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Forging Toward Coexistence

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TABLE OF CONTENTS

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> "Your corn is ripe to-day; mine will be so to-morrow. 'Tis profitable for us both, that I shou'd labour with you to-day, and that you shou'd aid me to-morrow."[1]

I. INTRODUCTION

There is little debate that the landscape of food production has changed rapidly since the advent of biotechnology[2] directed at agricultural innovation. As of 2011, the United States remains the global leader in the production of biotech crops holding the largest acreage—at over one hundred seventy million acres—and variety of commercialized crops, including maize, soybeans, cotton, canola, sugar beet, alfalfa, papaya, and squash.[3] In this current age of rapidly developing technology for the sake of engineering super crops possessed of only the most desirable traits, farmers who choose not to utilize these methodologies may be unwittingly forced to do so as nature provides the transport enabling these genetically altered microorganisms to find their way onto their growing fields. Concerns over genetically engineered (GE)[4] foods have recently received increasing attention in

1. DAVID HUME, 3 A TREATISE ON HUMAN NATURE 520 (L. A. Selby-Bigge ed., 1896).
2. Hungarian engineer Karl Ereky developed this term in 1919, referring to "the science and the methods that permit products to be produced from raw materials with the aid of living organisms." ORGANISATION FOR ECONOMIC POLICY AND DEVELOPMENT, MODERN BIOTECHNOLOGY AND THE OECD 1 (1999) *available at* http://www.oecd.org/science/biotechnologypolicies/1890904.pdf. "Modern biotechnology" began when James Watson and Francis Crick discovered the structure of DNA and produced their double helix model in 1953. *Id.*
3. *Global Status of Commercialized Biotech/GM Crops: 2011, Slides and Tables*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, http://www.isaaa.org/resources/publications/briefs/43/pptslides/default.asp (last visited Oct. 21, 2012). Notably, Brazil comes in second with less than half the amount of land at 30.3 hectares and only three types of crops. *Id.* While only the eight crops listed above are currently planted, "[o]ther crops approved for commercialization have included varieties of potatoes, radicchio, rapeseed, rice, squash, sugar beets, tobacco, and tomatoes. However, these are either not commercialized or not widely planted." SUSAN A. SCHNEIDER, FOOD, FARMING AND SUSTAINABILITY: READINGS IN AGRICULTURAL LAW 538 (2011).
4. Genetic engineering is the process of "[m]anipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques." *Glossary of Agricultural Biotechnology Terms*, USDA, http://www.usda.gov/wps/portal/usda/usdahome?contentid=BiotechnologyGlosary.xml&navid=AGRICULTURE (last visited Oct. 25, 2012). The term "genetic engineering" is often used synonymously with the term "genetic modification" even though the two terms are not identical. "Genetic modification" is defined as "[t]he production of heritable improvements in plants or animals for specific uses, via either genetic engineering or other more traditional methods. Some countries other than the United States use this term to refer specifically to genetic engineering." *Id.* The term genetic modification includes "more traditional methods" such as hybridization or cross breeding, *id.*, which do not involve the insertion of foreign genetic material whereas the term genetic engineering does not.

mainstream media. Advocacy groups struggle to make their voices heard to the federal agencies charged with ensuring the safety of our nation's food supply over the din of arguments by industry that such innovation is crucial to our nation's survival, economically and otherwise.[5] Yet, the disputes between farmers over how best to protect their crops receive far less attention.

Inevitable conflict over crop contamination due to pollen drift pits farmer against farmer as organic and non-GE farmers struggle to ensure the health and economic safety of their products. Simultaneously, the demand for increased access to, and support for, organic and non-GE foods is steadily increasing.[6] The non-GE category of foods is reported to be the fastest growing sector "in the natural and organic food industry."[7] Moreover, according to the most recent report released by the White House addressing the state of the agricultural economy, the U.S. organic industry "grew to $31.4 billion in 2011, up from $21.1 billion in 2008 [and t]he number of operations certified organic grew by 1,109—or more than 6%—between 2009 and 2011."[8]

5. *See, e.g.*, Cheryl Morley, *The Changing Landscape of American Agriculture*, MONSANTO (Jan. 8, 2007), http://www.monsanto.com/newsviews/Pages/Changing-Landscape-American-Agriculture.aspx ("I think the changing landscape of U.S. agriculture requires a profound shift in agricultural relationships among all participants in the value chain from growers to retailers. We'll have to evolve and figure out the way that these commodities are grown, handled, and used . . . Redefining our working relationships . . . how we work together to develop new markets and food platforms to meet the new and renewable sources of energy and consumer food demands. This requires change. Not only biotechnology, molecular breeding, but it will require new infrastructure data-gathering technology partnerships. At this stage I will tell you the magnitude seems pretty overwhelming, almost impossible, but it's already happening today at various stages. Change brings discomfort, but it also brings great opportunity."); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-60, GENETICALLY ENGINEERED CROPS: AGENCIES ARE PROPOSING CHANGES TO IMPROVE OVERSIGHT, BUT COULD TAKE ADDITIONAL STEPS TO IMPROVE COORDINATION AND MONITORING (2008), *available at* http://www.gao.gov/assets/290/283060.pdf ("Proponents cite the potential for enhanced crop yields; more environmentally friendly food production; more nutritious foods; and the increased use of plants to inexpensively produce pharmaceutical compounds, such as human or veterinary drugs, or industrial compounds, such as substances used in paper production or detergent manufacturing.").

6. Ken Roseboro, *Non-GMO is Fastest Growing Natural Food Category*, THE ORGANIC AND NON-GMO REPORT (May 1, 2011), http://www.non-gmoreport.com/articles/may2011/nonGMOgrowingnaturalfoodcategory.php ("According to natural food market research firm SPINS, Non-GMO Project verified product sales grew 27% over the past year, making it the fastest growing segment in the natural and organic food industry.").

7. *Id.*

8. COUNCIL OF ECONOMIC ADVISERS, WHITE HOUSE RURAL COUNCIL, UNITED STATES DEPARTMENT OF AGRICULTURE, STRENGTHENING RURAL COMMUNITIES: LESSONS FROM A GROWING FARM ECONOMY 3 (2012), *available at* http://www.whitehouse.gov/sites/default/files/docs/rural_communities_06_11_2012.pdf.

Such marked growth led the Administration to conclude that the U.S. agricultural economy will only benefit by growth and support of this sector.[9]

The notable growth in these sectors demonstrates clear evidence of the strong consumer demand for "natural" products. Polls conducted by various research organizations and media outlets show that over ninety percent of respondents believe strongly that they are entitled to information about the foods they eat and want GE foods to be labeled.[10] Consequently, countless individuals are entering the debate over GE foods by signing petitions demanding that industry "just label"[11] products containing GE ingredients and encouraging individuals to shop for non-GE verified foods.[12]

In the midst of this battle and despite farmers' efforts to protect their crops, the federal government continues to make decisions that operate to threaten meaningful coexistence between farmers. Consistently, the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (the APHIS) has taken the position that because its authority is limited to regulating plant pests under the Plant Protection Act (PPA),[13] once it has determined that a

9. *Id.*

10. *Polls on GMO Labeling*, Ctr. for Food Safety, http://gefoodlabels.org/gmo%20labeling/polls-on-gmo-labeling/ (last visited Oct. 21, 2012) (including the following statistics in the three most recent polls: (1) MSNBC: "'Do you believe genetically modified foods should be labeled?' Answer: Yes[—]96% of over 45,000 voters believe genetically modified foods should be labeled"; (2) Reuters/NPR: "Poll conducted by Thompson Reuters and National Public Radio finds 93% of Americans believe all GE foods should be labeled as such; only 35% willing to eat GE fish;" and (3) Washington Post: "Question: Should genetically-modified food be labeled? Answer: Yes[—]95%"). Additionally, "[a]wareness of genetically engineered foods increased as income and education levels increased. Only 51% of respondents who earn less than $25,000 said they were aware of genetically engineered foods—compared with 84% of those who earn over $100,000. Older respondents are the most willing to eat genetically engineered food. Only 32% of respondents ages 35–64 said they would eat altered fish, compared to 43% of those 65 and over." THOMAS REUTERS, NATIONAL SURVEY OF HEALTHCARE CONSUMERS: GENETICALLY ENGINEERED FOOD 3 (2010), *available at* http://www.factsforhealthcare.com/pressroom/NPR_report_GeneticEngineeredFood.pdf.

11. *See, e.g.*, *Tell FDA to Label Genetically Engineered Food*, CTR. FOR FOOD SAFETY, http://salsa3.salsalabs.com/o/1881/p/dia/action/public/?action_KEY=5452 (last visited Oct. 26, 2012); *Tell the FDA We Have a Right to Know if Our Food Has Been Genetically Modified*, JUST LABEL IT, http://justlabelit.org/take-action/ (last visited Oct. 21, 2012).

12. *Creating Change Through Action*, NON-GMO PROJECT, http://www.nongmoproject.org/take-action/consumers/ (last visited Oct. 26, 2012) (detailing an advocacy project directed at giving consumers access to information about genetically engineered/modified foods).

13. Plant Protection Act, 7 U.S.C. §§ 7701–7786 (2006). Under the PPA, "[t]he term 'plant pest' means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:
(A) A protozoan.

GE crop does not present a plant pest risk, the agency's only function is to grant nonregulated status and provide no further safeguards as the product enters the commercial market and becomes distributed and planted without restrictions.[14] APHIS's recent decisions demonstrate that the agency at least recognizes the potential for significant negative impacts to organic and non-GE farmers upon deregulation, yet suggests these are issues that must be worked out among farmers.[15] This position places organic and non-GE farmers in an incredibly weak position given that their GE counterparts have already received the necessary approval to plant crops without any additional requirements or further oversight from the USDA. In other words, these policy decisions have the practical effect of curtailing any motivation on the part of GE farmers to collaborate with organic and non-GE farmers when it means they will be required to take additional steps or provide safety mechanisms that have not been imposed on them by the responsible regulating authorities.

Recently, it appears the agency has started to recognize the inequity in such an approach and tasked the USDA Advisory Committee on Biotechnology and the 21st Century (AC21), originally created in 2003, to determine, among other things, an appropriate means by which farmers who have suffered injuries as a result of crop contamination can be remunerated.[16] In addition to considering the issue of

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(B) A nonhuman animal.
(C) A parasitic plant.
(D) A bacterium.
(E) A fungus.
(F) A virus or viroid.
(G) An infectious agent or other pathogen."
(H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs."
Id. § 702(14).

