soon after promulgation.<sup>310</sup> However, those challenging a promulgated rule under hard look review have a much more straightforward opportunity to challenge the promulgated rule than arguing for a NEPA violation. Under hard look review, APHIS would have to explain its choice in the face of the statutory mandates; here, assuming deregulation, APHIS would have to explain how scientific and economic data was considered and why it chose to deregulate in the face of such information.<sup>311</sup> This alone is a much more pleasing result for the coexistence of organic and GM crops.

Assuming, under the *Monsanto* facts, that APHIS chose to deregulate modified alfalfa, organic operations contaminated by genetic drift could bring a claim, within the proposed APHIS adjudication, against planters of GM alfalfa. The agency would then be required to broker the dispute and issue the appropriate remedy. The adjudication would benefit from the accrued expertise of the agency, which allows it to understand the science involved in the drift calculations and determine the appropriate remedy (if any) with a precision unavailable to judges in general courts. The parties can also expect reduced litigation costs before agency adjudication, which will not require educating the forum and may utilize streamlined procedures. Similarly, if Monsanto obtained deregulation of a crop and then suspected farmers of breaching licensing agreements or infringing patents, it could bring its claims before the agency tribunal. Additionally, if subsequent research reveals that GM alfalfa is

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<sup>308</sup> Hard look review requires agencies to provide a rational explanation for a decision that relates the found facts to the statutory requirements. *Motor Vehicles Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>309</sup> APHIS has now fully deregulated alfalfa. Pollack, *supra* note 29. This determination underscores the need for additional protection for organic crops outside the environmental context.

<sup>310</sup> See JAMES T. O'REILLY, ADMINISTRATIVE RULEMAKING: STRUCTURING, OPPOSING, AND DEFENDING FEDERAL AGENCY REGULATIONS § 13:1, at 295 (2d ed. 2011) (noting that challenges to regulations begin immediately after they are published); see also *Abbott Labs. v. Gardner*, 387 U.S. 136, 139–41 (1967) (allowing pre-enforcement review and paving the way for consistent pre-enforcement review in administrative rulemaking).

<sup>311</sup> Cf. *State Farm*, 463 U.S. at 52. Those challenging the decision will have to identify specific comments or accepted scientific information that APHIS was aware of but did not adequately address. See *id.*

more harmful than was understood at deregulation, non-GM interests could petition to return the strain to regulated status. Unlike the deregulation of GM alfalfa under the current regime, the process leading to the potential deregulation of modified alfalfa under the proposed regime would capture and consider the economic impacts of contamination and foster coexistence.

The foregoing discussion assumes that APHIS will faithfully fulfill its responsibilities, but history has shown that APHIS will not always do so. Unless statutory reform leads to renewed vigor within the agency, the prospects of successful reform are weak. Most likely, any change will continue to face agency capture and agency inertia, limiting the impact of the change.

### 5. *The Feasibility and Costs of Statutory Reform*

Despite the potential efficacy of a revised statute, the current legislative environment may not support legislative revisions. The organic-food/modified-food debate does not seem to be an issue of national importance during the economic downturn. Similarly, despite growing international demand for organic food, its domestic demand is probably not sufficiently high to spur Congress to action.<sup>312</sup> Additionally, the large agricultural companies that advocate the deregulation of GM crops under the current system have embedded influence within the federal government.<sup>313</sup> Overall, until the national consensus more heavily favors organic foods, it is unlikely that Congress will revise the current legal structure.

Legislation protecting diverse farming interests is not without precedent in the United States. The New Deal Era and subsequent years saw enormous growth in legislation protecting farming interests. These programs ranged from guaranteed government loans,<sup>314</sup> to crop loss protection,<sup>315</sup> to controlling prices

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<sup>312</sup> See Martin, *supra*, note 53 (noting the growth of the organic-food market but identifying its small size).

<sup>313</sup> See McGarity, *supra* note 148, at 476 (discussing the agribusiness industry and “its allies in the [Bush] Administration and Congress”).

<sup>314</sup> Agricultural Adjustment Act, ch. 25, 48 Stat. 31 (1933) (restricting production to boost prices during the New Deal), *invalidated by* U.S. v. Butler, 297 U.S. 1 (1936); *see also* Agricultural Adjustment Act of 1938, ch. 30, 52 Stat. 31 (codified as amended at 7 U.S.C. § 1281–1407 (2006)) (replacing the 1933 Act, which was held unconstitutional, with a system of price supports).

<sup>315</sup> Bankhead–Jones Farm Tenant Act, ch. 517, 50 Stat. 522 (1937) (codified as amended in scattered sections of 7 U.S.C.) (creating the eventual Farm Security Administration, which ultimately worked to protect small, impoverished farmers).

and crop yield.<sup>316</sup> The success of these programs was responsible for decades of security and stability in American farming.<sup>317</sup> Given this previous success, it may not be too radical to hope for an overhaul of the regulatory framework within the next few congressional sessions.

Both of these potential solutions, the agency-centered changes and the statutory changes, would impose costs on GM-crop producers. The statutory reform would also cost taxpayer money. GM producers would be forced to change development in research plans if APHIS adopts changes in its deregulation procedures. The companies would need to spend more money on field-testing procedures to explore contamination more thoroughly, and on research to justify deregulation, instead of just extrapolating from general research. The producers may also lose investments on developed products that would no longer meet APHIS standards. Taxpayers would largely foot the bill for an expanded adjudicatory arm that would necessarily entail an increase in staff and other outlays. However, as discussed, the adjudicatory arm would save money for both organic- and GM-farming interests. Overall, the additional costs would not outweigh the benefits of successfully fostering coexistence.

## CONCLUSION

The USDA goal for the coexistence of organic and GM crops is unattainable under the current regulatory system. The Coordinated Framework, a patchwork of agency responsibility, is unable to control effectively the introduction of GM crops into U.S. agriculture. This failure leads to uncontrolled contamination, which injures the interests of both organic operations and modified-crop producers. Recent cases have drawn attention to the weaknesses in the current system and have underscored the need for a solution to the weaknesses.

The USDA and Congress have both stated their desire to foster the coexistence of GM and organic programs. Recent evidence shows that large-

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<sup>316</sup> See, e.g., Bankhead-Jones Farm Tenant Act, 50 Stat. 522 (creating the eventual Farm Security Administration, which provided government loans and crop-loss protection); Agricultural Adjustment Act, 48 Stat. at 32 (controlling crop yield and price).

<sup>317</sup> See Mary Jane Angelo, *Corn, Carbon, and Conservation: Rethinking U.S. Agricultural Policy in a Changing Global Environment*, 17 GEO. MASON L. REV. 593, 624 (2010) (“[T]he policies in the original legislation continued to serve as the backbone of U.S. agricultural policy long after the farming crisis of the Great Depression was averted.”).

scale planting of GM crops has potential deleterious effects on agricultural health. Organic farms do not pose the same risks. However, organic crops are unable to offer some of the benefits associated with GM crops. The agricultural health of the United States requires beneficial coexistence of GM and organic crops.

The ideal solution to the current inability to foster coexistence involves statutory revisions (1) requiring APHIS to consider the economic implications of genetic drift when deregulating and (2) creating an adjudicative arm within APHIS. These revisions would ensure the economic feasibility of organic programs and thus encourage coexistence. However, such a revision may be unlikely in the current legislative environment. If such a modification is unfeasible, the USDA, the EPA, or the FDA could change their approaches to deregulating GM crops to limit the harmful effects of genetic drift. Such modifications may temper the harmful effects of contamination and enhance efforts toward coexistence.

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