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Regulating the Regulators: The Increased Role for the Federal Judiciary in Monitoring the Debate over Genetically Modified Crops

*Blake Denton**

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I.
INTRODUCTION

Tom Latham comes home to his wife, Jackie, and his four-year old daughter, Riley. It was a miserable day at work, but all of the stress disappears once Tom sees his family and realizes that it is his favorite night of the week, taco night. They sit down to dinner and the family shares their stories of the day over some excellent food. After dinner, Tom relaxes on the couch and turns

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on the news. In the first story, the anchorman informs the viewers, "Taco Bell brand taco shells are being pulled from the shelves today after it was discovered that genetically modified corn that was only approved for use in animal feed found its way into Kraft's Taco Bell shells. Officials say that the corn's effects on humans are unknown." Tom gets up, walks into the kitchen, and sure enough a box is sitting on the counter with "Taco Bell" printed across it. Tom immediately becomes worried about the safety of his wife and young daughter. He wonders, "How could unapproved food have ended up on the market? Isn't someone supposed to be regulating this stuff?"[1]

As genetic technology continues to advance, there is a growing public debate about the safety risks and potential adverse health effects that could stem from the use of biotechnology to alter crops.[2] There are various conflicting definitions of the term "biotechnology."[3] For the purposes of this Note, the term "biotechnology" will be used interchangeably with the terms "genetic

1. *See infra* Part IV.A. (discussing StarLink [corn unapproved for human consumption] that was found in several grocery products, including Kraft's Taco Bell Taco Shells).

2. *See* RUPERT LEE, HOW TO FIND INFORMATION: GENETICALLY MODIFIED FOODS 1 (British Library 2000) [hereinafter "LEE: INFORMATION"] ("[G]enetically modified foods have moved up the agenda of political issues. Media pundits hold forth on them, politicians announce policies on them, pressure-groups run campaigns about them."); Kurt Eichenwald, *Redesigning Nature: Hard Lessons Learned; Biotechnology Food: From the Lab to a Debacle*, N.Y. TIMES, Jan. 25, 2001, at A1 [hereinafter "*Eichenwald: Redesigning Nature*"] ("[W]orldwide protest has been galvanized. The European markets have banned the products and some American food producers are backing away."); Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 76 (2000) [hereinafter "*Merill & Francer: Food Safety*"] (explaining that "[t]he use of genetic techniques . . has raised fears over "Frankenstein Foods" in Europe, and similar popular uneasiness seems to be mounting in the United States.").

3. For example, in *Managing Biotechnology's [R]evolution*, Lars Noah points out that the Oxford English Dictionary definition of biotechnology as "[t]he branch of technology concerned with modern forms of industrial production utilizing living organisms, esp. micro-organisms, and their biological processes" is at odds with other uses of the word, such as treating it as synonymous with "genetically modified organisms" or applying the word to include "'more than minimally manipulated' human tissue and cellular products." Noah explains that the use of the term will often vary based on the agenda of the person invoking the word. Due to its elusive meaning, entrepreneurs, scientists, and regulatory officials can all manipulate the word to fit their respective agendas. Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 4, 2-7 (2006) [hereinafter: *Noah, Biotechnology's Revolution*]. *See, e.g.*, WILLIAM BAINS, BIOTECHNOLOGY FROM A TO Z 66 (Oxford University Press, 2d ed. 1998) ("biotechnology is the pragmatic combination of science and technology to make use of our knowledge of living systems for practical applications").

engineering" ("GE") and "genetically modified" ("GM"), both of which refer to the "[p]rocess by which DNA from one or more organisms is inserted into the genetic material of a second organism so that the second organism (host) expresses new traits."[4] While there has been considerable public concern over the effects of altered crops on humans and the environment, the United States government has written off concerns about biotechnology and continues to promote its application to crops.[5] Among potential consequences from using biotechnology to alter crops, opponents fear that these new plant varieties, or "Frankenfoods" as dubbed by some critics,[6] will produce allergens and result in insect immunities to pesticide.[7] Moreover, these critics fear that GM crops cultivated for pharmaceutical purposes, also known as "biopharmed crops," will cross-pollinate

4. Office of Inspector General, Southwest Region, *Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits*, U.S. Dept. of Agriculture, Dec. 2005, at 61 [hereinafter "*Inspector General: Audit*"]. The Food and Drug Administration uses a similar definition to refer to recombinant DNA techniques, but defines "genetic modification" much more broadly. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, at IV (May 29, 1992) [hereinafter "*FDA Policy*"]. In endorsing its view that genetic modification does not pose significant novel risks, it broadly defines genetic modification as including "the alteration of the genotype of a plant using *any technique*, new or traditional." *Id.* at I. n.3 (emphasis added).

5. *See id.* at V.A.

6. "Frankenfood" is a loaded term that has been adopted by activists to suggest the perils of genetically modified agricultural products." Lisa C. Ikemoto, *Disentangling Fact from Fiction: The Realities of Unequal Healthcare Treatment*, 9 DEPAUL J. HEALTH CARE L. 1101, 1110 (2005).

7. *See* Alliance For Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D.D.C. 2000) (plaintiffs seeking labeling of GE ingredients for the benefit of those with allergies and those whose religious views prohibit them from consuming GE foods). *See also* Kim Severson, *Taco Shells Symbol for Frankenfood*, S.F. CHRONICLE, Oct. 18, 2000, at ZZ1 [hereinafter "*Severson: Frankenfood*"] (reporting that environmental groups "believe that food allergies are on the rise because people are eating an increasing number of genetically modified food[s]"). The FDA has affirmed that allergenicity is their primary concern about GM products as well. *FDA Policy*, *supra* note 4, at IV.E. Additionally, increased immunity to pesticide has been cited as a concern. *See* Rebecca Bratspies, *The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L.J. 297, 306-07 (2002) [hereinafter "*Bratspies: Illusion of Care*"]; Donnachadh McCarthy, *The Seven Deadly Eco Sins*, Indep. (UK), Aug. 14, 2006, at 2. *But see* C. NEAL STEWART, JR., GENETICALLY MODIFIED PLANET 134-35 (Oxford University Press 2004) [hereinafter "STEWART: GM PLANET"] (arguing that while it is crucial to implement a high-dose strategy to deal with the possibility of insect immunity, "[m]ost of the Bt [a chemical pesticide that some plants are GM produce] resistance traits in insects characterized thus far are completely recessive.").

with plants intended for food crops and thereby contaminate whole harvests.[8]

Were biopharmed crops to contaminate food crops, it could yield disastrous economic and public health consequences.[9] If lucky, contaminated products would be quickly detected and destroyed.[10] However, if not discovered before distribution, products that are unapproved for human consumption and contain unknown effects on the human body could enter the food supply.[11] The United States would likely face floods of complaints from people claiming adverse health effects from consuming biopharmed crops and crop bans by nations that are concerned about biopharmed crops' effects on humans.[12]

This is not to say that adverse health and environmental effects will necessarily follow from the use of biotechnology. Many altered crops may ultimately have enormous benefits and no social costs.[13] Amongst potential benefits, proponents of GE cite the

8. The State PIRGs' Campaign On Genetically Engineered Foods, http://pirg.org/ge/GE.asp?id2=10570&id3=ge& (last visited Oct. 18, 2006) (defining "biopharming" as "an experimental application of biotechnology in which plants are genetically engineered to produce pharmaceutical proteins or industrial chemicals that they would never produce naturally."). Contamination of food crops by biopharmed crops also has the potential of happening during milling and grain transport. *See* Nat'l Ass'n of State PIRGs, *Risky Business: Financial Risks that Genetically Engineered Foods Pose to Kraft Foods, Inc. and Shareholders*, Apr. 2003, at 8 [hereinafter "*Kraft Shareholder Report*"].

9. The primary concern is allergic reactions. However, the economic consequences could actually be more severe. Europe and much of Asia have become very concerned over genetically engineered crops and have at times refused importation of American crops out of fear that crops may be genetically modified. *See infra* note 64 and accompanying text.

10. This has been the typical response when biopharming crops have been mixed with food crops. *See* Diane Carman, *Biopharming Reaps Fear of Contamination*, DENVER POST, Sept. 28, 2003, at B-01; Jonathan D. Rockoff, *Bioengineering Guides Issued*, BALTIMORE SUN, June 22, 2006, at 4A; Mike Toner, *Modified Crops' Usage Grows*, ATLANTA-JOURNAL CONSTITUTION, May 14, 2006, at 10D.

11. *See* Greg Burns & Julie Deardorff, *Modified Crops Raise Fears of Contamination*, CHI. TRIB., Nov. 17, 2002, at C1 [hereinafter "*Fears of Contamination*"]; Rachel Melcer, *Dow Biovaccine Could Bring Windfall to Washington U.*, ST. LOUIS POST-DISPATCH, Feb. 1, 2006, at C2.

12. *See* Marc Kaufman, *EPA Rejects Biotech Corn as Human Food*, WASH. POST, July 28, 2001, at A02 (seventeen people claimed to have experienced side effects from eating StarLink corn, including rashes and rising blood pressure) [hereinafter "*Side Effects Article*"]. *See also infra* note 215 and accompanying text.

13. For example, biotechnology may be used to kill insects and prevent damage to crops, without requiring the use of toxic chemicals. Furthermore, proponents argue that proteins utilized by biotechnology for insect control have been exposed to the public for years and are accepted as safe. STEWART: GM PLANET, *supra* note 7, at 90. *See also FDA Policy*, *supra* note 4, at I (claiming that use of biotechnology has not yielded any social costs); Roger Cohen, *The World: Heartburn; Fearful Over the*

potential for increased crop yields, reduced necessity for pesticides, more efficient farming practices, and increased shelf life of foods.[14] The federal government has embraced these arguments and endorsed the position that the benefits of GE far outweigh any alleged costs.[15] This sentiment was made explicit by the Reagan administration in 1984 when it adopted the Office of Science and Technology Policy's ("OSTP") *Coordinated Framework for the Regulation of Biotechnology*.[16] This report glorified the use of GM crops and has remained the dominant opinion in the federal government ever since.[17] In more recent years, the Bush administration and some other proponents have ventured further and suggested that the increased yields produced by GM crops are crucial in the battle to eradicate world hunger.[18]

Despite the considerable public debate over the pros and cons of GE, legal limitations imposed on those engaged in GE have been extremely lax, and often go unenforced by the executive agencies entrusted with regulating these crops.[19] The "patch-

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Future, Europe Seizes on Food, N.Y. TIMES, Aug. 29, 1999, at 41 (noting that, "[n]o discernable harm to Americans has occurred"); Bob Goldberg, *The Hypocrisy of Organic Farmers*, June 5, 2000, http://www.agbioworld.org/biotech-info/articles/biotech-art/hypocrisy.html (last visited Nov. 9, 2006) (arguing that the Bacillus thuringensis toxin has been used for almost 100 years, has no harmful effects on humans, binds to receptors in the gut of specific insects, and is very effective in controlling specific classes of insects).

14. Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 409 (2002) [hereinafter "*McGarity: Seeds of Distrust*"]; David Barboza, *Farmers Favor Genetically Altered Crops, Producers Say*, N.Y. TIMES, Feb. 13, 2001, at C2 [hereinafter "*Farmers Favor*"]. While biotechnology may be used to create bigger and better plants, "in the immediate future . . . genetic engineering is perhaps most likely to increase crop yields by making plants more resistant to pests." MICHAEL J. REISS & ROGER STRAUGHAN, IMPROVING NATURE? 145 (Cambridge University Press 1996) [hereinafter "REISS & STRAUGHAN: IMPROVING NATURE?"].