14. *See, e.g.*, *Frequently Asked Questions About Biotechnology*, U.S.D.A., http://www.usda.gov/wps/portal/usda/usdahome?contentid=BiotechnologyFAQs.xml&navid=AGRICULTURE (last visited Dec. 5, 2012) ("The regulations also provide for a petition process for the determination of non-regulated status. Once a determination of non-regulated status has been made, the organism (and its offspring) no longer requires APHIS review for movement or release in the U.S."); *Guidance on Petitions for Extension of Nonregulated Status*, U.S.D.A., http://www.aphis.usda.gov/biotechnology/extensions.shtml (last visited Dec. 5, 2012) ("If APHIS determines that the regulated article does not present a risk of introduction or dissemination of a plant pest, the petition will be granted, thereby allowing unrestricted introduction of the article.").
15. USDA, Draft Environmental Assessment, Dow AgroScience (DAS)'s Petition for Nonregulated Status of Herbicide Tolerant DAS-40278-9 Corn, Event DAS-40278-9, 22–24 (Oct. 2011), http://www.aphis.usda.gov/brs/aphisdocs/09_23301p_dea.pdf.
16. The USDA established the AC21 in accordance with the Federal Advisory Committee Act. 5 U.S.C. App. 2 §§ 1–16 (2006). In the Charter, one of the express duties of the Committee is to "provide information and advice to the Secretary of

remuneration, USDA Secretary Vilsack charged the AC21 to reach a decision by consensus on the ways to "bolster coexistence among different agricultural production systems"[17] and mitigate risk so that neighbors are not suing neighbors, and farmers are not forced to resolve their disputes in court.[18] Such a federal initiative is necessary since federal laws have not kept pace with advancing technologies and, while some states have attempted to address the issue of patent violations to ensure that farmers whose crops are contaminated through no fault of their own are shielded from liability,[19] no state has created legislation that permits farmers to recover when their crops have been contaminated.

This Article argues that because current federal policies hamper the ability of organic and non-GE farmers to ensure the safety and authenticity of their products, the AC21 needs to meet its charge and reach consensus on USDA supported mechanisms that encourage and facilitate farmers to develop long term, viable solutions that address the interests of all parties. Without USDA support, farmers have little incentive to attempt collaboration under the umbrella of existing federal policies. Part II of this Article provides a detailed history of the regulatory scheme that governs genetically engineered plants and products and demonstrates the clear preference for the development and support of GE products. In Part III, this Article examines the scope of authority granted to the USDA under the Plant Protection Act to regulate genetically engineered organisms. Part IV addresses the issue of gene flow from GE crops to non-GE and organic crops, and provides a discussion of the cases that have brought this issue before the courts. Finally, Part V of this article concludes by analyzing the

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Agriculture on topics related to the use of biotechnology in agriculture. The committee is charged with examining the long-term impacts of biotechnology on the U.S. food and agriculture system and USDA, and providing guidance to USDA on pressing individual issues, identified by the Office of the Secretary, related to the application of biotechnology in agriculture." USDA, ADVISORY COMM. ON BIOTECHN. & 21ST CENTURY AGRIC. (AC21), CHARTER 2 (2003), *available at* http://www.usda.gov/documents/AC21%20Charter%202011.pdf.

17. The AC21 has defined coexistence as referring "to the concurrent cultivation of conventional, organic, and genetically engineered crops consistent with underlying consumer preferences and farmer choices." USDA ADVISORY COMM. ON BIOTECH. & 21ST CENTURY AGRI. (AC21), MTG. TRANSCRIPT, MAY 29, 2012, at 12:24–13:2 (2012), *available at* http://www.usda.gov/wps/portal/usda/usdahome?contentid=AC21Main.xml&contentidonly=true.

18. *Id.*

19. *See* CAL. AGRIC. CODE § 52305 (West 2012) ("A farmer shall not be liable based on the presence or possession of a patented genetically engineered plant on real property owned or occupied by the farmer when the farmer did not knowingly buy or otherwise knowingly acquire the genetically engineered plant, the farmer acted in good faith and without knowledge of the genetically engineered nature of the plant, and when the genetically engineered plant is detected at a de minimis level.").

work of the AC21 and arguing that the working group needs to consider the implementation of collaborative mechanisms to aid farmers in achieving some degree of coexistence.

II. REGULATION OF GENETICALLY ENGINEERED CROPS

A. Creation of the Coordinated Framework for the Regulation of Biotechnology

1. Proposal for a Coordinated Framework for Biotechnology

Operating from the position that "new techniques for manipulating genetic information offer exciting advances, as remarkable as the discovery of antibiotics or the computer chip,"[20] the federal government drafted a "Proposal for a Coordinated Framework for Biotechnology"[21] to address health and safety concerns about what were then newly developed fields of biotechnology, collectively known as genetic engineering, while simultaneously attempting to foster growth of a relatively new and seemingly promising sector.[22] According to Al Gore, the Investigations Subcommittee in the House of Representatives, which he chaired, determined the "absence of good risk assessment practices and methods" made it virtually impossible for the government to determine the safety of these products.[23] Consequently, the Subcommittee recommended the government coordinate its regulatory efforts and develop a scheme that properly addressed the needs of this industry.[24]

The government drafted its first iteration of this proposal in 1984[25] following the recognition by the White House Cabinet Council on Natural Resources and the Environment,[26] also known as the interagency working group, that federal agencies needed a mechanism by which

20. Proposal for a Coordinated Framework for Biotechnology, 49 Fed. Reg. 50,856 (Dec. 31, 1984).
21. *Id.*
22. *Id.* at 50,857 ("The Working Group recognizes the need for a coordinated and sensible regulatory review process that will minimize the uncertainties and inefficiencies that can stifle innovation and impair the competitiveness of U.S. industry.").
23. Al Gore, *Planning a New Biotechnology Policy*, 5 HARV. J. L. & TECH. 19, 22 (1991).
24. *Id.*
25. Proposal for a Coordinated Framework for Biotechnology, 49 Fed. Reg. at 50,856.
26. "The member agencies included the Departments of Justice, State, Agriculture, Commerce, Defense, Energy, Health and Human Services, Labor, and the Interior, EPA; the Council on Environmental Quality, the Council of Economic Advisors; OMB; the Office of Policy Development; the National Science Foundation; the Office of the U.S. Trade Representatives; and OSTP." U.S. GEN. ACCOUNTING OFFICE, RCED-92-167, BIOTECHNOLOGY: DELAYS IN AND STATUS OF EPA'S EFFORTS TO ISSUE A TSCA REGULATION, 3 n.1 (1992), *available at* http://www.gao.gov/assets/220/216370.pdf.

they could share scientific information to "adequately consider[ ] health and environmental safety consequences of the processes of the new biotechnology as they move[d] from the research laboratory to the marketplace."[27] By adopting such an approach, the Administration explicitly rejected the idea of creating a "superagency" that would provide oversight within a single agency.[28]

In the 1984 proposal, the working group acknowledged that concerns about recombinant DNA (rDNA) research had existed in the scientific community since the early 1970s,[29] although attempts at regulation in this field proceeded without any meaningful comprehensive review of the regulatory requirements pertaining thereto.[30] Therefore, the working group proposed a coordinated agency regulatory scheme wherein the responsible agencies, the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the USDA would approach regulation of these new products of genetic engineering under an existing statutory regime while developing individual statements of policy that would detail their regulatory approaches.[31]

Specifically, the working group acknowledged that the FDA intended to regulate genetically engineered products in the same manner as their non-genetically engineered counterparts under the Federal Food, Drug, and Cosmetics Act (FDCA).[32] It charged the EPA with both determining whether these products constitute pesticides or industrial products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[33] and either designating acceptable levels of

27. Proposal for a Coordinated Framework, 49 Fed. Reg. at 50,857–58. The Proposal noted specifically that the interagency working group "recognize[d] that not only should approaches be consistent from agency to agency and within each agency from application to application, but also that regulatory decisions should be based upon the *best available science*." *Id.* (emphasis added).

28. Gore, *supra* note 23, at 22.

29. Christine C. Vito, *State Biotechnology Oversight: The Juncture of Technology, Law and Public Policy*, 45 ME. L. REV. 329, 332 (1993) ("In the summer of 1973, nearly 100 scientists at the Gordon Conference on Nucleic Acids in New Hampshire expressed a collective concern as to the safety and potential risks associated with the recombinant DNA experiments presented at the Conference."). These scientists then asked for assistance and recommendations from both the National Institutes of Health and the National Academy of Sciences. *Id.*

30. Proposal for a Coordinated Framework for Biotechnology, 49 Fed. Reg. at 50,857.

31. *Id.* at 50,858.

32. *Id.*; Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 342 (2006); While not explicitly stated in either version of the Framework, this approach was consistent with the FDA's interpretation of their statutory authority under the FDCA. *See* Statement of Policy, Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

33. Proposal for a Coordinated Framework for Biotechnology, 49 Fed. Reg. at 50,858; Federal Insecticide, Fungicide, & Rodenticide Act, 7 U.S.C. § 136a(a); 40 C.F.R. 3.150–89 (2011).

pesticide residue in food or animal feed products or establishing exemptions from these limits under the FDCA.[34] Finally, it required the USDA to determine whether products containing genetically engineered microorganisms were "plant pests, animals biological, or other agricultural products" subject to regulation within their authority under the PPA.[35] In other words, the working group assigned agencies to regulate the products of biotechnology under the existing statutory framework that pertained to food, pesticides, and plants rather than under any new laws specifically targeted to address this field.[36]

One of the early responses to the concerns raised in the 1970s by the scientific community was the creation of the National Institutes of Health's Recombinant (NIH) DNA Advisory Committee,[37] which developed "Guidelines for Research Involving Recombinant DNA Molecules" to "specify practices for constructing and handling" rDNA molecules, as well as the organisms containing them.[38] In these early stages, the government's approach seemed precautionary or at least it attempted to give the appearance that this was its methodology.[39] To that end, the original proposed policy emphasized that "[t]he importance of the *highest caliber scientific advice* to the decision-making process for oversight of biotechnology is undisputed."[40] Specifically,

34. 21 U.S.C. §§ 331(a), 342(a)(2)(B), 346a(a)(1)–(2), (b)(2)(A)(i).
35. Proposal for a Coordinated Framework, 49 Fed. Reg. at 50,858; Plant Protection Act, 7 U.S.C. § 7701–7721 (2006).
36. *Id.*; *see also* Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 KAN. J.L. & PUB. POL'Y. 393, 407 (2007) ("The Coordinated Framework fits the products of genetic engineering into an already-existing set of laws and regulations. Because these laws were drafted before the development of this technology, they are not always well suited to their new tasks.").
37. *About Recombinant DNA Advisory Committee (RAC)*, NAT'L INST. OF HEALTH, http://oba.od.nih.gov/rdna_rac/rac_about.html (last visited Oct. 21, 2012); *see also* DEPARTMENT OF HEALTH AND HUMAN SERVICES, CHARTER, RECOMBINANT DNA ADVISORY COMMITTEE (2011) ("The Committee makes recommendations on research involving the use of recombinant DNA and on developments in recombinant DNA technology.").
38. DEP'T OF HEALTH AND HUMAN SERVICES, NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (2011), *available at* http://oba.od.nih.gov/oba/rac/guidelines/nih_guidelines.htm. These Guidelines have been revised many times since their initial drafting in 1976. *Id.* To reflect the concept of a coordinated agency effort at regulation, the guidelines specify that "[a]ny recombinant DNA experiment, which according to *NIH Guidelines* requires approval by NIH, must be submitted to NIH or to another Federal agency that has jurisdiction for review and approval." *Id.* However, once approval is received from another Federal agency, "the experiment may proceed without the necessity for NIH review of approval." *Id.*
39. D.L. Uchtmann, *Starlink—A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159, 165 (2002) ("These initial guidelines represented a cautious approach to the regulation of rDNA research but they did allow such research to continue.").
40. Proposal for a Coordinated Framework, 49 Fed. Reg. at 50,858 (emphasis added).

