"Show-Me" No Rice Pharming: An Overview of the Introduction of and Opposition to Genetically Engineered Pharmaceutical Crops in the United States

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"SHOW-ME" NO RICE PHARMING: AN OVERVIEW OF THE INTRODUCTION OF AND OPPOSITION TO GENETICALLY ENGINEERED PHARMACEUTICAL CROPS IN THE UNITED STATES

Jillian S. Hishaw[*]

I. INTRODUCTION

Farmers in California and Missouri have one thing in common—opposition to the production of genetically modified (GM) "pharma" crops.[1] A pharmaceutical crop, or "pharma" crop, is a plant that has been genetically altered so that it produces proteins which are used as drugs.[2] Pharmaceutical companies can then harvest the crop and isolate the proteins, which may be used to make

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1. David Bennett, *Ventria BioScience hits roadblocks in Missouri*, DELTA FARM PRESS, May 20, 2005, at 16.

2. *See* Genetically Engineered Pharmaceutical and Industrial Crop Safety Act of 2005, H.R. 5267, 109th Cong. § 2(1) (2006).

human or veterinary drugs. Farmers' fears include a variety of health and environmental hazards; in particular, they fear contamination of their regular crops and the associated market loss. These concerns surfaced in both states where Ventria Bioscience announced plans for production of pharma rice.[3]

Ventria is a biopharmaceutical corporation that utilizes pharma crop technology through rice production.[4] Using "proteins found in human saliva, tears, and mother's milk," Ventria grows rice as a host, later extracting the proteins for pharmaceutical purposes.[5] Ventria hopes to market its products for use as poultry feed and to treat topical wounds, dehydration, and diarrhea.[6] Ventria's pharma rice is just one example of this growing trend. This article discusses the complex interaction of local, state, and federal laws that regulate pharma crop production. It will then investigate past and present issues regarding the introduction of pharma crops. It will also discuss some significant incidents involving genetically engineered crops that, although they were not pharma crops, provide some important lessons for the future of pharma crop regulation.

II. INEFFECTIVE REGULATORY CONTROLS

Three federal agencies regulate biotechnology in the United States: the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA).[7] Despite the attention of those three agencies, the field of biotechnology is nevertheless inadequately supervised according to some critics.[8]

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3. Bennett, *supra* note 1.

4. *See* Ventria Bioscience, *About Us*, http://www.ventria.com/aboutus (last visited Mar. 16, 2008); *see also* Ventria Bioscience, *Technology Platform*, http://www.ventria.com/technology/default.asp (last visited Mar. 16, 2008).

5. Bennett, *supra* note 1.

6. BILL FREESE, FRIENDS OF THE EARTH (FOE), FOE BRIEFING PAPER: PHARMACEUTICAL RICE IN MISSOURI (Feb. 2005), *available at* http://www.foe.org/biopharm/biopharmMObriefing305.pdf.

7. For an overview of the regulatory process, see Ctr. for Biological Informatics, *United States Regulatory Agencies Unified Biotechnology Website*, http://usbiotechreg.nbii.gov (last visited Mar. 15, 2008).

8. *See generally* EARTHJUSTICE, DANGERS OF BIOPHARMING: THE GOVERNMENT'S FAILURE TO PROTECT PUBLIC HEALTH AND THE ENVIRONMENT, *available at* http://www.earthjustice.org/library/factsheets/biopharm.pdf; *see also* FOE, MANUFACTURING DRUGS AND CHEMICALS IN CROPS: BIOPHARMING POSES NEW RISKS TO CONSUMERS, FARMERS, FOOD COMPANIES AND THE ENVIRONMENT (2004), *available at* http://www.foe.org/biopharm/bioqanda.pdf.

Although each agency may have a specific task, lax regulation and a lack of enforcement have been problematic.

APHIS regulates the import, transportation, and field testing of genetically modified crops through a permitting procedure.[9] This procedure requires a developer or company to introduce evidence proving that the genetically engineered (GE) organism will pose no more of a risk than a common plant pest.[10] The developer may petition APHIS to grant the GE organism a non-regulated status, which allows the GE organism to be introduced into the U.S. without further APHIS supervision.[11] If APHIS rejects the petition for a non-regulated status, the developer must be approved for a permit to introduce the specimen into to the environment.[12]

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA regulates the sale, distribution, and use of pesticides that are bioengineered.[13] In addition, under the Toxic Substance Control Act (TSCA), the EPA monitors the entire regulatory spectrum of chemicals placed in commerce that are created for industrial use, including those derived from genetically modified organisms.[14]

The FDA determines food safety by attempting to regulate what types of products can be used in human food.[15] Under the Food, Drug, and Cosmetics Act (FDCA), the FDA requires that all food and feed manufacturers' products are safe and properly labeled.[16] Any food additives, including those derived from pharmaceutical crops, that are to be introduced into the food chain must receive FDA approval.[17] Although the FDA has a "zero tolerance" policy regarding the presence of plant-made pharmaceuticals and other contaminants from GE crops within the commercial food supply,

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9. Ctr. for Biological Informatics, *Roles of U.S. Agencies*, http://usbiotechreg.nbii.gov/roles.asp (last visited Mar. 15, 2008); *see also* United States Dep't of Agric. (USDA), *Biotechnology Permits: Notifications, and Petitions*, http://www.aphis.usda.gov/biotechnology/submissions.shtml (last visited Mar. 15, 2008).

10. USDA, *supra* note 9.

11. *Id.*

12. *Id.*

13. *See generally* 7 U.S.C. § 136 (2000); *see also* Ctr. for Biological Informatics, *supra* note 9.

14. *See generally* 15 U.S.C. §§ 2601-2692 (2000); *see also* Ctr. for Biological Informatics, *supra* note 9.