15. *See* Proposal for Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50856 (Dec. 31, 1984) [hereinafter "*Coordinated Framework*"].

16. *See id.*

17. *Id.*; *see* Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 599-601 (2003) [hereinafter "*Bratspies, StarLink*"].

18. *McGarity: Seeds of Distrust*, *supra* note 14, at 409; David E. Sanger, *Bush Links Europe's Ban on Bio-Crops With Hunger*, N.Y. TIMES, May 22, 2003, at A3 [hereinafter "*Bush on Hunger*"]. *But see* REISS & STRAUGHAN: IMPROVING NATURE?, *supra* note 14, at 153-55 (examining the argument that "genetic engineering, with its attendant patents, is unfair to farmers and others in developing countries," and thus actually inflicts significant harm upon farmers in the third world).

19. *See Inspector General: Audit*, *supra* note 4, at i (finding multiple deficiencies in the Department of Agriculture's regulatory procedures and determining that it needs to "strengthen its accountability"); STEVEN P. MCGIFFEN, BIOTECHNOLOGY:

work arrangement" of statutes and administrative agencies responsible for regulating GM crops has prevented careful regulation of this growing industry.[20] There are currently three agencies responsible for regulating GM crops: the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), and the United States Department of Agriculture ("USDA").[21] Under this "patchwork arrangement," the EPA regulates the safety of GE crops that constitute pesticides, the FDA has jurisdiction over GE products that it deems to be "food additives,"[22] and the USDA has control over the determination of whether and when GM crops may be considered "plant pests."[23] In some situations, jurisdictional responsibility for a particular GM crop might not even be clear.[24]

To date, lawmakers have ignored the arguments put forth by opponents of GE. Congress has left the existing regulatory framework largely unaltered since its creation in the mid-1980s and the President continues to promote the advancement of biotechnology.[25] The federal judiciary has refused to take an active role in this debate, and typically upholds GE policies based on its traditional policy of deference to the procedures and determinations of administrative agencies.[26] However, a recent case brought in the United States District Court for the District of

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CORPORATE POWER VERSUS THE PUBLIC INTEREST 62 (Pluto Press 2005) [hereinafter "MCGIFFEN, CORPORATE POWER"] ("regulation of biotechnology and its products varies, in the United States, from weak to non-existent").

20. *Noah, Biotechnology's Revolution*, *supra* note 3, at 14.

21. MCGIFFEN: CORPORATE POWER, *supra* note 19, at 64-73; United States Regulatory Oversight in Biotechnology Responsible Agencies – Overview, http://www.aphis.usda.gov/brs/usregs.html (last visited Oct. 18, 2006).

22. "Food additive" is defined as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(s).

23. *Coordinated Framework*, *supra* note 15. "Plant pests" are defined as "any living stage [both active and inactive forms] of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious agents or substances which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." 7 C.F.R. § 340.1.

24. *FDA Policy*, *supra* note 4, at IX.

25. *See id.* at V.A; MCGIFFEN: CORPORATE POWER, *supra* note 19, at 64; *Bush on Hunger*, *supra* note 18.

26. *See, e.g.*, Alliance For Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 166 (D.D.C. 2000) (holding, *inter alia*, that the FDA had broad discretion in its 1992 Statement of Policy in interpreting the meaning of "material" for purposes of determining whether or not genetically engineered ingredients must be labeled as such).

Hawaii premised liability against those responsible for regulating biopharming under an alternative rationale.[27] A lawsuit was brought by opponents of GE based upon one of the core tenets of administration law, namely that a congressional act can limit an agency's discretion even if the statute does not address the agency by name.[28] So, while the USDA, EPA, and FDA are granted great deference in interpreting their responsibilities under the statutes that delegate their authority over GM crops, they are not given this same leeway in interpreting their duties under other congressional acts, such as the Endangered Species Act[29] ("ESA") and National Environmental Policy Act[30] ("NEPA"). In the September 1, 2006 opinion, *Center for Food Safety v. Johanns*,[31] District Judge J. Michael Seabright of the District of Hawaii concluded that the ESA and NEPA were violated when a subdivision of the USDA issued permits for biopharming crop tests without considering the impacts on Hawaii's environment and endangered species.[32]

While the application of the ESA and NEPA to federal agencies is not groundbreaking on its own, this opinion does constitute the first federal decision to address the issue of biopharming.[33] In this decision, Judge Seabright properly concluded that the simple investigative procedures under these acts had been ignored by the USDA.[34]

This Note will argue that violations, such as those by the USDA in *Center for Food Safety*, are prevalent in the realm of biotechnology.[35] Thus, more suits are likely to be brought in the

27. Center for Food Safety v. Johanns, 451 F. Supp. 2d 1165 (D. Haw. 2006).

28. *See id.*; *see generally* Administrative Procedure Act, 5 U.S.C. § 501 *et seq.* (2000) (allowing for the establishment of regulations to govern agency behavior and for the federal government to review those decisions).

29. 16 U.S.C. § 1531 *et seq.*

30. 42 U.S.C. § 4321 *et seq.*

31. 451 F. Supp. 2d 1165 (D. Haw. 2006).

32. *Id.* at 1170-72. Judge Seabright granted summary judgment to the plaintiffs on eight counts of the amended complaint, and granted summary judgment to the defendants on three counts. *Id.* at 1196. The first version of the opinion was published on August 10, 2006, however District Judge J. Michael Seabright withheld ruling on two counts of the plaintiffs' amended complaint and scheduled a remedies hearing for August 22, 2006. Center for Food Safety v. Johanns, 03 CV 621, 2006 WL 2348109, at *19 (D. Haw. Aug. 10, 2006). After the hearing, a subsequent opinion was published on September 1, 2006. *Center for Food Safety*, 451 F. Supp. 2d 1165.

33. Bernadette Tansey, *Hawaii judge rules 'biopharming' illegal*, S.F. CHRONICLE, Aug. 15, 2006, at D2 [hereinafter: "*Judge Rules*"].

34. *Center for Food Safety*, 451 F. Supp. 2d at 1182.

35. This Note will only focus upon the increased role of the federal judiciary in monitoring the debate over genetically modified crops that are used for human con-

coming years by opponents of GM, under precisely the same theory articulated in *Center for Food Safety*.[36] This is unfortunate because the agencies responsible for regulating GM crops could avoid liability under these two statutes by complying with clear statutory requirements, which simply involve exploring whether adverse impacts are likely to result from issuing permits for GM crops.[37] However, despite multiple disasters involving GM crops,[38] the USDA, EPA, and FDA have remained lax in their regulation of biotechnology, both under the specific statutes that delegate their power, and under more far reaching statutes like the ESA and NEPA.[39] Although the executive and legislative branches have proven unwilling to correct the inadequacies in the existing biotechnology regulations,[40] the federal judiciary will likely come to play a greater role in forcing the agencies responsible for regulating GM crops to assume accountability. With GE disasters looming,[41] opponents of GM are likely to start utilizing the federal judiciary to make their voices heard.

Part II of this Note will address the development of GM crops in America and the concerns that go along with the growth of biotechnology. It will outline the history of GM products in America and the minimalist regulatory attitudes that have existed since the inception of GE. Part III will examine the existing agency structure entrusted with regulating GM crops. Next, Part IV, through examination of a major GE disaster involving StarLink corn, will illustrate the deleterious effects that are likely to arise under the current regulatory structure.[42] Part V will address the *Center for Food Safety v. Johanns* opinion and its rationale for holding agencies responsible under the ESA and NEPA. This opinion is likely the first in a string of attacks against the

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sumption and biopharming. It will not address genetically modified animals and animal products, which pose concerns of their own and are similarly handled through an incomplete regulatory rubric. *See* Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2209-10 (2004).

36. *See infra* Part V.B.

37. *See Center for Food Safety*, 451 F. Supp. 2d at 1182.

38. *See infra* Part IV.

39. *See infra* Part III – V.

40. *See infra* notes 82-93 and accompanying text.

41. *See infra* Part IV.

42. StarLink is corn grown from genetically modified seeds that were produced by Aventis CropScience. Bill Hord, *Back in Good Graces StarLink Corn Appears to Have Been Isolated and Contained*, OMAHA WORLD HERALD, Oct. 20, 2002, at 1D; Anthony Shadid, *EPA: Altered Animal Feed Must Pass Human Standard*, BOSTON GLOBE, Mar. 8, 2001, at E3.

USDA, EPA, and FDA's neglect of statutory duties. Part VI will focus on the roles the public and the federal judiciary will come to play in the regulation of biotechnology.

II.
DEVELOPMENT OF GENETICALLY ENGINEERED CROPS IN AMERICA

Genetically altering crops involves the utilization of recombinant deoxyribonucleic acid ("recombinant DNA") technology to select DNA segments from one organism, and insert them into another, without actually breeding the organisms.[43] Today, GM crops are currently cultivated for both consumption and pharmaceutical purposes.[44] Despite public opposition to GE, the United States government has remained committed to a minimalist regulatory regime that emphasizes the benefits of GE, while discounting the risks.[45]

The United States government's policy of "strictly limited regulatory oversight" over GM foods has been in place since the days of the Reagan Administration.[46] The December 31, 1984 OSTP *Proposal for Coordinated Framework for Regulation of Biotechnology* proclaimed the ability of "biotechnology [to] . . . alleviate many problems of disease and pollution and increase the supply of food, energy, and raw materials" and boasted of America's position as "the world leader in biotechnology."[47] Because of the perceived benefits of GE, the Reagan Administration and subsequent administrations were hesitant to impose new regulations on the biotechnology industry that could compromise the United States' position as an innovator of GE technology.[48]

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43. Found. on Econ. Trends v. Heckler, 756 F.2d 143, 147 (D.C. Cir. 1984); Gerhold K. Becker, Biotechnology – The New Ethical Frontier, *in* CHANGING NATURE'S COURSE: THE ETHICAL CHALLENGE OF BIOTECHNOLOGY 1, 3 (Gerhold K. Becker & James P. Buchanon eds., Hong Kong Univ. Press 1996) [hereinafter: "Becker: New Frontier"]; Kelly A. Leggio, *Limitation on the Consumer's Right to Know: Settling the Debate Over Labeling of Genetically Modified Foods in the United States*, 38, SAN DIEGO L. REV. 893, 904 (2001).

44. Christina L. Richmond, *Genetically Modified Crops in the Philippines: Can Existing Biosafety Regulations Adequately Protect the Environment?*, 15 PAC. RIM L. & POL'Y J. 569, 585 (2006); Norman C. Ellstrand, *Genetic Colonialism*, CHI. TRIB., Apr. 3, 2005, at C1.

45. *See infra* notes 46-49, 63-78 and accompanying text.

46. *Bratspies, StarLink*, *supra* note 17, at 601.

47. *Coordinated Framework*, *supra* note 15.