"[t]he experience of the [Recombinant DNA Advisory Committee] over the past ten years serves as a valuable model to the Working Group in structuring the proposed scientific review coordinating mechanism."[41] However, because the original NIH Guidelines applied solely to activities that either took place at, or were sponsored by, the NIH, private parties were essentially permitted to conduct unrestricted research of their own.[42]

While these early attempts at assurances that agency decisions would be informed by the best available science may have assuaged the worries of some, they ultimately yielded a regulatory scheme that provides little substantive federal oversight in a field in desperate need. The government intentionally left a fair amount of ambiguity in the 1984 proposal to allow the different agencies flexibility in their regulatory approach; but, perhaps the unintended effect was a great deal of confusion over any activities that fell outside the NIH Guidelines.[43]

2. The 1986 Coordinated Framework for the Regulation of Biotechnology

In the wake of the confusion and unrest generated by the 1984 Proposal for a Coordinated Framework, the Office of Science and Technology Policy (OSTP) again convened to create the Biotechnology Science Coordinating Committee (BSCC).[44] Specifically, the OSTP proposed the BSCC to cure the deficiencies in the two-tiered approach suggested under the 1984 proposal.[45] Under that approach, the first tier, comprised of "research sponsoring" agencies and the regulatory agencies (FDA, USDA, and EPA) would use science advisory committees to provide advice on "scientific questions raised by applications seeking approval for scientific research or for product testing or marketing."[46] The second tier was to act as a parent advisory board that would help facilitate "interagency review and coordination."[47]

After careful consideration and review of the comments received in response to the 1984 Proposal for a Coordinated Framework, the OSTP determined that any application had the potential to be of interest to multiple agencies and, given the rapid pace of development in

41. *Id.*
42. Vito, *supra* note 29, at 333 (citing NIH Guidelines, 41 Fed. Reg. 27,902 (July 7, 1976); Guidelines for Research Involving Recombinant DNA Molecules, 48 Fed. Reg. 24,556, 24,563 (Jun. 1, 1983)).
43. *Id.* at 335.
44. Proposal for a Coordinated Framework, 49 Fed. Reg. at 50,858.
45. *Id.*
46. Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174–75 (Nov. 8, 1985).
47. *Id.*

this sector, such a two-tiered approach was insufficient to tackle the unique challenges posed by these decisions.[48] Consequently, it proposed an "interagency coordinating committee" with representatives from each of the involved agencies "to coordinate science issues related to research and commercial applications of biotechnology . . . ."[49] Importantly, the BSCC was charged only with coordinating scientific information between the agencies and was not intended to focus on or address any issues related to the problems surrounding regulatory oversight. Despite this mandate, the BSCC was criticized for the fact that it became involved in issues of regulatory policy rather than science, conducted much of its business outside of the discerning eyes of the public, and ultimately failed to meet its obligation of establishing standards to guide agency decision making in this regard.[50] Eventually, the BSCC enlisted the National Research Council of the National Academies of Science to "evaluate scientific information pertinent to making decisions about the introduction of genetically modified organisms and microorganisms into the environment."[51]

With the help of the BSCC,[52] in 1986, the OSTP published its revised Coordinated Framework for the Regulation of Biotechnology.[53] This second attempt at developing a coordinated agency response to biotechnology outlined the regulatory framework that currently remains largely unchanged and was premised on the same notion as its predecessor—that "[r]ecombinant DNA techniques have opened up new and promising possibilities in a wide range of applications and can be expected to bring considerable benefits to mankind."[54] As suggested in the 1984 proposed policy, the Coordinated Framework determined that the creation of new laws to regulate the products of genetic

48. *Id.*

49. *Id.* at 47,176. The express purposes of the BSCC were to "[s]erve as a coordinating forum for addressing scientific problems, sharing information, and developing consensus; promote consistency in the development of Federal agencies' review procedures and assessments; facilitate continuing cooperation among Federal agencies on emerging scientific issues; and identify gaps in scientific knowledge." U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 176 (1991).

50. Gore, *supra* note 23, at 22; Linda Maher, *The Environment and the Domestic Regulatory Framework for Biotechnology*, 8 J. ENVTL. L. & LITIG. 133, 140 (1993) (citing BUREAU OF NATIONAL AFFAIRS, UNITED STATES BIOTECHNOLOGY: A LEGISLATIVE & REGULATORY ROADMAP, BNA SPECIAL REPORT ON BIOTECHNOLOGY # 2, at 7 (1989)) (explaining the emphasis on policy may have been due, in part, to several Bush appointees to the Committee who were lawyers rather scientists).

51. NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: A FRAMEWORK FOR DECISIONS 1 (1989).

52. Maher, *supra* note 50, at 140 (noting the original chairman of the BSCC, David Kingsbury, helped to draft the Coordinated Framework).

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

54. *Id.* at 23,308.

engineering was unnecessary, as "[t]he existing health and safety laws had the advantage that they could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation."[55] Moreover, the OSTP did not feel that any alternative approach was viable given the broad range of products, of which the regulatory responsibility is vested in different agencies.[56] Its focus was, and remains, on the end product rather than the process. Overall, the revised proposal left much of the substance of the 1984 draft in place; but, it also included "certain refinements" such as the BSCC's definitions of "intergenic (new) organism" and "pathogen"[57] and outlined some additional specifics regarding the regulatory landscape.

Notably, the OSTP specified that it intended the Coordinated Framework to provide guidance on those decisions that required regulatory approval and review and those that did not.[58] For example, the OSTP referred to the fact that, within agriculture, new plants, animals, and microorganisms have long been introduced without federal regulation, and only some of those that are non-native or pathogenic would now require federal oversight.[59] However, this oversimplification ignores the fact that those introductions took place through conventional breeding techniques rather than by genetic engineering. Additionally, by the time of publication of this version of the Coordinated Framework, the NIH Guidelines, which were intended to provide assurances to the scientific community, had been meaningfully relaxed.[60] Consequently, the OSTP noted that not all experiments involving the environmental release of genetically engineered organisms

55. *Id.* at 23,303.

56. *Id.*; Maher, *supra* note 50, at 138 ("Biotechnology is a multi-discipline science, and at times, its products cross traditional barriers that distinguish foods from pesticides, medicines from poisons, and even tomatoes from fish.").

57. Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. at 23,302, 23,307.

58. *Id.* at 23,302.

59. *Id.* ("Within agriculture, for example, introductions of new plants, animals and microorganisms have long occurred routinely with only some of those that are not native or are pathogenic requiring regulatory approval. It should be noted that microorganisms play many essential and varied roles in agriculture and the environment and that for decades agricultural scientists have endeavored to exploit their advantages through routine experimentation and introduction into the environment; and as a rule these agricultural and environmental introductions have taken place without harm to the environment.").

60. *Id.* at 23,305 ("Since [their adoption,] the guidelines have been modified many times with gradual relaxation of these requirements."); Uchtmann, *supra* note 39, at 165 (citing Susan Wright, *The Status of Hazards and Controls*, 24 ENVIRONMENT 13 (1982)) ("Over time, the experience gained in rDNA laboratories mitigated many of the concerns associated with rDNA research, at least in the minds of many scientists, and led to a modest relaxing of the initial guidelines and oversight mechanisms.").

would be subject to prior approval.[61] This was especially true for plant applications since those presented low risk.[62]

Commenting on the agencies' individual statements of policy, the OSTP appeared to reiterate that each responsible agency needed to conduct its assessments on a "case by case basis" while considering "the ultimate safety of the product as a primary concern," but also taking into account "other issues, such as efficacy."[63] Interestingly, the OSTP's choice of language in this document reflected its clear position that the products of genetic engineering were not only identical to their non-genetically engineered counterparts, but also had the potential to be superior.[64] The policy was driven by two major premises, which were alluded to, although not specifically stated. First, the techniques used in genetic engineering are not necessarily any less safe than the traditional methods of genetic modification through breeding or hybridization.[65] Second, these new products of genetic engineering were not necessarily fundamentally different from their natural counterparts.[66] While some might suggest that such flexibility was necessary to ensure the growth of this sector, concerns that the "ultimate safety" of these products has become relegated to "other issues" abound.

Not surprisingly, given the contentious nature of all things related to genetic engineering and biotechnology, the Coordinated Framework was not without its controversy. Just a few months after the notice for comments was issued in the Federal Register, the District Court for the District of Columbia handed down its decision in *Foundation on Economic Trends v. Johnson.*[67] The plaintiffs, including a non-profit organization in Washington D.C., that were "concerned . . . with the various implications of certain technological developments involving

61. Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. at 23,305.
62. *Id.*
63. Proposal for a Coordinated Framework, 49 Fed. Reg. at 50,858.
64. "While the recently developed methods are an extension of traditional manipulations that can produce similar or identical products, they enable more precise genetic modifications, and therefore hold the promise for exciting innovation and new areas of commercial opportunity." Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).
65. Albert C. Lin, *Size Matters: Regulating Nanotechnology*, 31 HARV. ENVTL. L. REV. 349, 377 (2007) (citing Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302–03); *cf.* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 738 (2003) ("Undergirding the Coordinated Framework—and the determination that biotechnology could be addressed under existing statutes and regulations—were two critical assumptions: first, that the techniques of biotechnology are not riskier than traditional breeding techniques; and second, that GMOs are not fundamentally different from other organisms.").
66. *Id.*
67. 661 F. Supp. 107 (D.D.C. 1986).

biochemical and genetic engineering," sought a declaratory judgment to enjoin the operation of the Coordinated Framework on the basis that the BSCC's biotechnological definitions included in the Coordinated Framework were inaccurate and inexact.[68] Such inaccuracy, the plaintiffs argued, would allow for potentially harmful genetically-engineered products to be either incorrectly or far too leniently regulated, which would fail to protect the health and safety of the natural and human environments.[69] Because these definitions had the potential to have such serious impact and would either affect future regulations or be incorporated into already existing regulations, the plaintiffs claimed the Coordinated Framework was "defective for lack of notice or hearing, . . . and in any case constitutes irrational agency action."[70]

The plaintiffs in *Foundation on Economic Trends* were ultimately unsuccessful because of their failure to demonstrate both that the Coordinated Framework constituted an agency action subject to judicial review and that they had suffered any harm as a result of it;[71] however, the court's perspective on the significance of the Coordinated Framework provided interesting insight regarding the manner in which the agencies charged with regulating biotechnology were intended to interpret it. The court noted that the document was not intended to regulate, but rather was meant to "guide policymaking."[72] The manner in which the responsible agencies have chosen to effectuate those policy directives has been the source of considerable debate in the realm of genetic engineering, particularly since they have essentially chosen not to provide for any additional regulation beyond the fractured set of already existing laws and regulations outlined therein.[73] Critics of the Coordinated Framework suggest that so little

68. *Id.* at 108.
69. *Id.*
70. *Id.*
71. *Id.* at 110 (citing Action Alliance of Senior Citizens v. Heckler, 789 F.2d 931, 940 (D.C. Cir.1986)) ("In this abstract factual setting, where no specific agency actions with an identifiable impact on the environment have been alleged, the Court can determine neither the probable effect of the Framework definitions nor their rationality. Because no specific injury has been alleged, there can be no showing of the 'immediate and significant' hardship from deferral of adjudication that could support review of plaintiffs' claim at this juncture.").
72. *Id.* at 109 ("While the document is not a model of clarity, its treatment by the agencies involved conclusively establishes it is merely a first effort to aid in formulation of agency policy with respect to control of microorganisms developed by genetic engineering techniques.").
73. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,303 (June 26, 1986); Maggie Ellinger-Locke, *Food Sovereignty is a Gendered Issue*, 18 BUFF. ENVTL. L.J. 157, 168 (2011) ("[T]he Framework has been implicitly upheld because neither agencies nor the legislature has sought to provide additional regulation of genetically engineered products."); Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM

was accomplished in this regard because of inter-agency disputes that discouraged any semblance of real coordination among the responsible agencies.[74]

In what represented an arguably unsuccessful attempt to try and balance the interests of keeping pace in a global market of rapidly developing technology with ensuring the health and safety of the human and natural environment, the Coordinated Framework ultimately provided little guidance to the responsible agencies. The jumbled and confusing discussion of the mechanisms by which existing laws were equipped to regulate products of genetic engineering, despite the fact that many of these laws had never considered biotechnology, proved relatively unhelpful. Problematically, the OSTP left the bulk of regulation up to a group of agencies that could not collectively agree on how to regulate these products.