48. Kurt Eichenwald acknowledges that "through three administrations . . . [w]hat Monsanto [a GM crop producer] wished for from Washington, Monsanto – and, by extension, the biotechnology industry – got." *Eichenwald: Redesigning Nature*,

Thus, the OSTP framework has remained in place for over twenty years.[49]

Although pro-GE policies were adopted by the government in the mid-1980s, the first major commercial planting of GM crops did not take place until 1996.[50] Since this time, farmers have become increasingly receptive to GM crops and have primarily cultivated three modified crops: soy, corn, and canola.[51] In 1996, three million acres had been devoted to GM crops and GM corn constituted only four percent of acres planted, whereas by 2000, over one hundred million acres had been devoted to GM crops.[52] Today the bulk of all soy, corn, cotton, and canola sold in the United States has been GM.[53]

In explaining the rationale behind a virtual industry-wide adoption of GE technology, farmers cite the potential for "higher yields," "fewer chemicals," and the fact that "most markets accept the crops."[54] The most common use of GM technology is to engineer plants with the gene *Bacillus thuringiensis* ("Bt"), which

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supra note 2. *See also* Stephan Pendorf, *Regulating the Environmental Release of Genetically Engineered Organisms: Foundation on Economic Trends v. Heckler*, 12 FLA. ST. U. L. REV. 891, 921 (1985).

49. MCGIFFEN: CORPORATE POWER, *supra* note 19, at 64. Despite the President's position, the United States public was not enamored with the alleged benefits of biotechnology. Public alarm with GM began in 1987 when strawberry and potato plants in two California cities were "sprayed with bioengineered bacteria meant to make the plants resistant to frost." Pictures of scientists cloaked in biohazard suits as they sprayed plants were shown in various news mediums and public outcry became rampant. *Eichenwald: Redesigning Nature*, *supra* note 2. To this day, GE is a hot topic in the public sphere that has "generated the most shareholder resolution proposals since corporations were challenged for doing business in South Africa during apartheid." *Kraft Shareholder Report*, *supra* note 8, at 13. However, the United States government has continued to endorse a pro-GE view and has written off concerns about "Frankenfood."

50. Nathan A. Adams, IV, *Creating Clones, Kids & Chimera: Liberal Democratic Compromise at the Crossroads*, 17 NOTRE DAME J.L. ETHICS & PUB. POL'Y 71, 81 (2003); *Kraft Shareholder Report*, *supra* note 8, at 6.

51. *Farmers Favor*, *supra* note 14; *Kraft Shareholder Report*, *supra* note 8, at 6. Some other notable GM crops include potatoes, tomatoes, and cotton. REISS & STRAUGHAN: IMPROVING NATURE?, *supra* note 14, at 132-33; STEWART: GM PLANET, *supra* note 7, at 90-92.

52. *Farmers Favor*, *supra* note 14; Greg Lucas, *Efforts to Ban Genetically Altered Crops Spreading*, S.F. CHRONICLE, Mar. 30, 2004, at B3; Pew Initiative on Food and Biotechnology, *Factsheet*, *available at* http://pewagbiotech.org/resources/factsheets/display.php3?FactsheetID=2 (last visited Dec. 27, 2006) [hereinafter "*Pew Factsheet*"].

53. *Pew Factsheet*, *supra* note 52.

54. *Farmers Favor*, *supra* note 14; *see also* STEWART: GM PLANET, *supra* note 7, at 106.

causes plants to produce their own pesticides.[55] Currently, over ninety-nine percent of the GM crops on the market produce their own pesticides, or are engineered to be immune to herbicides.[56] In addition, farmers have accepted GE technology because of its potential to allow for the manipulation of a wide range of plant characteristics including resistance to disease, resistance to herbicide, ability to thrive under adverse conditions, accelerated growth, delayed ripening, and improved quality characteristics affecting preservation, nutrition, and flavor.[57]

GE technology has not only impacted the raw food market, but processed foods as well. By 2000, the widespread adoption of GE methods by farmers led to the inclusion of GM ingredients in approximately sixty percent of processed foods sold in grocery stores.[58] Six years later, Mike Johanns, Secretary of Agriculture, acknowledged that the figure had risen to approximately seventy percent.[59] Governmental support has accompanied the growth of the biotechnology industry.[60] The United States government has denied that GM ingredients pose novel risks to consumers and has instead continued to endorse the policy that using recombinant DNA techniques to insert genes into plants results in "more precise . . . safe[r], better-characterized, and more predictable foods."[61] Consequently, the United States remains the largest producer of GM crops.[62]

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55. LEE: INFORMATION, *supra* note 2, at 2; Clifton E. Anderson, *Biotech on the Farm: Realizing the Promise*, FUTURIST, Sept. 1, 2005, at 38. Bt enables plants to synthesize a protein that poisons the insects that attack it. Bt "is one of the closest relatives of *Bacilus anthracis*, the bacterium that causes anthrax. Like the anthrax bacterium, it lives in the soil, forms spores, and produces crystal toxins," which affect the digestion of some insects. STEWART: GM PLANET, *supra* note 7, at 92.

56. "Herbicides" are "chemical substance[s] used to destroy or inhibit the growth of plants, especially weeds." Answers.com, http://www.answers.com/topic/herbicide (last visited Dec. 27, 2006); *see also Kraft Shareholder Report*, *supra* note 8, at 21. The National Association of State PIRGs further points out that most GE foods are not engineered "to be healthier, taste better, have increased nutritional value, or have other consumer benefits." *Id.* at 18.

57. *FDA Policy*, *supra* note 4, at IV; GEORGE WEI, AN INTRODUCTION TO GENETIC ENGINEERING, LIFE SCIENCES AND THE LAW 32-33 (Singapore University Press 2002).

58. *Severson: Frankenfood*, *supra* note 6. Other 2000 estimates ranged as high as seventy percent. *See Kraft Shareholder Report*, *supra* note 8, at 8.

59. *Rice Farming: Grains of Doubt*, 950 ECONOMIST 81, Sept. 16, 2006 [hereinafter "*Grains of Doubt*"].

60. *See, e.g.*, *Bush on Hunger*, *supra* note 18.

61. *FDA Policy*, *supra* note 4, at IV.

62. *Bratspies: Illusion of Care*, *supra* note 7, at 304; *Pew Factsheet*, *supra* note 52.

Despite the fact that many politicians and farmers appear to be sold on the benefits of biotechnology, consumers have been more reluctant to jump on the bandwagon. Studies indicate that consumers overwhelmingly support the labeling of GM food.[63] Recognizing this, "[l]egislation calling for a ban, moratorium, or labeling of genetically modified foods has been brought before the legislature" of at least eleven different states.[64] The organic foods movement has also distanced itself from pro-GE policies.[65] Public demand for non-GM crops has led to a huge market for foods labeled as "organic."[66] Organic food sales have consistently grown since 1997 and have become a multi-billion dollar industry, further evidencing the public concern over GM foods.[67]

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63. *See* ABC News Poll, *microformed on* Public Opinion Online, Question ID USABC.071503, R2 (Roper Center at Univ. of Conn., July 15, 2003) (in a telephone survey of 1,024 adults, forty-six percent of those surveyed indicated that they did not think genetically modified food was safe to eat); *Kraft Shareholder Report*, *supra* note 8, at 9 (citing two studies, one of which found that ninety-three percent surveyed thought that the government should require labels saying whether food has been genetically modified).

64. According to the National Association of State PIRGs, these states include "California, Colorado, Iowa, Hawaii, New York, New Hampshire, Vermont, Massachusetts, Maine, Michigan, and Minnesota in the past few years." *Kraft Shareholder Report*, *supra* note 8, at 14.

65. *See* Frank J. Miskiel, *Voluntary Labeling of Bioengineered Food*, 38 CAL. W. L. REV. 223, 223 (2001) (discussing the organic food movement's adoption of the term "non-GMO" meaning "non-genetically modified organisms"). *But see* STEWART: GM PLANET, *supra* note 7, at 12 (arguing that there is really no such thing as "natural or organic food" because everything we eat is over-bred, domesticated, and generally mixed with "unnatural" ingredients).

66. The National Organic Standards Board defines "organic agriculture" as "an ecological production management system that promotes and enhances biodiversity, biological cycles and soil biological activity. It is based on minimal use of off-farm inputs and on management practices that restore, maintain and enhance ecological harmony." National Organic Standards Boards, Definition of "Organic" (Apr. 1995), *available at* http://www.nal.usda.gov/afsic/ofp (last visited Jan. 21, 2007). *See* Carie-Megan Flood, *Pollen Drift and Potential Causes of Action*, 28 IOWA J. CORP. L. 473, 474 (2003) ("the organic food sector has been growing an incredible twenty percent per year since 1990").

67. By 2004, organic food sales totaled $10.38 billion, a 20.4 percent increase from the year before. Organic Trade Association, *Food Fact*, http://www.ota.com/organic/mt/food.html (last visited Dec. 27, 2006). Some estimates project organic food sales to reach $32 billion by 2009. Nanette Hanson, *Organic Food Sales See Healthy Growth*, CNBC, *available at* http://www.msnbc.msn.com/id/6638417 (last visited Dec. 27, 2006). "National organic food sales have grown 20 percent annually since 1990 . . . Retail sales in the United States climbed to $8.5 billion in 2002, up from $1 billion in 1990." Jilian Mincer, *Growth Industry: Organic Farming is a Budding Alternative*, KANSAS CITY STAR, Mar. 18, 2003, *available at* http://www.ofrf.org/press/Press%20Clippings/KC.Star.031803.2ppdoc.pdf (last visited Nov. 7, 2006). *See also* Anup Shah, *A Huge Waive of Public Concern*, Jan. 18, 2002, http://www.globalissues.org/EnvIssues/GEFood/PublicReaction.asp (last visited Nov. 8, 2006).

Moreover, in October 2002 the USDA, under extreme public pressure, passed new organic standards that ban GM foods from being sold under the name "organic."[68] These nationwide standards regulate "any farm, wild crop harvesting, or handling operation that wants to sell an agricultural product as organically produced."[69]

In addition to food, recombinant DNA techniques have become increasingly prevalent with regard to crops designed for pharmaceutical purposes, known as biopharmed crops.[70] Some speculate that "at least ten percent of agricultural lands . . . [will be] devoted to biopharming by the end of the decade."[71] But while GM plants may eventually prove to have beneficial pharmaceutical purposes, there are related dangers. The most significant concern with biopharming is "genetic pollution."[72] This term refers to the "cross-pollination[73] [of GM plants] with native plants and food crops."[74] Because these plants are not intended for human consumption and are being modified to produce genes that they do not naturally create, their effects upon human beings and the environment are unknown.[75] In the FDA's *State-*

68. *See* Brian Faler, *USDA: No Organic Labels for Cosmetics*, WASH. POST, June 2, 2005, at A21; *Kraft Shareholder Report*, *supra* note 8, at 10.

69. United States Department of Agriculture, *Organic Certification*, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?navid=ORGANIC_CERTIFICATIO&parentnav=PRODUCERS&navtype=RT (last visited Dec. 27, 2006).

70. *See Bratspies: StarLink*, *supra* note 17, at 636; Arti K. Ray, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 815 (2001).

71. *Bratspies: StarLink*, *supra* note 17, at 630. *See also* Dawn Willow, *The Regulation of Biologic Medicine: Innovators' Rights and Access to Healthcare*, 6 CHI.-KENT J. INTELL. PROP. 32, 32 (2006) ("The biopharmaceutical industry represents one of the fastest growing segments of U.S. healthcare.").

72. *Noah, Biotechnology's Revolution*, *supra* note 3, at 40.

73. "Cross-pollination" refers to the transfer of pollen from the anthers of one plant to that of another. iVillage GardenWeb, http://glossary.gardenweb.com/glossary/cross-pollination (last visited Dec. 27, 2006). With genetically modified crops, the fear is that pollen, spores, or seeds from biopharming crops will end up amongst crops intended for human consumption. Elizabeth Becker, *New Worries of Planting Altered Corn*, N.Y. TIMES, Mar. 2, 2001, at C3.

74. *Noah: Biotechnology's Revolution*, *supra* note 3, at 40. Genetic pollution has already become a reality. Editorial, *Biopharming Gone Awry*, Denver Post, Aug. 22, 2006, at B6 [hereinafter "*Gone Awry*"] ("The creeping bentgrass, genetically modified to be resistant to common herbicides such as Roundup, was found to have crossed with wild grasses, the first known transgenic crop escape in the U.S.").

75. Rebecca M. Bratspies, *Consuming (F)ears of Corn: Public Health and Biopharming*, 30 AM. J.L. & MED. 371, 385 (2004) [hereinafter "*Bratspies, Corn*"]; *ICCR-Sponsored Proxy Resolutions on Genetically Modified Organisms Gain Recognition Among Shareholders at Wendys, McDonalds, DuPont and Dow*, FIN. WIRE, July 21, 2006.

ment of Policy, it recognized cross-pollination as a significant problem and warned of the importance of segregating biopharm crops from food crops.[76] However, as critics have pointed out, "[t]o date . . . [biopharm crops] are indistinguishable from those intended for human consumption."[77] Furthermore, since biopharming can produce novel genes that have not previously entered the food supply, the FDA has no practical means of determining which new proteins will turn out to be allergy inducing.[78] Therefore, not only is there a realistic danger that biopharm crops could go undetected and contaminate the food supply, but the effects of most of these crops on human beings are unknown.[79]

Genetically modified crops have taken a dominant place in the market; in part because the United States government has remained committed to its pro-GE goals, but also because American farmers have noticed improved yields and insect-resistance in their crops.[80] The American public's concerns about using biotechnology to alter crops have been ignored by governmental decision makers and the agricultural industry.[81] Until it is determined whether the benefits of biopharming will ultimately outweigh the grave risks, it is important that cultivation of GM crops be closely regulated and dangers of cross-pollination between GM and non-GM crops be minimized.

III.
REGULATORY AGENCY STRUCTURE

Despite the potential dangers associated with GM crops and biopharming, the regulatory system remains decentralized.[82] In fact, critics of the current regulatory regime contest that there is really no organization to this system at all.[83] Instead responsibility "is dispersed among several agencies that lack central direction and administer diverse, sometimes inconsistent, statutes."[84] The coordination amongst the agencies is very poor and areas of

76. *FDA Policy*, *supra* note 4, at IV.G.
77. *Bratspies, StarLink*, *supra* note 17, at 632.
78. *FDA Policy*, *supra* note 4, at IV.E.
79. *See supra* note 12.
80. *See supra* notes 46-57 and accompanying text.
81. *See supra* notes 63-79 and accompanying text.
82. *Merill & Francer: Food Safety*, *supra* note 2, at 65.
83. *Id.* (arguing that food safety functions should be consolidated under a single organization).
84. *Id.*

agency control are often blurred.[85] Despite these deficiencies, this "patchwork arrangement" of regulatory authority has remained in place since the advent of GE.[86]

When the Reagan Administration was first presented with the issue of GE, it endorsed utilization of the currently existing regulatory framework, instead of advocating for the formation of a separate GE agency or granting all of the power to one regulatory agency rather than three.[87] It asked United States agencies to "self-assess their abilities to regulate products made with biotechnology."[88] The OSTP codified the result of this process in its *Proposal for Coordinated Framework for Regulation of Biotechnology*.[89] It announced a "multi-layered" scheme "separated by statutory boundaries defined either by product category or regulatory function."[90] Under this rubric, the three agencies are delegated power over specific aspects of the cultivation of GM crops depending upon factors such as whether the plants are designed for consumption or involve utilization of pesticides.[91] Unfortunately, this framework has not been updated since its creation in 1984 to account for changes in technology and the growth of the GE industry.[92] As the system currently stands, there is minimal oversight and the public interest goes unserved.[93]

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85. Christine C. Vito, *State Biotechnology Oversight: The Juncture of Technology, Law, and Public Policy*, 45 ME. L. REV. 329, 353 (2003) [hereinafter "*Vito, Juncture*"].

86. *Noah, Biotechnology's Revolution*, *supra* note 3, at 14. Congress concluded that biotechnology could be regulated within the existing body of law. *Id* at 33-34.

87. *See* Michael J. Malinowski & Nick Littlefield, Transformation of a Research Platform into Commercial Products, *in* THE COMMERCIALIZATION OF GENETIC RESEARCH 29, 32-33 (Timonthy A. Caulfield & Bryn Williams-Jones eds., Kluwer Academic/Plenum Publishers 1999) [hereinafter "Malinowski & Littlefield: Commercialization"]; *Bratspies: Illusion of Care*, *supra* note 7, at 310.

88. Malinowski & Littlefield: Commercialization, *supra* note 87, at 34.

89. *Coordinated Framework*, *supra* note 15.

90. *Merill & Francer: Food Safety*, *supra* note 2, at 90.

91. *See* Malinowski & Littlefield: Commercialization, *supra* note 87, at 33 ("The US's official policy on the regulation of biotechnology is to evaluate and regulate products based upon what they are rather than the processes used to make them. Agencies with jurisdiction over products developed with biotechnology are supposed to coordinate their efforts to avoid overlapping regulations."); MCGIFFEN: CORPORATE POWER, *supra* note 19, at 62 (explaining that the "FDA is responsible for food, animal feed, and pharmaceuticals," the USDA is concerned with the safety and suitability of "farm animals and crop plants," and the EPA "decides such things as whether and under what conditions a pesticide is safe to use").

92. *See FDA Policy*, *supra* note 4, at V.A.; MCGIFFEN, CORPORATE POWER, *supra* note 19, at 64; *Bush on Hunger*, *supra* note 18.

93. *See, e.g.*, *infra* Part IV.

A. *The United States Department of Agriculture*

The first of the agencies responsible for regulation of biotechnology is the USDA, which derives its power from the Plant Protection Act ("PPA").[94] The PPA gives the USDA the power to regulate "plant pests."[95] Plant pests include a variety of organisms that "can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[96] The USDA exercises its regulatory power over plant pests through the Animal and Plant Health Inspection Service ("APHIS").[97] APHIS' authority and purpose is broadly defined by the USDA as "protecting American agriculture."[98] In interpreting its role in the process of regulating GM crops, APHIS has adopted a very restrictive reading of the PPA, and almost solely limits its statutorily mandated duties to determining whether or not a "GM crop will itself pose a conventional plant pest risk when introduced into the environment and/or interstate commerce."[99]

In order for a GM crop to be planted for the first time, the institution that wants to bring the plant to market must first gain clearance from APHIS.[100] This is done through the utilization of two methods: "notification"[101] and "permit."[102] A notification is a "streamlined procedure . . . by which regulated articles may be introduced into the environment."[103] This is the most common method and is used for plants that are not considered to present "novel . . . risks."[104] Thus, if APHIS determines that it has extensive experience regulating a particular use of biotechnology, then

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94. 7 U.S.C. § 7701 *et seq.*

95. 7 U.S.C. § 7701.

96. 7 U.S.C. § 7702(14).

97. *Inspector General, Audit*, *supra* note 4, at 1.

98. United States Department of Agriculture Animal and Plant Health Inspection Service, http://www.aphis.usda.gov/ (last visited Dec. 27, 2006).

99. *Bratspies, StarLink*, *supra* note 17, at 602.

100. This process is known as a "field trial." S.L. Hutner & H.I. Miller, *USDA Regulation of Field Trials of Recombinant-DNA-Modified Plants: Reforms Leave Severe Flaws*, Trends in Biotechnology, Oct. 1997, at 387-89, *available at* http://www.biotech-info.net/USDA_regulation.html (last visited Dec. 27, 2006). Field trials involve "[p]lanting of GE crops in the environment to test their agronomic properties." *Inspector General: Audit*, *supra* note 4, at 61. The rules for field tests are governed by 7 C.F.R. 340.3(c)(5). Until such approval is gained, the crop may only be grown in a laboratory under regulated conditions. STEWART: GM PLANET, *supra* note 7, at 34.

101. 7 C.F.R. 340.3.

102. 7 C.F.R. 340.4.

103. *Inspector General, Audit*, *supra* note 4, at 62.

104. *Id.* at 32. The Office of Inspector General found that during its study of APHIS, almost ninety-seven percent of all field trials of GM crops were conducted under notifications. *Id.* at 2.

a company can apply online, APHIS will evaluate its proposal for safety concerns, and a notification can be issued within thirty days.[105] Permits, on the other hand, must be obtained for plants that may pose greater safety risks.[106] These are more rarely used and require written authorization from APHIS before the article can be released into the environment.[107] APHIS reserves permits for "crops that don't meet current notification criteria including pharmaceutical and industrial products, plants with a high potential to persist outside the field site, and multi-year field trials."[108]

The permit/notification procedure has resulted in a loosely organized system that relies primarily on self-reporting.[109] When GE companies submit reports to APHIS in order to gain clearance, they generally do not classify their proposed tests as ones that present "novel risks," and thereby avoid the onerous permit procedure.[110] Instead, they utilize the notification procedure and APHIS generally takes the companies at their word rather than visiting the proposed site and determining the actual safety of the crops.[111] Additionally, APHIS relies upon the parties that are being regulated to submit information about the progress of the field tests and when the field tests have been terminated.[112] Thus, GM applications are not scrutinized on an individual basis and closely monitored, but rather are rubberstamped through the notification procedure.[113] Voluntary compliance and self-reporting are cornerstones of this system.[114]

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105. United States Department of Agriculture, *APHIS: Permits*, http://www.aphis.usda.gov/permits/brs_epermits.shtml (last visited Jan. 20, 2007) [hereinafter "*APHIS Permits*"].

106. *Inspector General, Audit*, *supra* note 4, at 86.

107. *Id.*

108. *APHIS Permits*, *supra* note 105.

109. *See Bratspies, Corn*, *supra* note 75, at 394-95. *See also* MCGIFFEN: CORPORATE POWER, *supra* note 19, at 75 ("The FDA relied entirely on the producers themselves for safety data, setting up a clear conflict of interests which may result in lax standards of enforcement.").

110. *Inspector General, Audit*, *supra* note 4, at 86.

111. The Office of Inspector General determined that APHIS lacked basic information about the field tests that it approved including where crops were being grown and what becomes of the crops at the end of the field tests. *Id.* at i.

112. *See, e.g.*, 7 C.F.R. § 340.4(f)(9) ("A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test."). *See also* MCGIFFEN: CORPORATE POWER, *supra* note 19, at 75.

113. By 2005, APHIS had approved over 10,000 applications for almost 50,000 field test sites. *Inspector General, Audit*, *supra* note 4, at i.

114. *See Bratspies, StarLink*, *supra* note 17, at 596. *See also Inspector General: Audit*, *supra* note 4, at 86.