3. OSTP Final Statement of Policy

The OSTP issued its final statement of policy in 1992 upon the recognition that the Coordinated Framework provided broad strokes for the agencies sharing responsibility over the regulation of the products of biotechnology, but failed to address how they were to exercise that responsibility.[75] This policy was intended to provide the responsible agencies with the "proper basis" for the exercise of decision making within the bounds of the discretion afforded by the statutory framework.[76]

Specifically, the policy detailed three principles that continue to guide federal oversight of introductions of genetically-engineered products into the environment. First, decision making should be focused on "the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created."[77] Second, the responsible agencies should base their decisions on "the risk posed by the introduction and [decisions] should not turn on the fact that an organism has been modified by a particular process or technique."[78] With regard to this principle,

403, 432 ("[F]or all its complexity, the regulatory regime requires remarkably little of the companies that develop and market GM foods. The sponsor of a GM food can at all critical junctures either substantially diminish regulatory oversight or avoid it altogether . . . .").

74. Gore, *supra* note 23, at 24 (citing *Proposal to End Regulatory Turf Fights, Amend TSCA Is Drafted By Committee Staff*, Chem. Reg. Rep. (BNA) 84–85 (April 27, 1990)).

75. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992).

76. *Id.*

77. *Id.*

78. *Id.*

the OSTP was clear that "limited federal oversight" should occur only when the risk is "unreasonable," meaning "when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed."[79] Third, organisms that have "new phenotypic trait(s)" which do not pose a greater risk than the "parental organisms" should not be subject to a greater level of oversight than the original unaltered organism.[80]

According to the policy, this risk-based approach provided the appropriate balance between ensuring safety while not unnecessarily hindering innovation and development, and was supported by the "great majority" of public comments received during the proposal stage.[81] This approach relied heavily on the findings of the National Research Council, which determined that "organisms that have been genetically modified are not *per se* of inherently greater risk than unmodified organisms."[82] Following this line of reasoning, the policy is careful to note that federal oversight may, in some instances, be either duplicative of existing state laws or industry standards, or interfere with those efforts, and, in those cases, the agencies should not be wasteful of resources by exercising unnecessary oversight by deferring to the efforts of industry when appropriate.[83] Moreover, if an agency

79. *Id.* ("The extent and type of oversight measure(s) will thus be commensurate with the gravity and type of risk being addressed, the costs of alternative oversight options, and the effect of additional oversight on existing safety incentives.").

80. *Id.* at 6756.

81. *Id.* at 6755.

82. *Id.* (citing NATIONAL RESEARCH COUNCIL, *supra* note 51, at 3, 14–15, 123). The NRC made a number of findings. National Research Council, *supra* note 51, at 3, 14–15, 123. First, it determined that "[t]he same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods." *Id.* at 15. Second, "[i]nformation about the process used to produce a genetically modified organism is important in understanding the characteristics of the product. However, the nature of the process is not a useful criterion for determining whether the product requires less or more oversight." *Id.* at 14–15. Third, "no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes." *Id.* at 14. Fourth, "[c]rops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits. As the molecular methods are more specific, users of these methods will be more certain about the traits they introduce into the plants. And finally, "[i]n many respects, molecular methods resemble the classical methods for modifying particular strains of microorganisms, but many of the new methods have two features that make them even more useful than the classical methods." *Id.* at 123.

83. *See* Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. at 6761 ("[U]ncertainty related to the extent or effectiveness of Federal regulation may lead to the enactment of a patchwork of conflicting and burdensome state regulations. . . . In general, to avoid unnecessary burdens on biotechnology, the Administration has sought to eliminate unneeded regulatory burdens for all

was evaluating the release of a comparable organism that had previously been released in a similar target environment, the policy discouraged performance of another detailed risk evaluation.[84] In addition, the policy did not require any sort of assessment of the "health and environmental effects of individual [genetically engineered organisms]."[85] Consequently, much of the precaution witnessed in the early stages was replaced by a risk based approach that essentially employed a cost-benefit analysis,[86] which critics suggest has led to the weak exercise of statutory authority on the part of the responsible agencies.[87] It has been suggested that this final policy statement, therefore, "opened the way for deregulation of large-scale environmental releases of transgenic plants," which has had profound impact on individuals choosing not to invest in these technologies.[88] Regardless of whether GE plants and their non-GE counterparts are the same, the federal policies failed to consider the practical effects of the release of GE organisms in a manner that impacted another person's product that was dependent on it not containing GE organisms.

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phases of the development of new biotechnology products . . . . Existing regulatory structures . . . provide an adequate framework for regulation of biotechnology in those limited instances where private markets fail to provide adequate incentives to avoid unreasonable risks to health and the environment."). One critic suggests that because this policy "is based in large part on a policy determination that agencies and companies should not have to waste resources on unnecessary testing and evaluation[;] . . . it [provides] an excuse for regulatory agencies to avoid their responsibilities." McGarity, *supra* note 73, at 431.

84. *See* Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. at 6757.

85. Albert C. Lin, *Technology Assessment 2.0: Revamping Our Approach to Emerging Technologies*, 76 BROOK. L. REV. 1309, 1315 (2011).

86. Some considered this a watershed moment for both the regulation of biotechnology, as well as in the realm of risk assessment generally. *E.g.*, Peter Mostow, *Reassessing the Scope of Federal Biotechnology Oversight*, 10 PACE ENVTL. L. REV. 227, 232 (1992).

87. Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 525, 559 (2004) (citing Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297 (2002); Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167 (2004); Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733 (2003); McGarity, *supra* note 73).

88. David J. Earp, Comment, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1658 (1994).

III. USDA'S REGULATORY AUTHORITY UNDER THE PLANT PROTECTION ACT (PPA)[89]

Finding that "the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds is necessary for the protection of the agriculture, environment, and economy of the United States,"[90] Congress vested the USDA with responsibility for regulating articles that could pose a plant pest risk. The PPA, enacted in 1957, "was intended as 'gap filling' legislation for the purpose of protecting American agriculture against invasion by plant pests and diseases which are new to or not theretofore known to be widely prevalent or distributed within and throughout the United States."[91] Additionally, the PPA granted the USDA authority to regulate insects or plants that might present a future risk to cultivated crops.[92] While not specifically drafted to address biotechnology, the Act gives the USDA control over the introduction (which includes "importation, entry, exportation, or movement"[93]) of certain genetically engineered products or organisms.[94] Through the Animal and Plant Health Inspection Service (the APHIS),[95] the division of the USDA charged with "*protect[ing] the health and value of American agriculture*"—the Department of Agriculture—exercises regulatory control over genetically-engineered products that the agency determines could be plant pests.[96] The USDA promulgated regulations to address the introduction of genetically engineered organisms consistent with the mandates under the PPA following the creation of the Coordinated Framework.[97]

89. 7 U.S.C. §§ 7701–7786 (2006).

90. *Id.* § 7701.

91. Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,342 (June 26, 1986).

92. *Id.*

93. 7 U.S.C. § 7711(a).

94. *Id.*

95. APHIS describes itself as "a multi-faceted Agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities. These efforts support the overall mission of USDA, which is to protect and promote food, agriculture, natural resources and related issues." *About APHIS*, U.S. DEP'T OF AGRIC. ANIMAL & PLANT INSPECTION SERV., http://www.the APHIS.usda.gov/about_the APHIS/ (last visited Oct. 14, 2012).

96. *Id.*

97. Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. at 23,336.

Under the regulations, the APHIS restricts the "introduction"[98] of "regulated articles"[99] that present a plant pest risk, unless the agency has received notification of the introduction,[100] the introduction is authorized by permit,[101] or the introduction is "conditionally exempt."[102] Plant pests are defined as "[a]ny living stage . . . or any organisms . . . or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants."[103] Arguably, the APHIS has the ability to regulate any release of potential plant pests that could constitute a threat to agriculture regardless of whether the release is intrastate or interstate.[104] In addition, because of the manner in which the APHIS defined specific terms in the regulations, the agency has authority over genetically engineered plants either because of the type of plant, or the materials and methods used in the process.[105] Because the Act limits the agency's authority to regulating plant pests, a genetically engineered organism is no longer subject to the provisions of the Act once the APHIS has determined it does not pose a plant pest risk.

A. Releases into the Environment

For most introductions of genetically engineered plants, the APHIS determined that the notification procedure was sufficient, ne-

98. 7 C.F.R. § 340.1 (2012) (defining "introduce" or "introduction" as "[t]o move into or through the United States, to release into the environment, to move interstate, or any attempt thereat").

99. *Id.* (defining "regulated articles" as "[a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 and meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only noncoding regulatory regions").

100. *Id.* § 340.0(a)(1) (requiring notification to be in accordance with 7 C.F.R. § 340.3).

101. *Id.* (requiring permits to be obtained in accordance with the requirements under 7 C.F.R. § 340.4).

102. *Id.* (explaining that conditions for exemptions are specified in 7 C.F.R. § 340.2(b)(2)).

103. *Id.* § 340.1. The PPA also defines the term "plant pest." *See* Plant Protection Act, 7 U.S.C. § 7702(14) (2006).

104. John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 839 (2001).

105. *Id.* (citing Earp, *supra* note 88, at 1644). The agency "makes a default assumption that GM crops qualify as plant pests" under the regulations. Andrew W. Torrance, *Planted Obsolescence: Synagriculture and the Law*, 48 IDAHO L. REV. 321, 337 (2012).

gating the need for a permit authorized by the agency.[106] The APHIS reached this conclusion based on its experience with hundreds of permit applications for field releases and over one thousand permits for movement.[107] Specifically, the APHIS determined that most regulated articles could be introduced into the environment with "little or no plant pest or environmental risk, provided that certain criteria and performance standards are met."[108] During the field-test–trial stage, because the release of the plants is still regulated by the APHIS, the agency can include certain conditions, such as containment protocols to protect surrounding crops from reproducing with or being contaminated by the test crops.[109]

Some argue that the regulations fail to address both the regulation of genetically engineered plants to minimize environmental risk and the additional risks posed by such products that go beyond the considerations of what constitutes a "plant pest."[110] Indeed, the regulations fail to take into account the fact that, if not controlled very specifically, the release of a genetically-engineered organism could seriously affect nearby organic and non-GE crops. An internal audit in 2005 by the Inspector General of the USDA revealed that the agency was unaware of the location of many field test trials and failed to review—and in some instances, even require—written containment protocols detailing how the applicant intends to contain the genetically engineered organisms.[111] Moreover, the USDA did not require applicants to submit any sort of final disposition information, which, in some instances led to storage of GE organisms, whose unintentional release could have posed a safety issue, for over a year without the APHIS' approval

106. Genetically Engineered Organisms & Products; Notification Procedures for the Introduction of Certain Regulated Articles; & Petition for Nonregulated Status, 57 Fed. Reg. 53,036–37 (explaining that prior to this proposal, all introductions had to occur by permit and each permit application was assessed on a "case by case basis").