The problems with the administration of the GE regulatory system are well known to the USDA.[115] An internal examination of the USDA revealed the flaws in its current system of voluntary compliance and self-reporting. In a USDA audit report, the Office of the Inspector General detailed numerous deficiencies in the USDA's existing regulatory scheme and made twenty-eight recommendations to improve it.[116] The Office of the Inspector General found inadequacies in, among other areas, the record keeping system of APHIS,[117] monitoring of GM crops,[118] and APHIS' lack of control over the disposal of experimental GM crops after field tests were complete.[119] The audit report concluded that "APHIS' public policy on the frequency of field test inspections differs from its actual practice," and that the USDA's existing regulatory scheme is full of holes.[120]

Unfortunately, the recommendations of the Office of the Inspector General were simply advisory and not binding upon APHIS.[121] While APHIS agreed to make several changes to its regulatory system, it disagreed with many of the Inspector General's recommendations.[122] Notably, APHIS did not see the importance of developing guidelines to restrict public access to edible GE crops that have not undergone safety reviews or having "biotechnologist reviews of notification protocols to ensure they are sufficient to meet performance standards."[123] Instead, APHIS argued that public access to edible crops, some of which

115. *See, e.g., id.*

116. *Id.* at 6-48. The Office of Inspector General is a division of the USDA that seeks to "promote effectiveness and integrity in the delivery of USDA agricultural programs." United States Department of Agriculture Office of Inspector General, http://www.usda.gov/oig/ (last visited Dec. 27, 2006).

117. In its study of ninety-one sites, thirteen instances of noncompliance, involving eleven sites, were discovered. The Office of Inspector General also learned about two additional violations at sites that it did not visit. *Inspector General, Audit, supra* note 4, at 6-25.

118. *Id.* at 28-40.

119. *Id.* at 41-46.

120. *Id.* at 7.

121. *See generally id.*

122. Based on the recommendations of this report, APHIS agreed that some improvements were needed. The Inspector General noted that, "We generally agree with APHIS' response for 23 of 28 recommendations in this report." *Id.* at v. While the Inspector General only wholeheartedly disagreed with APHIS' response to five of the recommendations, there were nine different recommendations in which APHIS only agreed in part and the Office of Inspector General responded, "We can not accept APHIS' management decision . . ." *Inspector General, Audit, supra* note 4, at 12, 17, 22-23, 33, 41-43.

123. *Id.* at 12, 23.

are biopharming crops that are visually indistinguishable from crops designed for human consumption, is already addressed by the APHIS' ability to require restricted access for special cases.[124] APHIS further insisted that its current notification procedure was adequate and that written review would be unnecessary.[125]

APHIS' response to the audit report reveals that while there is internal criticism of the USDA's lax monitoring of GM crops, it is unlikely that the USDA will make critical internal changes to compensate for its current deficiencies.[126] Instead, it continues to interpret its duties under the PPA narrowly and has not adopted all of the Office of Inspector General's recommendations to improve APHIS' regulatory role.[127] Therefore, many of the concerns involving inadequate monitoring and the danger of reliance upon self-reporting have not been quelled.

B. *The Environmental Protection Agency*

The second agency responsible for regulating biotechnology, the EPA, derives its statutorily delegated power from the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")[128] and the Federal Food, Drug, and Cosmetic Act ("FFDCA").[129] FIFRA requires that all pesticides[130] be registered with the EPA before they are used in field tests, while FFDCA grants the EPA power to set appropriate levels for pesticides.[131] Under these Acts, the EPA is granted the power to regulate "toxins as a pesticide, but cannot regulate the plants that produce the toxins."[132]

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124. *Id.* at 12; United States Department of Agriculture, *Biotechnology Regulatory Services*, http://www.aphis.usda.gov/brs/ (last visited Dec. 27, 2006). Biotechnology Regulatory Services ("BRS") is a subdivision of APHIS responsible for management of the GE inspection program. *Id; see also Inspector General, Audit, supra* note 4, at ii.

125. *Inspector General, Audit, supra* note 4, at 23.

126. *See generally id.*

127. *See supra* notes 99, 121-24 and accompanying text.

128. 7 U.S.C. § 136a.

129. 21 U.S.C. §§ 301-99.

130. "Pesticide" is defined as "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer." 7 U.S.C. § 136(u).

131. 7 USC § 136a(a); 21 U.S.C. § 346a.

132. *Bratspies: Illusion of Care, supra* note 7, at 314-15.

Therefore, while it plays an important role in defining acceptable uses of GE, its role is limited to the realm of pesticide levels.[133]

The EPA uses its authority to address plants that have been modified to produce their own pesticides.[134] It has the power to limit the distribution or sale of GM crops "[t]o the extent necessary to prevent unreasonable adverse effects on the environment."[135] Before 1994, all cultivation of GM plants required express EPA approval.[136] However, the EPA has since relaxed its standard, by exempting whole classes of pesticides that it deems "a low probability of risk to the environment, and . . . not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA."[137] This exemption has been invoked to exempt some GM crops on the theory that the chemicals they produce are "substantially equivalent" to those that could be found in nature.[138] Thus, while the EPA's only task in the domain of GE is to regulate pesticide levels, they have used exemptions to limit their role in the supervisory process.

C. *The Food and Drug Administration*

The third and final agency responsible for regulating biotechnology is the FDA. Like the EPA, the FDA also derives its authority to regulate from the FFDCA.[139] The FDA's regulatory power is limited and extends only to crops intended for consumption.[140] The FDA uses its power to regulate the marketing of

133. The EPA has been the target of criticism for poor enforcement and incomplete reporting requirements. *See, e.g.*, *Bratspies: Illusion of Care*, *supra* note 7, at 326-28; John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 824-38 (2001); *McGarity: Seeds of Distrust*, *supra* note 14, at 472. However, some commentators have praised the EPA for being more willing to protect consumer interests and intervene when GM crops pose dangers to public health. *See* MCGIFFEN: CORPORATE POWER, *supra* note 19, at 73 (noting that the EPA has "shown itself willing to act in extreme cases").

134. STEWART: GM PLANET, *supra* note 7, at 159; Celeste Marie Steen, *FIFRA's Preemption of Common Law Tort Actions Involving Genetically Engineered Pesticides*, 38 ARIZ. L. REV. 763, 767 (1996).

135. 7 U.S.C. § 136a(a).

136. MCGIFFEN: CORPORATE POWER, *supra* note 19, at 72.

137. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), Part IV, 66 Fed. Reg. 37,772, (July 19, 2001) (citing 7 U.S.C. § 136w(b)(2)).

138. *McGarity: Seeds of Distrust*, *supra* note 14, at 467-72.

139. 21 U.S.C. §§ 301-99.

140. "In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and infor-

GM foods,[141] including "food additives"[142] and labeling requirements.[143] Food additives are "substance[s] the intended use of which results or may reasonably be expected to result, in its . . . affecting the characteristics of any food" and must be approved by the FDA before being placed on the market.[144] This broad definition encompasses everything from salt to dyes to minute amounts of packaging substances that find their way into foods during storage.[145] Thus, to limit their regulatory responsibilities, the FDA has carved out an exception to this definition, which the FDA has applied to GM foods.[146] Substances added to food do not need special regulation if "generally recognized . . . to be safe" ("GRAS").[147] In its 1992 *Statement of Policy*, the FDA explicitly rejected the contention that GM crops pose greater risks than non-GM crops, and determined that GM crops are "presumed to be GRAS."[148] This policy results in a passive approach to monitoring duties that only really necessitates FDA intervention in GE when a company approaches the FDA with concerns about risks associated with its own GM crops.[149] Otherwise, the FDA plays a deferential role and "companies . . . must make a judgment about whether the resulting food substance is a food additive requiring premarket approval by the FDA."[150]

The FDA has further avoided taking an active role in regulating GM crops designed for human consumption by ignoring public demand for more stringent labeling requirements.[151] Under the FFDCA, "[a]n article . . . [is] misbranded [when] . . . the labeling or advertising fails to reveal a material fact" about that

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mation on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration." 21 U.S.C. § 346a(b)(2)(E)(i). It cannot regulate biopharming because biopharm products are intended for pharmaceutical purposes, not consumption. *Bratspies: Corn*, *supra* note 75, at 385.

141. *Bratspies, Illusion of Care*, *supra* note 7, at 311.

142. 21 U.S.C. § 321(s) (1994).

143. 21 U.S.C. § 321(n).

144. 21 U.S.C. § 321(s).

145. Food and Drug Administration, *FDA/CFSAN Food Additives*, http://www.cfsan.fda.gov/~lrd/foodaddi.html (last visited Jan. 22, 2007).

146. *See* McGIFFEN: CORPORATE POWER, *supra* note 19, at 65.

147. 21 U.S.C. § 321(s) (1994); McGIFFEN: CORPORATE POWER, *supra* note 19, at 65.

148. *FDA Policy*, *supra* note 4, at V.C., V.I.

149. *See* McGIFFEN: CORPORATE POWER, *supra* note 19, at 67.

150. *FDA Policy*, *supra* note 4, at V.A.

151. Amy Martinez Starke, *The Biotech Food Fight: To Label or Not to Label?*, OREGONIAN, May 30, 2000, at FD01 [hereinafter "*Food Fight*"].

article.[152] The FDA has been hesitant to apply the term "material fact," and thus require labeling, except for rare situations such as when food has been treated with ionizing radiation.[153] Advocates of mandatory labeling of GM food have urged that the "material fact" requirement should be read to include GM ingredients, and therefore, GM products should have to be labeled.[154] Opinion polls indicate that there is strong consumer demand for labeling of GM products.[155] Advocates urge that this public concern serves as evidence of the importance of labeling GM ingredients.[156] Instead, the FDA has rejected this interpretation of "material fact."[157] In its *Statement of Policy*, the FDA declared, "the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that new methods are used."[158]

The FDA's description of GM cultivations overly simplifies the problem. It brushes aside the fact that this technology is relatively novel and involves manipulating DNA so that plants produce substances and toxins that they would not naturally produce on their own.[159] Instead, the FDA boldly generalizes that recombinant DNA methods being used today by the biotechnology industry are simply "extensions at the molecular level of traditional methods" and therefore do not pose novel risks.[160] Thus, it treats GE methods in the same way it treats more conventional methods like cross-breeding, which has been utilized by farmers for centuries.[161] So, despite widespread consumer support for labeling products containing GM ingredients, the FDA has determined that the fact that a product is GM does not in and of itself trigger a labeling requirement.[162] Federal courts have refused to

152. 21 U.S.C. § 321(n).

153. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13376 (Apr. 18, 1986) (to be codified at 21 C.F.R. pt. 179).

154. *See, e.g.*, Alliance For Bio-Integrity v. Shalala, 116 F. Supp. 2d. 166, 174 (D.D.C. 2000).

155. *See Kraft Shareholder Report*, *supra* note 8, at 9 (citing two studies, one of which found that ninety-three percent surveyed thought that the government should require labels saying whether food has been genetically modified). *See also Food Fight*, *supra* note 151.

156. *See Alliance For Bio-Integrity*, 116 F. Supp. 2d at 174.

157. *FDA Policy*, *supra* note 4, at I.

158. *Id.*

159. *See* Foundation on Econ. Trends v. Heckler, 756 F.2d 143, 147 (D.C. Cir. 1984); Becker: New Frontier, *supra* note 43, at 3.

160. *FDA Policy*, *supra* note 4, at VI.