107. *Id.*

108. *Id.* (detailing criteria and standards). "In 2004, almost 97 percent of all field trials of regulated GE crops were conducted under notifications." U.S. DEP'T OF AGRIC., OFFICE OF INSPECTOR GENERAL, SW. REGION, AUDIT REPORT, ANIMAL & PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS 2 (2005), *available at* http:// www.usda.gov/oig/webdocs/50601-08-TE.pdf [hereinafter AUDIT REPORT]. "Currently, most regulated GE plants are introduced under notification, which is a streamlined procedure. Examples of GE plants introduced under the notification procedure are those GE plants altered to be resistant to certain insects or herbicides." Importation, Interstate Movement, & Release Into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. 60,008, 60,010 (Oct. 9, 2008).

109. 7 C.F.R. § 340.4 (2012).

110. *E.g.*, Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 WAKE FOREST L. REV. 93, 137 (2007).

111. AUDIT REPORT, *supra* note 108, at i–ii.

or knowledge of the storage facility's location.[112] The internal audit also revealed that the APHIS does not "effectively track information required during the field tests, including approved applicants' progress reports, which should contain the results of field tests, including any harmful effects on the environment."[113] The APHIS has since proposed eliminating the notification procedure, as the standards are too general and permits can "provide more specific information about what procedures the permit holder must follow in order to be in compliance."[114]

B. Petitions for Nonregulated Status

In 1993, the APHIS amended its original regulations and provided, among other things, for a petition process allowing individuals to seek determinations that certain plants would no longer be designated as regulated articles.[115] In response to the proposed regulations regarding the petition process, the APHIS received eleven comments in favor and ten comments that suggested further amendment or deletion.[116] In the notice, the APHIS discussed one comment that argued any data considered in the petition process must include "peer reviewed scientific studies."[117] The agency disagreed with this argument, suggesting that because any data submitted as part of the petition process is reviewed by the APHIS's scientific staff and those determinations are then passed on to the public during the notice and comment period,[118] adequate scientific review is provided.[119] In other words, for those individuals who wanted to ensure that the APHIS had considered the best science available when making a determination of a petition for nonregulated status, it was potentially their responsibility to not only perform those studies, but to then submit them as part of the comment process. The APHIS views the petition process as merely procedural despite the fact that it "may result in an organ-

112. *Id.*
113. *Id.* at ii.
114. Importation, Interstate Movement, and Release Into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. at 60,008, 60,016.
115. *See* Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 58 Fed. Reg. 17,044 (March 31, 1993) (to be codified at 7 C.F.R. pt. 340).
116. *Id.* at 17,054.
117. *Id.*
118. *See id.* ("The new procedures include an opportunity for public comment and public review of the data that has been submitted to THE APHIS in support of a petition for determination of nonregulated status. State regulatory agencies, academic institutions, and individual research scientists will have the opportunity to present all relevant information to the agency pertaining to a specific organism prior to a determination of nonregulated status by THE APHIS.").
119. *Id.*

ism no longer being regulated after a thorough and comprehensive plant pest and environmental analysis."[120]

In large part, the current version of 7 C.F.R. § 340.6 reflects the statements made in the 1993 notice, with the exception that the requirements demonstrate OSTP's desire for the agencies to make the best use of their resources and not engage in unnecessary work so that a person can now streamline a petition for nonregulated status on the basis that it is similar to an "antecedent organism."[121] Under the current regulation, any person can file a petition seeking non-regulated status of a particular genetically engineered plant.[122] Accompanying the petition, the petitioner must present "[r]elevant experimental data and publications"[123] and "[f]ield test reports."[124] Upon receipt of the petition, the APHIS will publish notice in the Federal Register and allow for a sixty (60) day comment period,[125] review the data to determine whether the article poses a "plant pest" risk,[126] and furnish a response to the petitioner within one hundred eighty days.[127] Once the agency makes the determination that a genetically-engineered plant does not present a "plant pest" risk and deregulates it, the plant can be introduced into the commercial market and planted without further federal oversight from the USDA.[128] Practically speaking, this means a farmer can plant a genetically engineered crop without necessarily taking into consideration the different methods of food production occurring in the vicinity. From the agency's perspective, the determination that a GE crop does not present a plant pest risk "takes into account various risk factors, including, among other things, a low risk that the GE organism or its progeny can persist, reproduce, and establish without human assistance."[129] For those plants that are similar to their predecessors, the process may be further streamlined. Effectively, this precludes any further consideration by the APHIS of negative effects or risks posed by the genetically engineered organism upon deregulation.

While the APHIS recognizes that it needs to revise the regulations pertaining to GE organisms, it has yet to take any final action on the rule proposed on October 9, 2008.[130] With regard to determinations of

120. *Id.* at 17,054.
121. 7 C.F.R. § 340.6(e) (2012).
122. *Id.* § 340.6(a).
123. *Id.* § 340.6(c)(2).
124. *Id.* § 340.6(c)(5).
125. *Id.* § 340.6(d)(2).
126. *Id.* § 340.6(e).
127. *Id.* § 340.6(d)(3).
128. USDA, *supra* note 15.
129. Importation, Interstate Movement, & Release Into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. 60,008, 60,010 (proposed Oct. 9, 2008) (to be codified at 7 C.F.R. pt. 340).
130. *Id.*

nonregulated status, the agency proposed a mechanism by which it can revisit that decision and revoke the status if it later receives information that the plant poses a plant pest risk.[131] Despite this proposed change, the APHIS is nonetheless comfortable that any decisions made prior to the rule change will be automatically approved for nonregulated status based on the demonstrated history of years of safe use.[132] It remains unclear what the status of these proposed revisions is and whether the agency will formalize them into a final rule. Until that point, determinations on petitions for nonregulated status continue to occur in the same manner without the opportunity for someone to later challenge that determination based on an injury. This presents significant problems for organic and non-GE farmers whose crops become contaminated by non-regulated GE plants.

IV. DISPUTES RESULTING FROM FEDERAL POLICIES REGARDING BIOTECHNOLOGY

Considering the federal government's historically strong endorsement of biotechnology, it is no wonder that the current lax and outdated regulatory scheme has led to disputes between farmers who embrace the technology and those who do not. By way of example, in a recent draft environmental assessment on a petition by Dow AgroScience (DAS) seeking nonregulated status of herbicide tolerant DAS-40278-9 Corn, Event DAS-40278-9 (referred to by advocacy groups as "Agent Orange" corn[133]), the agency acknowledged that crop contamination for organic and non-GE varieties of corn is not unlikely given the manner in which corn "naturally cross pollinates."[134] To avoid such contamination, the agency suggests that organic farmers notify their neighbors that they are using "organic production practices" and ask that "the neighbors also help the organic farmer reduce potential contamination events."[135] However, given the fact that organic pro-

131. *Id.* at 60,024.
132. *See id.*
133. *E.g.*, Ctr. for Food Safety, *Food Safety Fact Sheet, "Agent Orange" Corn: The Next Stage in the Chemical Arms Race* (Feb. 2012), *available at* http://www.centerforfoodsafety.org/wp-content/uploads/2012/05/Agent_orange_corn_fact-sheet.pdf.
134. USDA, *supra* note 15, at 23. "Contamination of organic corn crops is a concern because corn naturally cross pollinates. Contamination can occur from impure seed; seed admixture; volunteer plants; and residual non-organic seed in the equipment, vehicles, and facilities. Farmers using organic methods are requested to let neighboring farmers know that they are using organic production practices and request that the neighbors also help the organic farmer reduce potential contamination events. Delayed planting has been used successfully by some organic corn producers to control weeds and to avoid potential contamination by GE pollen from adjacent fields." *Id.* (internal citations omitted).
135. *Id.*

duction is so strongly regulated by the National Organic Program and genetically engineered corn that becomes deregulated is effectively not regulated, it appears the burden expressed by this agency policy flows in the wrong direction. Moreover, such cautionary advice is not provided to conventional farmers who choose not to use GE seed and may suffer the same fate.

A. Basics of Crop Contamination

Concerns about instances of crop contamination due to either the intentional or unintentional release of genetically engineered organisms have risen to the level that advocacy groups developed a GM Contamination Register, wherein all reported instances of national and international crop contamination are included in a public database.[136] Not surprisingly, given the nature of the plants and their ability to cross-pollinate, in the United States alone there have been numerous reports of instances of transgenic contamination, most notably in the papaya plant population in Hawaii.[137] Crop contamination can occur for many reasons. In some instances, crops can become contaminated simply due to the inadvertent planting of GE seed in a non-GE planting field or, more commonly, as the result of mixing of GE seed with non-GE seed.[138] The method that occurs with the highest degree of unpredictability and causes farmers understandable consternation is cross-pollination or hybridization, the potential for which depends on the plant species.[139] Hybridization between plants occurs from the spread of pollen.[140] Because hybridization can occur over long distances, as several studies have demonstrated, it "may be difficult to control gene flow" from GE to non-GE crops.[141] The degree of gene flow that can occur between a GE and non-GE crops depends on the reproductive strategy of the plant—some, like corn, are open pollinated, meaning pollination can occur by birds, insects, wind, or

136. *See* GM CONTAMINATION REGISTER, http://www.gmcontaminationregister.org (last visited Oct. 26, 2012).

137. *See Hawaii—GM papaya trees have contaminated both organic and conventional non-GM papaya on a wide scale*, GM CONTAMINATION REGISTER, http://www.gmcontaminationregister.org/index.php?content=re_detail&gw_id=19&reg=cou.1&inc=0&con=0&cof=0&year=2004&handle2_page= (last visited Oct. 15, 2012).

138. NATIONAL RESEARCH COUNCIL, THE IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES, 104 (2010) [hereinafter NRC, IMPACT] (citing Norman C. Ellstrand, *Current Knowledge of Gene Flow In Plants: Implications for Transgene Flow*, 358 PHIL. TRANSACTIONS OF THE ROYAL SOC'Y B 1163, 1163–70 (2003)), *available at* http://www.nap.edu/openbook.php?record_id=12804.

139. *Id.*

140. Anna Kuparinen, Frank Schurr, Oliver Tackenberg, & Robert B. O'Hara, *Air-Mediated Pollen Flow from Genetically Modified to Conventional Crops*, 17 ECOLOGICAL APPLICATIONS 431, 431 (2007).