161. *See id.*

162. *Id.*

get involved in the debate and have instead told opponents of the FDA's definition of "material fact" that "argument on this point is probably better directed at Congress."[163]

D. *An Incomplete Framework*

The existing framework of power sharing between the USDA, EPA, and FDA yields an incomplete regulatory scheme. There is no strong central organization that is entrusted with overseeing GM crops from the issuance of permits through regulating what products ultimately reach store shelves.[164] Instead, the OSTP division of power has yielded blurry lines and poor enforcement of GE safety requirements.[165] As one commentator notes, "Rather than fulfilling their statutory role as a watchdog and guardian of the public safety, the agencies are reduced to the role of cheerleaders, urging good behavior from the sidelines but powerless to require it."[166] This minimalist regulatory involvement certainly promotes OSTP's explicit goal of "reducing barriers to trade in biotechnology."[167] However, to date, this system has ignored activists' concerns about GE, and has instead adopted a loosely run, poorly regulated system that is largely dependent upon self-reporting.[168]

Although when Congress enacted the PPA, FIFRA, and FFDCA "it obviously could not account for the late twentieth-century technologies that would permit the genetic modification of food,"[169] it is puzzling why Congress has not installed a more efficient regulatory system as the biotechnology industry has evolved over the past twenty years.[170] Some commentators posit that the failure to create a centralized regulatory system may be a result of the inevitable political implications of a reorganization of power.[171] They point out that, "[t]aking a bureau out of one department and putting it into another often means shifting oversight responsibility . . . A willingness to surrender turf is as rare

163. Alliance For Bio-Integrity v. Shalala, 116 F. Supp. 2d. 166, 181 (D.D.C. 2000).

164. *See* STEWART: GM PLANET, *supra* note 7, at 159; *Merill & Francer: Food Safety*, *supra* note 2, at 65.

165. *Vito, Juncture*, *supra* note 85, at 353.

166. *Bratspies, StarLink*, *supra* note 17, at 605.

167. *Coordinated Framework*, *supra* note 15.

168. *See supra* notes 84-86, 109-14, 149-50 and accompanying text.

169. *Alliance For Bio-Integrity*, 116 F. Supp. 2d. at 177.

170. For an argument for a revamped regulatory framework, see *Bratspies, Corn*, *supra* note 75.

171. *See Merill & Francer: Food Safety*, *supra* note 2, at 168.

among members of Congress as it is among cabinet secretaries."[172] Whatever the reasons for Congress' refusal to reorganize the regulatory authority over GE, they have remained dedicated to OSTP's intention, as codified in 1992, "to regulate foods produced by new methods, such as recombinant DNA techniques, within the existing statutory and regulatory framework," rather than altering the framework to adapt to changes in the biotechnological field.[173] Subsequent GE disasters involving contamination of food crops reveal the implications of Congress' unwillingness to update the GE regulatory scheme.[174]

IV.
CAUSE FOR CONCERN

Recent GE "blunders" highlight the deficiencies in the current regulatory structure. The most serious GE incident, in 2000, involved StarLink corn, and stands as an example of the potential economic and social consequences that can result from lax regulatory treatment of GM products in the United States.[175] In crafting policies, Congress and the federal agencies responsible for monitoring GM crops have not taken into account the public's desire for stricter supervision over the biotechnology industry.[176] The StarLink disaster emphasizes the need for the judiciary to take an active role in forcing industry compliance with existing regulations, since the agencies clearly have not done so on their own.

A. *StarLink Corn*

StarLink corn seeds, created by Aventis CropScience,[177] were seeds that were genetically "engineered to include a gene for a protein called Cry9C,"[178] a bacterial toxin that kills

172. *Id.* at 167.

173. *Coordinated Framework*, *supra* note 15.

174. *See infra* Part IV.B.

175. *StarLink Corn Recap and Update*, KSU Ag Biotech Newsletter, Issue 2001-1, Jan. 17, 2001, *available at* http://www.oznet.ksu.edu/biotech/Newsletter/AGBio01-1.pdf (last visited Nov. 7, 2006).

176. *See, e.g.*, *Kraft Shareholder Report*, *supra* note 8, at 9 (citing studies finding that consumers overwhelmingly favor labeling requirements).

177. A United States company "aimed at providing crop solutions for the North American grower," which was created in 1999 by combining Rhone-Poulenc Ag Company and AgrEvo. Aventis CropScience Company Press Release, *Aventis CropScience is Created in North America*, Dec. 15, 1999, available at http://www.biotech-info.net/aventis.html (last visited Jan. 14, 2007).

178. *Modified-Corn Lawsuit is Settled*, N.Y. Times, Mar. 8, 2002, at C14 [hereinafter "*Lawsuit Settled*"].

insects.[179] Aventis obtained the requisite USDA and FDA approval needed to market StarLink.[180] When Aventis applied to register StarLink with the EPA, however, the EPA became concerned about attributes of Cry9C that were similar to human allergens.[181] Thus, the EPA refused to issue a permit approving its cultivation for human consumption.[182] Instead, the EPA issued a "limited registration, permitting StarLink's use for such purposes as animal feed."[183] Over twenty-nine months, the acreage devoted to cultivating StarLink corn expanded from 10,000 to 350,000 acres.[184] This dramatic increase in the cultivation should have raised eyebrows since StarLink was only supposed to be cultivated for a limited purpose, not for mass marketing. This in itself could have given reason to investigate, considering that the EPA feared that StarLink corn, if consumed by humans, may cause side effects such as rashes and increased blood pressure.[185] However, the EPA ignored the threat.[186] Despite the EPA's authoritative command that StarLink was not to be used for human consumption, in September 2000 environmentalists "announced they had discovered StarLink corn in twenty-three common grocery products."[187] Over time, StarLink corn continued to resurface in grocery items manufactured by prominent companies like Kraft,[188] and ultimately the FDA instituted a recall of over 300 types of processed food that contained StarLink corn.[189] Not only had Aventis blatantly disregarded the EPA's order not to produce StarLink corn for human consumption, but the effects that this GM food could have on human beings was unknown.[190]

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179. *Severson: Frankenfood*, *supra* note 6.

180. *Bratspies, StarLink*, *supra* note 17, at 617.

181. *In re* StarLink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828, 834 (N.D. Ill. 2002).

182. MCGIFFEN: CORPORATE POWER, *supra* note 19, at 79; *Lawsuit Settled*, *supra* note 178.

183. *In re StarLink Corn*, 212 F. Supp. 2d at 834. *See also* MCGIFFEN: CORPORATE POWER, *supra* note 19, at 79-80.

184. *In re StarLink Corn*, 212 F. Supp. 2d at 835.

185. *Side Effects Article*, *supra* note 12.

186. *See In re StarLink*, 212 F. Supp. 2d at 835; *Bratspies: Illusion of Care*, *supra* note 7, at 352-53.

187. *Bratspies, Corn*, *supra* note 75, at 386. *See also Fears of Contamination*, *supra* note 11.

188. Tina Hesman, *Taco Shell Incident Puts Genetic Testing in Spotlight*, ST. LOUIS POST-DISPATCH, Nov. 3, 2000, at A1; *Severson: Frankenfood*, *supra* note 6.

189. *Bratspies, Corn*, *supra* note 75, at 386-87; Andrew Pollack, *Judge Upholds F.D.A. Policy on Genetically Altered Foods*, N.Y. TIMES, Oct. 4, 2000, at C18.

190. *In re StarLink*, 212 F. Supp. 2d at 834.

The economic consequences of the StarLink disaster were vast. In addition to a massive recall,[191] lawsuits were initiated against Aventis alleging negligence, strict liability, private nuisance, public nuisance, and conversion.[192] Aventis ultimately settled the claims for $9 million.[193] Furthermore, the situation required intense investigations into which crops contained traces of the tainted corn.[194]

The StarLink disaster also triggered a severe response in Europe, where "the public has been reluctant to purchase any genetically modified products."[195] A general reluctance to American-grown agricultural products has arisen, and the economic and political implications are difficult to quantify.[196] Unlike in America, the European Union now requires GM products to be labeled.[197] President Bush has contended that Europe is blocking "all new bio-crops because of unfounded, unscientific fears."[198] Whether or not the fears of GE prove to be well-founded, they do represent an international debate with distinct economic ramifications.

Notably, the StarLink disaster is a situation that could have been prevented. The EPA knew that StarLink corn was going to be planted, and only approved its use for a limited purpose,

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191. Julie Vorman, *StarLink Recall Climb to 300 Different Items*, Organic Consumers Association, Nov. 1, 2000, *available at* http://www.organicconsumers.org/ge/starlink300.cfm (last visited Nov. 7, 2006).

192. *In re StarLink* represented a consolidation of fifteen separate cases filed against Aventis. *In re StarLink*, 212 F. Supp. 2d at 833.

193. *Lawsuit Settled*, *supra* note 178; *Kraft Foods, Inc.*, Hoover's In-Depth Company Records, Sept. 13, 2006.

194. "Non-StarLink corn is also damaged when it is commingled with StarLink corn. Once mixed, there is no way to resegregate the corn into its edible and inedible parts." *In re StarLink*, 212 F. Supp. 2d at 841.

195. *Bush on Hunger*, *supra* note 18. *See also* MCGIFFEN, CORPORATE POWER, *supra* note 19, at 9-11. Other nations outside of Europe, such as South Korea and Japan, similarly sought alternative sources of corn due to the StarLink disaster. *In re StarLink*, 212 F. Supp. 2d at 835; MCGIFFEN, CORPORATE POWER, *supra* note 9, at 120. *See also* BRIAN SHERIDAN, EU BIOTECHNOLOGY LAW & PRACTICE 5 (Palladian Law Publishing 2001) (citing a 1999 study finding that sixty-six percent of Europeans would not eat GM fruit even if it tasted better).

196. *See* Charlotte Denny, *America Challenges GM Crop Ban*, GUARDIAN (UK), May 14, 2003, at 2, *available at* http://www.commondreams.org/headlines03/0514-05.htm (last visited Nov. 9, 2006); Mark Kaufman, *Government Orders Test of Tainted Corn*, WASH. POST, Mar. 2, 2001, at A10.

197. Diana Heil, *Food For Thought*, SANTA FE NEW MEXICAN, Sept. 13, 2006, at A1.

198. *Bush on Hunger*, *supra* note 18.

namely animal feed.[199] Despite advance notice of Aventis' initial desire to produce this corn for human consumption,[200] the EPA did not keep an eye on this project, but rather relied upon the voluntary and virtually unmonitored compliance system that typifies the GE regulatory framework.[201] Aventis casually disregarded the EPA restrictions believing that it was "unnecessary for them to advise StarLink farmers to segregate their StarLink crop or create buffer zones because Aventis believed that the EPA would amend the registration to permit StarLink use for human consumption."[202] When this did not happen, Aventis did not contact growers to tell them not to use the corn for human consumption.[203] Even as red flags went up, such as the increased acreage devoted to StarLink corn, the EPA did not investigate further into the situation.[204] Furthermore, due to the fragmentation and lack of coordination amongst the three agencies responsible for monitoring the biotechnology industry, neither the FDA nor USDA stepped in to help inspect and enforce the EPA's orders until after disaster had struck.[205]

B. *Other Incidents of Contamination*

Although it was the biggest, StarLink does not stand alone as the only GE slipup. There have been other incidents involving both unapproved chemicals and the commingling of biopharmed crops with crops designed for consumption.[206] In late 2002, the USDA was forced to quarantine and then destroy 500,000 bushels of soybeans because they had been contaminated by biopharmed corn that was not approved for human

199. *In re StarLink*, 212 F. Supp. 2d at 834; Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution Into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 173 (2006).

200. *See Bratspies, StarLink*, *supra* note 17, at 617 ("Aventis initially requested that StarLink corn be exempted from a pesticide tolerance for all raw agricultural commodities. .").

201. Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 781 (2003).

202. *In re StarLink*, 212 F. Supp. 2d at 835.

203. *Id.*

204. *See supra* notes 184-86 and accompanying text.