141. *Id.*

other natural processes, whereas other plants are self or closed pollinated.[142] Those crops that are open pollinated possess the greatest potential for gene flow.[143]

While field trials have attempted to "study gene flow at a realistic agricultural scale," they fail to fully account for environmental variations that may have an effect.[144] However, one scientific study attempted to account for these variations.[145] It determined that while the "mean level of contamination" decreased as the distance between crops increased, there were "high levels of contamination over long distances" in some trials.[146] This led the researchers to conclude that the variation was due to vertical updrafts which were caused by instability in the atmosphere, making management practices or measures directed at reducing contamination unhelpful.[147] Consequently, "[f]rom the point of view of farmers and managers, variation in wind conditions is a component of inherent uncertainty that makes it difficult to forecast levels of contamination in a specific situation."[148] Of the factors that are "controllable," scientists concluded that "both the size of the [GE] field and the spatial configuration of the fields had some effect on the predicted level of gene flow."[149] In other words, smaller and shallower fields appeared to contribute less to gene flow meaning that farmers should engage in discussions about these issues when addressing coexistence.[150] Other scientists concluded that "the distances needed to prevent any cross-pollination in corn or other open-pollinated crops are so great that they are not practical in current commercial agricultural systems."[151]

Clearly, gene flow between GE and non-GE crops can have the effect of rendering an organic or non-GE farmer's entire crop "unsuitable" for its intended market due to the presence of GE organisms.[152] Thus, if the farmer has taken certain additional—and usually costly—

142. NRC, IMPACT, *supra* note 138, at 104.
143. *Id.* However, "[e]ven in self-pollinated plants, out-crossing occurs occasionally, the rate depending on the particular species and environment." *Id.*
144. Kuparinen et al., *supra* note 140, at 432.
145. *Id.* at 437.
146. *Id.*
147. *Id.*
148. *Id.* (citing James S. Clark et al., *Ecological Forecasts: An Emerging Imperative*, 293 SCIENCE 657 (2001); James S. Clark et al., *Estimating Population Spread: What Can We Forecast and How Well?*, 84 ECOLOGY 1979 (2003)).
149. *Id.* at 439.
150. *See id.*
151. NRC, IMPACT, *supra* note 138, at 105 (citing S. Luna V. et al., *Maize Pollen Longevity and Distance Isolation Requirements for Effective Pollen Control*, 44 CROP SCI., 1551 (2001); M. A. Matus-Cádiz et al., *Gene Flow in Wheat at the Field Scale*, 44 CROP SCI. 718 (2004)).
152. *Id.* at 169–70 (citing David S. Bullock et al., *The Economics of Non-GMO Segregation and Identity Preservation*, 27 FOOD POLICY 81 (2002)).

measures to produce a product for a high yield (such as organic or non-GMO) market, the farmer can suffer great economic loss from crop contamination. Beyond the economic impacts, such contamination can also have an impact on the level of trust between these different groups of farmers,[153] the federal government exacerbates the problem by requiring organic and non-GE farmers to protect themselves from contamination.[154] Because it is so difficult to control the adventitious presence[155] of GE organisms and organic producers have to comply with the National Organic Program ("NOP"), which does not permit the use of genetic engineering, policies allowing for a certain degree of adventitious presence have been developed to enable the coexistence of GE, non-GE, and organic foods.[156] However, the costs associated with keeping crops GE free, organic or otherwise, are significant. Farmers who wish to keep their products free of GE organisms must establish "buffer zones, whose needed size is uncertain, cleaning equipment, inspections of crops and processing facilities, and frequent testing" which can be quite expensive after harvest.[157] Even for farmers who undertake these precautionary measures, there remains a risk that other farmers will illegally plant GE crops, further decreasing the possibility of coexistence.[158] To date, there have been no reported lawsuits where a farmer has sued another farmer for harm due

153. *Id.*

154. A. Bryan Endres, *Coexistence Strategies, The Common Law of Biotechnology and Economic Liability Risks*, 13 DRAKE J. AGRIC. L. 115, 142 (2008) ("The government . . . has repeatedly resolved the question of who should be responsible for preserving the integrity of a non-genetically modified (conventional or organic) harvest in favor of the farmer adopting the new, genetically engineered technology, regardless of the amount of disruption it may cause on established farming practices.").

155. Defined as the "[g]ene flow of approved GE traits into non-GE varieties of the same crops." NRC, IMPACT, *supra* note 138, at 9.

156. *Id.* at 172 (citing Matty Demont, & Yann Devos, *Regulating Coexistence of GM and Non-GM Crops Without Jeopardizing Economic Incentive*, 26 TRENDS IN BIOTECH., 353 (2008); Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501–6522 (1990)) ("For example, in the United States, voluntary labeling of food as GE-free is allowed as long as a product contains less than 5-percent adventitious presence of GE material. In contrast, the EU allows up to 0.9-percent adventitious GE material in non-GE food, animal feed, and products labeled as organic if the GE crop has been approved in the EU; otherwise, the threshold is zero.").

157. HARVEY BLATT, AMERICA'S FOOD: WHAT YOU DON'T KNOW ABOUT WHAT YOU EAT 106 (2008). "Although requiring buffer zones between genetically engineered crops and natural crops is a step in the right direction, many farmers are not following the regulations, and even with full compliance, it would be impossible to entirely eliminate the risk of contamination by genetically engineered pollen." Sophia Kolehmainen, *Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, 20 VA. ENVTL. L.J. 267, 280 (2001) (citing *Farmers Unclear About Biotech Rules*, NEW YORK TIMES (Feb.1, 2001), http://www.nytimes.com/2001/02/01/health/01ap-biotech.html?pagewanted=all).

158. Alison Peck, *The New Imperialism: Toward an Advocacy Strategy for GMO Accountability*, 21 GEO. INT'L ENVTL. L. REV. 37, 46 (2008).

to genetic crop contamination,[159] however, farmers have at least put the issue of crop contamination before the courts in a few different contexts.

B. Bringing the Issue of Crop Contamination Before the Courts

1. In re StarLink Corn Products[160]

The issues raised in *StarLink* likely first came to the attention of the public when Kraft Foods announced a nationwide recall of its taco shells after discovering they contained genetically engineered corn that had not been approved for human consumption.[161] In 2002, a group of plaintiffs that included farmers whose crops had been contaminated by StarLink corn filed suit in District Court in the Northern District of Illinois (Eastern Division) alleging, among other things, that the defendant—manufacturers of StarLink—created a private nuisance by distributing the corn seeds "knowing that they would cross-pollinate with neighboring corn crops."[162] Specifically, they alleged that they could not "enjoy the profits of their land (selling food corn), because of an unreasonable activity on neighboring land (growing StarLink corn)."[163] The EPA had given the defendant a special mandate to only use its corn for "animal feed, ethanol production, and seed increase"—not for human consumption due to the presence of a protein in the corn that had attributes similar to human allergen properties.[164] To meet these obligations, the EPA required the defendants to take certain precautionary and protective measures and inform purchasers of the specific limitations on use.[165]

While *StarLink* involved a lawsuit attempting to hold a manufacturer responsible for distributing a product that the EPA had yet to approve, the language the court used when finding that the private nuisance claim was appropriate may likely have a future effect on any cases involving crop contamination due to drift. Additionally, it appears to flip the burden the APHIS has adopted as a matter of course on its head. Specifically, the court stated, that "[r]esidue from a product drifting across property lines presents a typical nuisance claim.

159. Neil D. Hamilton, *Forced Feeding: New Legal Issues in the Biotechnology Policy Debate*, 17 WASH. U. J.L. & POL'Y 37, 53–54 (2005) ("[T]he development of legal precedent addressing this issue has been limited.").
160. 212 F. Supp. 2d 828 (N.D. Ill. 2002).
161. Andrew Pollack, *Kraft Recalls Taco Shells With Bioengineered Corn*, NEW YORK TIMES (Sept. 23, 2000), http://www.nytimes.com/2000/09/23/business/kraft-recalls-taco-shells-with-bioengineered-corn.html?pagewanted=all&src=pm.
162. *StarLink*, 212 F. Supp. 2d at 844.
163. *Id.* at 847.
164. *Id.* at 834.
165. *Id.*

All parties who substantially contribute to the nuisance are liable."[166] This suggests that in a case where a farmer's crops have been contaminated such that the farmer cannot enjoy the profits because of the unreasonable activities on neighboring land, the farmer may be able to sustain claims to recover from multiple parties who "substantially contribute[d]" to the nuisance, including the manufacturers.[167] Moreover, the plaintiffs were able to maintain a public nuisance claim because, although "the general public has a right to safe food, plaintiffs depend on the integrity of the corn supply for their livelihood."[168] For some farmers unable to afford a lawsuit, they may be able to convince a local agency or authority to pursue a public nuisance suit under this theory.[169] Even though this case was ultimately settled, the court approved the $110 million settlement to compensate the farmers who suffered losses, demonstrating the court's willingness to hold manufacturers liable for market losses due to contamination from their GE products.[170]

2. Monsanto Co. v. Geerston Seed Farms[171]

As the first case before the United States Supreme Court to address genetically engineered plants, the decision in *Geerston* holds special significance even if the opinion ultimately left advocates disappointed. Specifically, the district court considered an issue of first impression: "[W]hether the introduction of a genetically engineered crop that might significantly decrease the availability or even eliminate all non-genetically engineered varieties is a 'significant environmental impact' requiring the preparation of an environmental impact statement, at least when it involves the fourth largest crop in the United

166. *Id.*

167. "The StarLink litigation and settlement is perhaps the most significant development because it establishes responsibility for damages resulting from the use of the technology. However, because the case involved a violation of the regulatory approval of the product, it may not serve as controlling precedent in the more difficult case where the lawful use of an approved product results in measurable commercial damages to a non-compatible crop." Hamilton, *supra* note 159, at 54.

168. *StarLink*, 212 F. Supp. 2d at 848.

169. Thomas Connor, *Genetically Modified Torts: Enlisting the Tort System to Regulate Agricultural Contamination by Biotech Crops*, 75 U. CIN. L. REV. 1187, 1205 (2007) ("A farmer who has suffered an economic loss due to the genetic contamination from his neighbor's crops might argue that although the public is harmed by a risk to the food supply's safety, he is harmed by physical damage to his crops and the inability to sell his crops . . . .").

170. A. Bryan Endres & Nicholas R. Johnson, *United States Food Law Update: Moving Toward a More Balanced Food Regulatory Regime*, 7 J. FOOD L. & POL'Y 383, 414 (2011) (citing Thomas P. Redick & Donald L. Uchtmann, *Coexistence Through Contracts: Export-Oriented Stewardship in Agricultural Biotechnology vs. California's Precautionary Containment*, 7 DRAKE J. AGRIC. L. 207, 214 (2008)).

171. 130 S. Ct. 2743 (2010).