205. *EPA's Regulation of Bacillus thuringiensis (Bt) Crops*, May 2002, http://www.epa.gov/pesticides/biopesticides/pips/regofbtcrops.htm (last visited Nov. 8, 2006) ("Upon discovery of StarLink corn in processed food, the Federal Government took several steps to ensure the diversion of StarLink from the human food supply. USDA, FDA, and EPA worked to test corn grain for the presence of StarLink and to remove any potentially contaminated corn seeds from the market.").

206. *See infra* notes 207-15.

consumption.[207] The contamination began when 500 bushels of soybeans were planted in a field that had been used one year earlier by ProdiGene, Inc.[208] to cultivate corn designed to produce chemicals for making insulin.[209] Although they were destroyed after the cultivation, some biopharming corn stalks sprouted the next year amongst 500 bushels of soybeans, which were then mixed with 500,000 bushels in a grain elevator.[210] Thus, $2.7 million of contaminated crops had to be destroyed since it was impossible to decipher contaminated from uncontaminated soybeans.[211]

Similarly, in July 2006, LLRICE601, unapproved rice that had been GM by Bayer CropScience[212] to resist certain herbicides, was found mixed amongst other rice in commercial bins in Arkansas and Missouri.[213] How this unapproved rice ended up amongst rice intended for human consumption has never been proven, but it is suspected that it crossbred with rice in a neighboring farm.[214] Nonetheless, Japan and the European Commission subsequently banned all imports of U.S. long-grain rice, unless it could be proven that the rice did not contain LLRICE601.[215]

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207. Christopher Doering, *Biotech Nears Deal on Quarantined Soybeans*, SAN DIEGO UNION-TRIBUNE, Nov. 19, 2002, at C-5; Jerry W. Jackson, *Bioengineering Opponents Slam Escape of Modified Corn*, ORLANDO SENTINEL, Nov. 15, 2002, at C1 [hereinafter "*Opponents of Corn*"]; Thomas P. Redick, *Biopharming, Biosafety, and Billion Dollar Debacles: Preventing Liability for Biotech Crops*, 8 DRAKE J. AGRIC. L. 115, 131 (2003).

208. A small spinoff of Pioneer Hi-Bred International Inc., which was incorporated in Texas in 1996. Lynn Graebner, *Two Tales of Biotech and Texas*, SACRAMENTO BUSINESS JOURNAL, Nov. 5, 1996, *available at* http://www.bizjournals.com/sacramento/stories/1996/11/18/story2.html (last visited Jan. 14, 2007).

209. Tina Hesman, *Crop Experiments Get More Watchful Look*, ST. LOUIS POST-DISPATCH, Nov. 22, 2002, at A1; *Opponents of Corn*, *supra* note 207.

210. Andrew Pollack, *Spread of Gene-Altered Pharmaceutical Corn Spurs $3 Million Fine*, N.Y. TIMES, Dec. 7, 2002, at A15.

211. *Fears of Contamination*, *supra* note 11; Mike Toner, *Alarms Sound Over Biopharming*, ATLANTA JOURNAL-CONSTITUTION, Nov. 12, 2002, at 1C.

212. Bayer CorpScience advertises itself as "one of the world's leading innovative crop science companies in the areas of crop protection, non-agricultural pest control, seeds and plant biotechnology." Bayer CropScience World, http://www.bayercropscience.com/bayer/cropscience/cscms.nsf/id/Home_EN (last visited Jan. 14, 2007).

213. *Grains of Doubt*, *supra* note 59; Rick Weiss, *Gene Altered Profit-Killer: A Slight Taint of Biotech Rice Puts Farmers' Overseas Sales in Peril*, WASH. POST, Sept. 21, 2006, at D01 [hereinafter "*Rice Profit Killer*"].

214. *Rice Profit Killer*, *supra* note 213.

215. *See Aldi raumt angeblichen Genreis aus den Verkaufsregalen (Aldi Removes Genetically Modified Rice From Shelves)*, HANDELSBLATT (Germany), Sept. 16, 2006; *Grains of Doubt*, *supra* note 59.

With each disaster, the American regulatory structure loses further international credibility and American agriculture suffers from the long and short-term monetary effects of crop bans.[216] The repetition of these disasters demonstrates that the current regulatory framework is ineffective at deterring and detecting violations. Since Congress, the FDA, EPA, and USDA have proven unwilling to make changes to the existing regulatory scheme, it is important for the federal judiciary to step in and force more stringent agency regulation. However, to date the judiciary has been unable to actively intervene because of its traditional policy of deference towards agency determinations.[217]

V.
CENTER FOR FOOD SAFETY V. JOHANNS AND THE ROAD TO COME

It is in this context of inefficient regulations, poor enforcement, and looming GE disaster that the *Center for Food Safety v. Johanns* decision was decided. In the first federal opinion to address the GE category of biopharming,[218] U.S. District Judge J. Michael Seabright found that APHIS had violated both the ESA and NEPA in issuing permits to plant GM sugarcane and corn in Hawaii.[219] This fifty-two page opinion operates as a reminder that agencies' responsibilities do not end with their statutorily granted power.[220] They must also comply with other statutorily mandated duties when agency actions touch upon other congressional areas of concern, such as endangered species and environmental protection.[221] APHIS' procedural deficiencies, however, extend beyond the facts of the *Center for Food Safety* case. Instead, they reflect decades of vague regulatory authority and insufficient enforcement.[222] Preliminary evidence reveals that there may be other ESA and NEPA violations that have been

216. David Barboza, *Negligence Suit is Filed Over Altered Corn*, N.Y. TIMES, Dec. 4, 2000, *available at* http://www.nytimes.com/2000/12/04/business/04CORN.html.

217. *See supra* note 26 and accompanying text.

218. *Judge Rules*, *supra* note 33.

219. Center for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1171 (D. Haw. 2006). This case was ultimately decided on summary judgment. Judge Seabright granted in part and denied in part plaintiffs' motion for summary judgment, and also granted in part and denied in part defendants' motion for summary judgment. *Id.* at 1196.

220. *Gone Awry*, *supra* note 74.

221. *Center for Food Safety*, 451 F. Supp. 2d at 1177.

222. *See supra* Part III.

committed by APHIS.[223] Therefore, as opponents of GE bring more lawsuits, the federal judiciary will come to play a larger role in the realm of biotechnology. The federal judiciary will be the one crafting remedies to deal with the problems that have been imposed by the "patchwork" GE regulatory system.[224]

A. *APHIS' Disregard of its Statutory Duties*

The *Center for Food Safety* case arose in the context of permits granted by APHIS to four companies: ProdiGene, Monsanto, Hawaii Agricultural Research Center, and Garst Seed.[225] These permits were issued to allow the growth of GM corn and sugarcane that contained "hormones, vaccines, or proteins that could be used to treat human illnesses."[226] After the companies submitted permit applications to APHIS requesting that they be able to conduct field tests in Hawaii, APHIS approved the permits, noting that while the donor organisms being used by the companies were "plant pests" under the PPA, they were "confined" and thus in compliance with the PPA.[227] However, a challenge was brought by activist groups, including the Center for Food Safety and Friends of the Earth, on different grounds.[228]

The *Center for Food Safety* Court held that in considering whether or not to approve this cultivation, the USDA could not limit its review of the proposal to the specifications of the PPA.[229] Instead, the ESA and NEPA also had to be considered, because these acts confer responsibilities amongst agencies in the operation of their statutorily delegated duties.[230] These congressional acts essentially impose strict liability upon violators.[231]

For the purpose of "conserv[ing] endangered species,"[232] the ESA requires that before acting, federal agencies request information from the Secretary of Interior about which endangered species may be present in the area of an "agency

223. *See infra* notes 269-71.

224. *See infra* Part. V.B. – VI.

225. *Center for Food Safety*, 451 F. Supp. 2d at 1170.

226. *Id.* at 1170.

227. *Id.* at 1176-77.

228. *Id.* at 1165.

229. *Id.* at 1177.

230. *Id.*

231. Center for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1182 (D. Haw. 2006).

232. 16 U.S.C. § 1531(c)(1).

action."[233] It was not contested that the approval of a permit to cultivate GM crops fits within this mandate.[234] Furthermore, per the ESA, if it is discovered that an endangered species may be present in the requested planting area, the agency must conduct a "biological assessment" to conclude if the species are likely to be harmed by the action.[235]

The court held that these requirements were not met since APHIS did not obtain information about listed species and critical habitats from Fish and Wildlife Service or National Marine Fisheries Service before granting permits.[236] It determined that APHIS had violated the ESA in its "utter disregard for this simple investigative requirement" to examine the potential adverse effects that this series of biopharming field tests could have upon Hawaii's 329 endangered species.[237] The investigative requirement is not overly burdensome because, even should APHIS discover that species are likely to be adversely effected, it must merely pursue further informal consultation with Fish and Wildlife Service.[238] However, here APHIS did not make a good faith effort to consider the environmental impact of these specific GM crops.[239]

NEPA contains similar requirements that instruct "federal agencies to evaluate the impact of their actions on the natural environment."[240] To be in conformity with this duty, for every "major Federal action . . . significantly affecting the quality of the human environment,"[241] the agency must either prepare an "environmental assessment" or "environmental impact statement."[242] An environmental assessment is a "'concise public document' that an agency prepares when deciding whether it needs to prepare a more extensive [environmental impact state-

233. 16 U.S.C. § 1536(c)(1). An "agency action" is "any action authorized, funded, or carried out by such agency." *Center for Food Safety*, 451 F. Supp. 2d at 1173 (quoting 16 U.S.C. § 1536(a)(2)).

234. *Id.* at 1174.

235. *Id.* at 1173 (citing Forest Guardians v. Johanns, 450 F.3d 455, 457 (9th Cir. 2006)).

236. *Id.* at 1181-83.

237. *Id.* at 1182. Judge Seabright also noted that Hawaii has more endangered and threatened species than any other state. *Id.* at 1181.

238. Center for Food Safety v. Johanns, No. 03-621, 2006 U.S. Dist. LEXIS 74431, at *6 (D. Haw. Oct. 11, 2006).

239. *Center for Food Safety*, 451 F. Supp. 2d at 1182.

240. *Id.* at 1174 (citing 42 U.S.C. § 4332).

241. 42 U.S.C. § 4332(2)(c).

242. 40 C.F.R. §§ 1508.09-11.

ment]."[243] This document discusses the need for the proposal, the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted.[244] Should this reveal that the environmental consequences of a proposed agency action might be significant, an environmental impact statement must be prepared.[245] An environmental impact statement is a "detailed written statement"[246] that contains "discussions of the purpose of and need for the action, alternatives, the affected environment, the environmental consequences of the proposed action, lists of preparers, agencies, organizations and persons to whom the statement is sent, an index, and an appendix."[247] An agency can avoid the requirements of environmental assessments and environmental impact statements if it produces a "convincing statement of reasons why potential effects are insignificant."[248]

In *Center for Food Safety*, Judge Seabright concluded that APHIS failed to articulate a reasoned explanation for declining to prepare an environmental assessment or environmental impact statement.[249] This inaction constituted a violation of NEPA.[250] Furthermore, APHIS behaved "arbitrarily and capriciously" by failing to consider possible categorical exclusions to NEPA.[251]

Faced with these findings, APHIS tried to avoid liability by pointing out that since there was no "evidence to show that a single species or habitat was harmed in any way, the Plaintiffs' claims [must] necessarily fail."[252] The court called this argument "absurd" and determined that the ESA is violated whenever an agency fails to follow the congressionally mandated procedures.[253] Thus, not only did the court hold APHIS liable for ig-

243. *Center for Food Safety*, 451 F. Supp. 2d at 1174 (citing 40 C.F.R. § 1508.11).