States."[172] The plaintiffs, composed of the Sierra Club, consumers, and farmers, originally brought suit against the USDA for its decision to deregulate Roundup Ready (RR) Alfalfa without completing an environmental impact statement (EIS), as required by the National Environmental Policy Act.[173] After completing an environmental assessment (EA), the agency made a finding of no significant impact (FONSI) despite receiving 663 comments, 520 of which were opposed to the deregulation.[174] One of the primary concerns expressed in the public comments addressed the recognized potential for gene flow due to pollen drift from the genetically engineered alfalfa to organic and conventional alfalfa, which could result in crop contamination.[175]

Despite these concerns, the APHIS granted the petition in whole and deregulated the RR alfalfa acknowledging that, upon deregulation, the crop would not be subject to any isolation distances.[176] The APHIS predicated this determination on the position that organic and conventional growers who wish to avoid contamination should employ production methods to avoid cross-pollination.[177] The court found this point significant—the APHIS rested its finding of no significant impact to organic and conventional growers without making any determination about whether those farmers could "in fact, protect their crops from contamination."[178] Consequently, the court held this determination did not provide the "hard look" NEPA required and opined that the drafting of an EIS would give the agency the opportunity to more fully analyze the "realistic measures" that might be taken to prevent contamination, particularly since the agency chose not to exercise its authority to approve the "petition with a geographic limitation stipulating that the Roundup Ready could only be grown without the APHIS authorization in certain geographic areas."[179]

At the remedies phase, Monsanto and Forage Genetics intervened because of the possibility of a preliminary injunction enjoining the APHIS from deregulating the alfalfa without completing an EIS, as well as all planting of RR alfalfa and all sales of RR alfalfa seed.[180] After hearing Monsanto's arguments about the impacts such an injunction could have on farmers who already purchased the seed, the

172. Geertson Seed Farms v. Johanns, No. C 06-01075 CRB, 2007 WL 518624 at *1 (N.D. Cal. Feb. 13, 2007).
173. *Id.*; 42 U.S.C. § 4332(2)(C)(i) (2006).
174. *Geerston*, 2007 WL 518624, at *2.
175. *Id.*
176. *Id.*
177. *Id.*
178. *Id.* at *6.
179. *Id.*
180. Geertson Seed Farms v. Johanns, 541 F.3d 938, 942 (9th Cir. 2008), *aff'd*, 570 F.3d 1130 (9th Cir. 2009), *rev'd sub nom.* Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010).

court entered the injunction with prospective effect.[181] On appeal, the only issue before the Court involved the question of whether the district court should have imposed the injunction pending the completion of an EIS by the APHIS.[182] The Court assumed, without making a decision, that the district court's determination to vacate the APHIS's deregulation decision without an EIS was lawful since the parties did not challenge it.[183] While the Court ultimately determined that the injunction was unlawful because it forbade the APHIS from partially deregulating RR alfalfa and allowing for its release subject to restrictions aimed at preventing cross-pollination, the Court did, at least acknowledge that such contamination presents an issue.[184] It noted that "if the scope of the partial deregulation is sufficiently limited, the risk of gene flow to their crops could be virtually nonexistent."[185] In other words, the Court did not simply ignore the fact that contamination due to gene flow is not only a possibility, but it challenged the assumption that organic and non-GE farmers must, alone, be responsible for segregation to avoid contamination.[186]

3. Center for Food Safety v. Vilsack[187]

After yet another controversial deregulation decision by the APHIS, this one involving RR sugar beets, a group of plaintiffs, including the Center for Food Safety, Organic Seed Alliance, High Mowing Organic Seeds, and the Sierra Club, challenged the decision on the basis that the APHIS again failed to complete an EIS prior to deregulation, and sought a preliminary injunction enjoining the "planting, cultivation, processing, or other use" of RR alfalfa seeds.[188] The lower court cited statements by the APHIS that echoed the same policy determinations from *Geerston*, as the agency concluded that it did not need to consider the potential economic impacts from crop contamination to organic and conventional farmers, and, in any event, those farmers were responsible for taking measure to ensure that such cross-pollination did not occur.[189]

Following the same line of reasoning as the court in *Geerston*, the district court found that "the potential elimination of farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food, and an action that potentially elimi-

181. *Id.*
182. *Monsanto*, 130 S. Ct. 2743 (2010).
183. *Id.* at 2756.
184. *Id.* at 2760.
185. *Id.*
186. Endres, *supra* note 154, at 142.
187. 734 F. Supp. 2d 948 (N.D. Cal. 2010).
188. *Id.* at 950.
189. Ctr. for Food Safety v. Vilsack, No. C 08-00484 JSW, 2009 WL 3047227, at *8 (N.D. Cal. Sept. 21, 2009).

nates or reduces the availability of a particular plant has a significant effect on the human environment" requiring the APHIS to complete an EIS.[190] On appeal, while deciding not to grant an injunction based on the decision in *Geerston*, the court agreed that vacatur of the APHIS's deregulation decision was appropriate.[191] It took matters a step further, suggesting that "the APHIS's apparent position that it is merely a matter of time before they reinstate the same deregulation decision, or a modified version of this decision, and thus apparent perception that . . . conducting the requisite comprehensive review is a mere formality, causes some concern that Defendants are not taking this process seriously."[192] This admonishment from the court, coupled with the fact that this represented another decision to remand a deregulation determination back to the APHIS with instructions that the EIS needs to more fully consider the effects on organic and non-GE farmers suggests courts are likely to be sympathetic to the real risk posed by gene flow.

4. Organic Seed Growers and Trade Association (OSGATA) v. Monsanto[193]

The most recent case to address the issue of crop contamination was decided in February, 2012. In *OSGATA*, a group of farmers, seed businesses, and advocacy organizations sought declaratory judgments preventing Monsanto from attempting to hold the plaintiffs liable for patent violations when their crops become contaminated with patented genetically-engineered organisms.[194] The plaintiffs were ultimately unsuccessful because they failed to adequately allege that any of their crops were actually contaminated, or that Monsanto had pursued actions either against them or others who were similarly situated.[195] The court, however, acknowledged that despite Monsanto's restrictions, "some unlicensed—and unintended—use of transgenic

190. *Id.*
191. *Ctr. for Food Safety*, 734 F. Supp. 2d at 954.
192. *Id.* at 953.
193. 851 F. Supp. 2d 544 (S.D.N.Y 2012).
194. *Id.* at 547.
195. The issue of whether the plaintiffs failed to make the requisite showing that Monsanto has pursued similar actions against similarly situated farmers is one that critics suggest the court decided incorrectly. While there are no reported cases of Monsanto suing a farmer whose crop was contaminated by their seed through no action on the farmer's part, the case of David Runyon, a farmer who did not purchase Monsanto seed was threatened with a lawsuit after Monsanto discovered that his crops contained traces of their seed, has received national attention. *See e.g.*, *CBS Evening News: Agricultural Giant Battles Small Farmers*, (CBS television broadcast Jan. 4, 2011), *available at* http://www.cbsnews.com/2100-18563_162-4048288.html. Monsanto has ceased any further action, yet his experience forms the basis for the plaintiffs' claims in *OSGATA*. *See OSGATA*, 851 F. Supp. 2d at 547–48.

seeds is inevitable."[196] Similar to other courts considering the issue of crop contamination, this court recognized that "transgenic seeds may contaminate non-transgenic crops through a variety of means."[197] Moreover, the court did not foreclose the possibility that a farmer could become decertified as organic through the National Organic Program as a result of such contamination.

Advocates were understandably incensed about the court's decision and have since appealed it.[198] However, in one sense, it represents yet another court that has recognized the real harm posed to organic and non-GE farmers by GE crops. Each of these decisions increases the knowledge base of the judicial system and also paves the way for a suit where a farmer who has suffered harm through crop contamination can seek to recover. However, the issues of causation and identifying the appropriate responsible party may pose insurmountable challenges for some parties.[199] For the GE grower, the tort system will likely prove insufficient to minimize the risk of such disputes and fail to provide the appropriate standard of care.[200] In addition, such suits may be cost prohibitive for the small organic or non-GE farmer. Taking these considerations into account, it is imperative for farmers and the agencies involved in these disputes, whether directly or indirectly, to identify resolutions that provide some degree of certainty to the parties involved.

V. MOVING FORWARD

The issue of coexistence is not one that receives much attention from advocates; yet, the past few years have witnessed a surge in discussions about sustainable agriculture and the need for farmers to reconsider the way they do business. An important consideration

196. *OSGATA*, 851 F. Supp. 2d at 548.
197. *Id.*
198. Brief of Appellants, *OSGATA*, 851 F. Supp. 2d 544 (No. 11-CV-2163), *available at* http://www.pubpat.org/assets/files/seed/OrganicSeedCAFCBrief.pdf.
199. Amanda L. Kool, *Halting Pig in the Parlor Patents: Nuisance as a Tool to Redress Crop Contamination*, 50 JURIMETRICS J. 453, 482 (2010) (suggesting that farmers might be better served suing the seed patent owners rather than farmer neighbors because "attempting to establish liability against a farmer who grows GM crops likely would present a serious causation problem, especially in geographic areas in which GM crops are pervasive"); Michael Faure & Andri Wibisana, *Liability for Damage Caused by GMOs: An Economic Perspective*, 23 GEO. INT'L ENVT'L. L. REV. 1, 33–34 (2011) ("Then the question arises of how the law should deal with uncertainty when it cannot be established with certainty who caused the problem. This is especially true if liability is channeled to the farmers, by which the plaintiff has to prove which of the neighboring GM farmers caused the damage.").
200. Connor, *supra* note 169, at 1211–12 (compounding the issue of "ambiguity of the reasonableness standard is that public attitudes differ sharply on the value and danger associated with biotech crops").

lacking from many of these conversations, however, is the recognition that, justifiably or not, agriculture in the United States is comprised of several different methods of production. To achieve a system that is truly sustainable, it is necessary to start seriously considering the ways in which these different production methods can coexist, because it is unlikely the United States will ever completely ban the products of genetic engineering. To effectively do this, advocates need to take into account the interests of all parties and find the areas of agreement while encouraging farmers to work collaboratively with one another to protect their own products while also ensuring the protection of their neighbors' crops.

To date, the burden of ensuring that organic and non-GE crops are protected from gene flow has been on organic and non-GE farmers,[201] this position is both reflected in the APHIS's policies and supported by the assumption that because organic products yield higher costs, those farmers are in the best position to undertake additional precautionary measures.[202] However, this is not necessarily the same position taken outside the United States. In the European Union (EU), for example, the European Commission has taken the position that "[c]o-existence measures should avoid any unnecessary burden for farmers, seed producers, cooperatives and other operators associated with *any* production type."[203] One potential measure the Commission identified to aid in coexistence is the creation of GE free zones, which requires the exclusion of GE crops from large areas.[204] Rather than placing the burden exclusively on organic and non-GE growers, the EU Commission recognizes this is a responsibility to be shared by all farmers without one segment being unnecessarily burdened. Some of these measures have also been considered in the United States, however, there is not yet an overarching national policy guiding these determinations, as there is in the EU.

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201. *Infra*, section IV.A.

202. Erik Stokstad, *Can Biotech and Organic Farmers Get Along?*, 332 SCIENCE 166, 167 (2011) ("Economists point out that these costs are generally compensated by the premium price fetched by organic crops.").

203. EUROPEAN COMMISSION, COMMISSION RECOMMENDATION OF 13 JULY 2010 ON GUIDELINES FOR THE DEVELOPMENT OF NATIONAL CO-EXISTENCE MEASURES TO AVOID THE UNINTENDED PRESENCE OF GMOS IN CONVENTIONAL AND ORGANIC CROPS 1 (2010) (emphasis added), *available at* http://ecob.jrc.ec.europa.eu/documents/CoexRecommendation.pdf.

204. *Id.* (stating that, with regard to the creation of GE free zones, "[t]his possibility should rest on the demonstration by the Member States that, for those areas, other measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops. Moreover the restriction measures needs to be proportionate to the objective (i.e. protection of particular needs of conventional or organic farmers)").

Rather, in the United States, coexistence is addressed through a myriad of stewardship best practices developed by industry,[205] voluntary efforts on the part of organic and non-GE growers,[206] and state and local regulation[207] aimed at restricting the planting of GE organisms in certain areas. Such a fragmented system fails to incorporate the coordinated response needed to address the issue of how farmers can coexist to best serve the food production needs of the American public. Recognizing the need for a multi-stakeholder group, composed of representatives from various interested sectors, to collectively consider the issue of coexistence, USDA Secretary Tom Vilsack, reconvened the Advisory Committee on Biotechnology and the 21st Century to specifically address three issues, with the third to be considered only after completion of the first two:

1. What types of compensation mechanisms, if any, would be appropriate to address economic losses by farmers in which the value of their crops is reduced by unintended presence of GE material(s)?
2. What would be necessary to implement such mechanisms? That is, what would be the eligibility standard for a loss and what tools and triggers (e.g., tolerances, testing protocols, etc.) would be needed to verify and measure such losses and determine if claims are compensable?
3. In addition to the above, what other actions would be appropriate to bolster or facilitate coexistence among different agricultural production systems in the United States?[208]

Since August, 2011, the AC21 met several times with the ultimate goal of creating a report for submission to Secretary Vilsack on September 30.[209] Completion of the final report was delayed for delivery between November/December to allow the parties an opportunity to reach consensus on the recommendations included therein.[210] Farm-

205. *See, e.g.*, *Biotech Stewardship*, EXCELLENCE THROUGH STEWARDSHIP, http://www.excellencethroughstewardship.org/BiotechStewardship.aspx (last visited Oct. 26, 2012).

206. Blatt, *supra* note 157 ("[B]uffer zones, whose needed size is uncertain, cleaning equipment, inspections of crops and processing facilities, and frequent testing.").

207. In California, several counties and cities passed GMO bans prohibiting the raising, growing and cultivation of seeds and crops containing genetically engineered organisms. Anne Hillson, *A New View of U.S. Agriculture*, Center for Food Safety 6 (May 2006), http://www.centerforfoodsafety.org/pubs/US_Ag_Report.pdf. In Boulder, Colorado, it is illegal to plant GEOs on public land. *Id.* at 7. In Maine, a town passed a resolution declaring itself a GMO free zone. *Id.* at 15. In Vermont, 83 towns passed resolutions against GMOs. *Id.* at 32.

208. USDA, ADVISORY COMM. ON BIOTECH. & 21ST CENTURY AGRIC. (AC21), WORKING DRAFT OF AC21 REPORT FOR DISCUSSION AT AUGUST 27–28 MTG. 1 (2012), *available at* http://www.usda.gov/wps/portal/usda/usdahome?contentid=AC21Main.xml&contentidonly=true.

209. USDA ADVISORY COMM. ON BIOTECH. & 21ST CENTURY AGRIC. (AC21), MTG. TRANSCRIPT 17, MAY 29, 2012, at 18 (2012), *available at* http://www.usda.gov/wps/portal/usda/usdahome?contentid=AC21Main.xml&contentidonly=true.

210. USDA ADVISORY COMM. ON BIOTECH. & 21ST CENTURY AGRIC. (AC21), MEETING SUMMARY, AUGUST 27-28, 2012, at 5 (2012), *available at* http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=AC21Main.xml.

ers, advocates, and the agricultural industry monitor the work of the AC21 closely, as their recommendations could have major ramifications for the development of national policy addressing coexistence.

At the May 29, 2012 meeting, the committee noted that it had not yet been able to reach consensus on the first two issues, specifically because disagreement existed regarding the assumption that a compensation mechanism is necessary.[211] In addition, because of the diverse interests collaborating in the development of the report for Secretary Vilsack, the committee determined it would be best to provide broad guidance in the form of a series of recommendations to the Secretary so that it could be considered a true consensus report and alleviate the need for a separate minority report.[212] When the Secretary had the opportunity to speak to the group, he strongly encouraged them to consider the ways in which they might reach consensus, suggesting that the United States desperately needs an agricultural policy that protects all farmers.[213] He stated: "[P]lease, don't tell me it's too difficult. Please don't tell me that folks are too locked in. The vision is to[o] compelling. And the example is needed now more than ever."[214] He pleaded with the committee to meet its charge and provide the catalyst necessary for the USDA to implement programs.[215]

In response to a question about the potential for the USDA to launch a program whereby farmers would be educated about what farming production methods their neighbors are engaged in to mitigate risk, the Secretary noted that it would require a tremendous effort on the part of the agency but would be a positive step in the right direction.[216] The Secretary also acknowledged the tremendous amount of uncertainty generated by the risk that currently exists without a viable set of coexistence strategies.[217] In turn, he pushed the committee to consider how to provide certainty and balance the responsibilities where the legal system will inevitably fail to do so.[218] While some might shrug off the Secretary's comments about our farmers and food producers forming a community that needs to figure out

211. *Id.* at 10–11.
212. *Id.* at 28–30.
213. *Id.* at 37 ("There's ways to figure all that stuff out, if you focus on reducing and mitigating the risk and covering the risk. And everybody comes to the table and gives a little bit. If you could do that, you walk out of this room having met your responsibility, which is a big deal. You walk out of this room sending a message to all of agriculture and all of rural America that there are ways in which reasonable people can sit around a table and reach some form of consensus and recognition and understanding.").
214. *Id.* at 39.
215. *Id.* at 43.
216. *Id.*
217. *Id.* at 54–55.
218. *Id.*

how to best help and protect one another, his statements reflect an ideology that has been lost in our farming communities and one that needs to be recaptured.

Regardless of any federal policies that favor biotechnology or fail to recognize a difference between GE and non-GE crops, the USDA needs to think more critically about a national agriculture policy that employs some of the same considerations as those in the EU to provide the safety and certainty so desperately lacking in our current regulatory structure. To do so, the AC21 needs to meet its charge and provide real, substantive recommendations that can help guide a national policy on food production that operates by mitigating risk and distributing responsibility equitably among the parties. While some may question the need for the USDA to receive these recommendations before taking action on these issues, the agency should be commended for its approach. Because this issue has been contentious for so long, a consensus report submitted by a diverse group of stakeholders that includes representatives from all interested groups provides a strong basis for the agency to develop national policy that has the support of most affected parties.

In May, the AC21 provided a list of "potential framing points" for the report,[219] which was followed by a draft report in August.[220] To the dismay of some, the committee did not reach consensus on the development of a compensation mechanism to address economic losses resulting from the adventitious presence of genetically engineered organisms due to the perceived lack of data suggesting the need for such a program.[221] It did, however, tentatively agree on crop insurance as a mechanism should one prove necessary, however, this recommendation was conditioned on the Secretary evaluating any "economic data" it has collected regarding "actual economic losses."[222] Moreover, the committee urged the Secretary to consider the "domestic and global policy implications, as well as the potential trade/economic implications."[223] In addition, the committee agreed that an agency created education initiative and mitigation strategy is necessary to address the risks posed by adventitious presence.[224] One of the points in-

219. USDA ADVISORY COMM. ON BIOTECH. & 21ST CENTURY AGRIC. (AC21), POTENTIAL FRAMING POINTS/THEMES FOR THE AC21 REPORT (2012), *available at* http://www.usda.gov/wps/portal/usda/usdahome?contentid=AC21Main.xml&contentidonly=true.

220. *Id.* at 24–47.

221. *Id.* at 29.

222. *Id.* at 33–34.

223. *Id.*

224. *Id.* at 38–39 ("[T]his effort should highlight the need for good on-farm production practices, strategies for neighborly farmer- to-farmer collaboration, the value of private marketing contracts, and the risks and responsibilities associated with meeting private contractual agreements for IP production. . . . It should seek to

cluded in the executive summary, in particular, provides the necessary beginnings for a USDA sponsored program directed towards helping farmers achieve coexistence. Specifically, the committee recognized the need for farmers to have ongoing discussions about coexistence at the local level.[225] And, where appropriate, the committee urged farmers to create "coexistence zones or other local mechanisms to support farmer preferences and strengthen communities."[226]

In its final report, submitted on November 19, 2012,[227] the committee reiterated its position that the members were unable to agree on a compensation mechanism due to the perceived difficulties in "identifying and quantifying *actual* losses to farmers resulting from unintended presence of GE material in their crops."[228] Because of this fundamental disagreement, the committee acknowledged that a compensation mechanism viewed as "placing unfair burdens" on a specific sector would only serve to further create divisions within agriculture.[229] On the other hand, most members of the committee were in agreement that a compensation mechanism would likely reduce the potential for farmers to sue other farmers due to crop contamination, but would probably have little or no effect on prospective litigation challenging the USDA's approaches to regulating GE crops.[230] In considering the different alternatives, the committee was clear that the USDA should refrain from regulating in a manner that suggests it believes legally developed GE products are, in any way, unsafe.[231]

Ultimately, the committee echoed its earlier recommendations and urged the USDA to evaluate data on actual economic losses and, if warranted, develop a compensation mechanism based on a crop insurance model and implement it as a pilot project that "would include incentives for the development of joint coexistence plans by neighboring farmers."[232] In addition, the committee recommended the agency give special consideration to the "potential inequities" placed on farmers who grow GE crops because of the premiums they pay for such products.[233] To that end, the recommendations suggest that farmers growing GE crops should have the option to purchase insurance, but

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promote local, voluntary solutions and accommodate local and regional diversity in agriculture and should be mindful of the range of farmer production needs.")

225. *Id.*

226. *Id.* at 38.

227. AC21 ENHANCING COEXISTENCE: A REPORT OF THE AC21 TO THE SECRETARY OF AGRICULTURE (2012), *available at* http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pdf.

228. *Id.* at 9 (emphasis added).

229. *Id.*

230. *Id.* at 11.

231. *Id.* at 12.

232. *Id.* at 14.

233. *Id.*

benefit from reduced premiums if they enter into a joint coexistence agreement with their neighbors.[234]

Beyond compensation, the committee restated many of the points it made in earlier drafts, urging the agency to work with diverse groups of stakeholders,[235] to provide incentives for "neighborly farmer-to-farmer collaboration" and help educate farmers about different agricultural methods of production to work toward meaningful coexistence.[236] Perhaps these measures appear insignificant, but when considered in the context of our existing federal policies towards agricultural biotechnology and the burdens they place on farmers who choose not to use it, the creation of a new national policy that begins to allocate responsibility among farmers in a more equitable manner represents substantial innovation. To this point, the agency has yet to take a position that imposes any responsibility on farmers planting GE crops, yet the recommendations from the committee take into account the need for balance. It has yet to be determined what the final outcome of these measures will be, and whether they will, in fact, translate to a new national policy on coexistence. But, the very fact that members of these different sectors were able to come together and talk about issues that have been contentious for decades while reaching consensus on the fundamental principle that *all* farmers could benefit by having more knowledge about one another's production methods and should adopt measures to minimize their neighbor's losses evidences substantial progress. Ultimately, the outcome will likely not be acceptable to everyone, but it does represent the first steps toward meaningful agreement about farmer coexistence.

234. *Id.*
235. Specifically, the agency suggested collaboration between "technology producers, seed companies, commodity and farmers' organizations, agricultural trade and marketing companies and organizations, education and extension services, public organizations, and State and local governments." *Id.* at 19.
236. *Id.*