244. Environmental Protection Agency, *Basic Information: Compliance and Enforcement*, http://www.epa.gov/compliance/basics/nepa.html (last visited Jan. 20, 2007) [hereinafter "*EPA Compliance*"].

245. *Id.*

246. 40 C.F.R. § 1508.9.

247. *EPA Compliance*, *supra* note 244.

248. Center for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1175 (D. Haw. 2006) (citing Alaska Ctr. for the Env't vs. U.S. Forest Serv., 189 F.3d 851, 859 (9th Cir. 1999)).

249. The court declined to allow APHIS to apply a "categorical exclusion post hoc." *Id.* at 1183.

250. *Id.*

251. *Id.* at 1186.

252. *Id.* at 1182.

253. *Center for Food Safety*, 451 F. Supp. 2d at 1182 (D. Haw. 2006).

noring its statutory obligations under the ESA and NEPA, but the court determined that this was a strict liability offense which does not require proof by the plaintiffs of harm to the environment or endangered species.[254]

Once the case reached the remedies stage, the plaintiffs in *Center for Food Safety* only requested declaratory relief because the four permits at issue had already expired.[255] Judge Seabright noted that another judge "raised the possibility of an environmental study of the effects of the open-air field tests as one possible remedy, [but] Plaintiffs' counsel candidly stated that he did not believe this to be a prudent use of taxpayers' money [given that the permits were long expired]."[256] Therefore, APHIS was scolded, but not punished in any tangible way.

B. *The Effect of* Center for Food Safety

Center for Food Safety seems like a pretty easy case. There were clear statutory requirements, which APHIS blatantly ignored.[257] Since there were no damages nor an injunction imposed,[258] one would think that the discussion over this case would have ended once the decision was published. However, it has not. APHIS has since unsuccessfully sought to challenge Judge Seabright's ruling, and plaintiffs, including Center for Food Safety, are pursuing more lawsuits against APHIS in other states.[259] The hype over this case indicates that the role of the federal judiciary in monitoring the debate over genetically modified food is far from over. Both the activists and agencies see statutes such as the ESA and NEPA as a way for the federal judiciary to influence policy in the realm of biotechnology.[260] If opponents of GM are able to win future lawsuits, other remedies such as injunctions prohibiting the planting of certain GM crops are likely to follow. Thus, the stakes remain high.

While on its face the reasoning in *Center for Food Safety* looks correct, APHIS nevertheless came back to court to argue that the ESA does not require them to obtain a species list from the

254. *Id.*

255. *Id.* at 1195. Judge Seabright also noted that an injunction would be useless because APHIS was already required to comply with the NEPA, ESA, and the APA. *Id.* at 1196.

256. *Id.*

257. *See id.* at 1182.

258. *See supra* notes 236-39, 249-51 and accompanying text.

259. *See infra* notes 261-71 and accompanying text.

260. *See infra* notes 272-74.

Fish and Wildlife Service or the National Marine Fisheries Service.[261] In a motion to amend, APHIS attacked Judge Seabright's interpretation of the ESA and argued that the species list requirement is only triggered if the action is a "major construction activity,"[262] in which case a biological assessment is also required.[263] However, upon review of the statutory text, Judge Seabright concluded that this argument was without merit.[264] The ESA first refers to the species list requirement and then later mentions the biological assessment.[265] While the statute confusingly contains the species list requirement under the subheading of "Biological Assessment," the language of the statute unequivocally states that a species list must be obtained, regardless of whether a biological assessment turns out to be necessary.[266] Thus, the ruling against APHIS remains on the books.[267] However, the question remains, why did APHIS craft another argument and file a motion to amend the judgment? After all, the requirements of the ESA and NEPA are easy to comply with and the only remedy granted in *Center for Food Safety* was declaratory relief.[268] There must have been a reason for APHIS to invest more time and money in the *Center for Food Safety* litigation, even though the plaintiffs were not granted any compensatory or injunctive relief.

A look to California sheds light on why APHIS was eager to have the *Center for Food Safety* opinion overturned. In *Geerston Farms v. Johanns*,[269] a federal lawsuit in California, more claims alleging violations of the ESA and NEPA have been brought against APHIS.[270] In fact, plaintiff's motion for summary judgment relies heavily upon the ruling of the court in *Center for Food Safety*.[271] While this authority is not binding in California,

261. Center for Food Safety v. Johanns, No. 03-621, 2006 U.S. Dist. LEXIS 74431, at *11 (D. Haw. Oct. 11, 2006).

262. A "major construction activity is a construction project (or other undertaking having similar physical impacts) which is a major Federal action significantly affecting the quality of the human environment." 50 C.F.R. § 402.02.

263. *Center for Food Safety*, 2006 U.S. Dist. LEXIS 74431, at *11-12.

264. *See id.* at *12.

265. *Id.* at *12-13 (citing 16 U.S.C. § 1536(c)).

266. *Id.* at *12-13.

267. *See id.*

268. Center for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1195 (D. Haw. 2006).

269. Geerston Farms, Inc. v. Johanns, 439 F. Supp. 2d 1012 (N.D. Cal. 2006).

270. These include charges against both the EPA and APHIS. *Id.*

271. In this case, charges against the EPA were dismissed for lack of subject matter jurisdiction, however the claims against the USDA for, amongst other things,

it provides judicial insight into how to construe APHIS's responsibilities under ESA and NEPA.

In addition to precedential value, the existence of other lawsuits shows that APHIS's violations of the ESA and NEPA in Hawaii might not stand alone. The California lawsuit is based on the same grounds asserted in *Center for Food Safety* and reveals that ignorance of the ESA and NEPA more likely reflects APHIS's longstanding practice rather than isolated instances of noncompliance. Plaintiffs like Center for Food Safety are not content with only one ruling against APHIS.[272] Should a string of ESA and NEPA violations be found, the federal judiciary will necessarily become active in influencing USDA. For example, courts could strike at the heart of the USDA's autonomy by issuing injunctive remedies that revoke permits or force the USDA to conduct environmental studies.[273] Similarly, compensatory remedies could indirectly influence the USDA by shedding light on their insufficiencies and exerting pressure on Congress to fix the current regulatory framework.[274] Thus, activists may have found a new realm to voice their grievances about biotechnology.

VI.
MOVING FORWARD

The decentralized nature of the system currently in place for regulating GM crops has outlived its usefulness. Despite the increasing prevalence of GM crops, changes in technology, and growing public concern, the American government continues to discount the risks of GE crops.[275] The *Center for Food Safety* opinion is likely the first in a string of attacks against the inadequacies of the agencies responsible for regulating biotechnology.[276] Although the court did not impose any penalties upon APHIS aside from declaratory relief, it left open the possibility of other remedies in future cases, such as revocation of planting

violations of the ESA and NEPA remain pending. *Id.* at 1023. Unsurprisingly, in plaintiffs' motion for summary judgment in this suit, *Center for Food Safety v. Johanns* is cited seven times. *See id.*

272. *See supra* notes 269-71 and accompanying text.

273. *See* Center for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1195-96 (D. Haw. 2006) (Judge Seabright's discussion of possible remedies available).

274. To date Congress has ignored this opportunity, *see supra* notes 82-93, but the more violations against APHIS that are found, the more difficult it will be to write off concerns over the USDA's efficiency in the realm of biotechnology.

275. *See supra* notes 54-71, 81 and accompanying text.

276. *See supra* notes 272-73 and accompanying text.

permits and environmental studies of the effects of GM crops on endangered species and the environment.[277] Should agencies comply with the requirements of statutes like the ESA and NEPA on their own and "successfully manage[ ] the risks and benefits associated with biotechnology, [the courts] may play only a supporting role; otherwise, courts have to step into the breach, so to speak, and allow private litigants to help shape public policy in their field."[278] A review of agency history leaves little reason to be optimistic that the agencies responsible for regulating biotechnology will enact reform on their own, and therefore, the federal judiciary will likely become a major player in forcing agency compliance.[279]

Since the advent of GE, the American government has largely ignored the arguments by opponents that GM crops may propose novel risks to human health and the environment, and instead left in place a "patchwork arrangement" that divides responsibility amongst three agencies.[280] This incomplete framework has remained unaltered for nearly twenty years, and the judiciary has been characterized by deference to the USDA, EPA, and FDA's interpretations of their own authority.[281] Amongst the agencies themselves, regulatory authority is unclear and lines of enforcement are often blurred.[282] The agencies have continued the long-standing American practice of writing off the public's concerns, by adopting a passive role and refusing to impose labeling requirements on GM food.[283] The current regulatory system is typified by self-enforcement and lax regulations.[284]

While there have been multiple GE disasters, including the contamination of food crops by biopharmed crops, the agencies have done very little to prevent reoccurrences.[285] Thus, the possibility of a large-scale GE disaster continues to loom.[286] Until quite recently, the public seemed powerless to effect change in the GE regulatory system.[287] However, the *Center for Food Safety* opinion constitutes an example of how the public and fed-

277. *See supra* notes 255-56 and accompanying text.
278. *Noah, Biotechnology's Revolution*, *supra* note 3, at 53.
279. *See supra* Part III.
280. *See supra* notes 81, 86 and accompanying text.
281. *See supra* notes 92-93, 163 and accompanying text.
282. *See supra* notes 84-85 and accompanying text.
283. *See supra* notes 151-58 and accompanying text.
284. *See supra* note 114 and accompanying text.
285. *See supra* Part IV.
286. *See supra* notes 216-17 and accompanying text.
287. *See supra* note 81 and accompanying text.

eral judiciary can have a voice in the debate over genetically modified food.[288] By looking to agencies' statutory duties under congressional acts like the ESA and NEPA, opponents of GM are able to bring the agencies' neglect of their duties to center stage. The vehemence with which the defendants contested the ruling in *Center for Food Safety* shows that this is an opinion of potential importance.[289]

APHIS' erroneous interpretation of its responsibilities under ESA and the fact that another lawsuit has already been brought on the same grounds as *Center for Food Safety* reveal that this issue is far from over.[290] Moreover, more than twenty years of haphazard, spotty regulation, coupled with resistance to change, gives reason to be skeptical that agencies will suddenly engage in massive reform. Thus, the federal judiciary will likely come to play a crucial role in critiquing the sufficiency of agency oversight in the regulation of biotechnology. It is in this forum that the public will have a chance to bring to light their grievances with the current regulatory system.

While courts will continue to defer to agency's judgments about their own interpretations of their statutorily delegated power, violation of other congressional acts like the ESA and NEPA calls attention to the inadequacies of the agencies responsible for regulating biotechnology.[291] In the forum of the federal judiciary, opponents of GE are able to show that the complaints about poor enforcement are more than mere rhetoric. Instead, violations of congressional statutes constitute proof that there is something wrong with the current regulatory system. In this context the federal judiciary has the ability to craft policies that go beyond the ESA and NEPA, and instead directly touch upon GM regulation. Remedies such as damages, injunctive orders revoking GE permits, and specific relief requiring the regulatory agencies to conduct environmental studies, will influence the inner workings of the agencies responsible for regulating GM crops. It is through this avenue that the federal judiciary will come to be a crucial player in the discussion about GM crops.

288. *See supra* Part V.
289. *See supra* notes 261-68 and accompanying text.
290. *See supra* Part V.B.
291. *See supra* Part V