15. *See generally* 21 U.S.C. §§ 301-399 (2000).

16. *Id.*

17. *Id.* § 348.

the greatly-feared potential for cross contamination of nearby commercial crops still exists.[18]

Some food safety advocates are concerned about the ways in which the federal government is bending the rules to favor the production of genetically modified crops. For example, the Center for Food Safety argues that under the current APHIS permit provisions, the National Environmental Protection Act (NEPA), the Endangered Species Act (ESA), and the Migratory Bird Treaty Act (MBTA) are being violated.[19] Under NEPA, all federal agencies are required to complete an Environmental Assessment or Environmental Impact Statement before they proceed with any actions that may be detrimental to the environment.[20] NEPA compliance correlates with the ESA, which requires all federal agencies to request a list from the U.S. Fish and Wildlife Service containing all threatened or endangered species.[21] If a species or critical habitat is present, the agency must conduct a biological assessment in accordance with NEPA to determine if its actions would cause harm.[22] Unlike NEPA, the ESA contains a citizen suit provision which allows anyone to "enjoin any person, including the United States and any other governmental instrumentality or agency" who is in violation of any provision.[23] In addition, under the MBTA all federal agencies are prohibited from pursuing any type of action that may be considered a taking of a migratory bird.[24] Due to the nature of open-air fields, the potential for seed-eating birds to consume pharma rice that may cause harm to their habitat and survival is clearly present.[25] Addressing these very issues, the Ninth Circuit Court of Appeals has held that APHIS was in clear violation of NEPA and the ESA.[26]

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18. Letter from Avrid Hawk, Food Safety Comm'n Chairman, Nat'l Grain & Feed Assoc. to Dockets Mgmt., Food & Drug Admin. (FDA) (Feb. 6, 2003), *available at* http://www.ngfa.org/FSC_response_pharma_guidance2-6-03.pdf; *see also* Bennett, *supra* note 1.

19. Letter from Ctr. for Food Safety to Regulatory Analysis & Dev. & PPD at 2-5 (June 2, 2005), *available at* http://www.centerforfoodsafety.org/pubs/comments VentriaNorthCarolinaEA6.2.2005.pdf.

20. 42 U.S.C. § 4332(2)(C) (2000).

21. 16 U.S.C. § 1536(c)(1) (2000).

22. *Id.*

23. *Id.* § 1540(g)(1)(A).

24. *Id.* § 701.

25. Letter from Ctr. for Food Safety, *supra* note 19, at 3-4.

26. *See generally* Ctr. for Food Safety v. Veneman, 364 F. Supp. 2d 1,202 (D. Haw. 2006). In the case of *Center for Food Safety v. Veneman*, several non-profit organizations filed suit in a Hawaii District Court seeking declaratory and injunctive relief against several biotech firms that were undergoing permitted field testing of

In 2002, there were two incidents of pharmaceutical corn contaminating "500,000 bushels of soybeans in Nebraska and 155 acres of corn in Iowa."[27] These and other related incidents caused great concern. In 2003, while APHIS responded and began requiring all producers of genetically modified organisms (GMOs) to obtain permit approval for all field trials,[28] local governments still wanted

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pharmaceutical crops. *Id*. For several years, the court addressed standing issues, but the merits were finally decided in favor of the plaintiffs. Ctr. for Food Safety v. Johanns, 451 F. Supp. 2d 1,165 (D. Haw. 2006). The Center for Food Safety argued that the Animal and Plant Health Inspection Service (APHIS) violated several federal statutes including the Endangered Species Act (ESA), the National Environmental Protection Act (NEPA), and the Plant Protection Act. *Id.* Between 2001 and 2003, ProdiGene, Monsanto, the Hawaii Agriculture Research Center, and Garst Seed had genetically engineered pharmaceutical producing plant varieties (GEPPV) permits that were approved by APHIS. After reviewing each application, APHIS concluded that the potential risk of harm was controlled due to confined field testing. The court concluded that APHIS violated the ESA by not requesting a species list before pursuing its actions, since Hawaii has the largest number of protected species, making up twenty-five percent of all listed species. *Id*. at 1,181-82. Next, the court addressed whether APHIS violated NEPA by not completing an Environmental Assessment (EA) or Environmental Impact Statement (EIS). *Id.* Due to the unknown environmental and health effects surrounding pharma crops, the plaintiffs alleged that APHIS violated NEPA principles which require all federal agencies to assess the environmental impact of their action before they act. *Id*. at 1,175-76. The court concluded that APHIS's actions were arbitrary and capricious because it neglected to provide a reasonable explanation for not providing an EA or EIS. *Id*. at 1,183. Lastly, the court concluded that APHIS's actions denying the plaintiff's proposal for the implementation of new GEPPV regulations was not ripe, and that APHIS's denial of the plaintiffs' request for an immediate moratorium on field testing was not arbitrary and capricious. *Id*. at 1,166. The court opted not to grant injunctive relief since the field tests were completed years ago. *Id*. at 1,196.

27. FREESE, *supra* note 6.

28. BARBARA A. JOHNSON, CONGRESSIONAL RES. SERV., ISSUE BRIEF FOR CONGRESS, AGRICULTURAL BIOTECHNOLOGY: OVERVIEW & SELECTED ISSUES, CRS-15 (Dec. 8, 2004); *see also* NAT'L CORN GROWER'S ASSOC., AG BIOTECHNOLOGY REFERENCE GUIDE 36, *available at* http://www.ncga.com/biotechnology/pdfs/ReferenceGuide/guide.pdf.

Between 1991 and 2005, Monsanto had forty-four permits approved but discontinued operations in October 2003 due to "uncertainty of the longer-term rewards from a highly capital-intensive business." BILL FREESE & RICHARD CAPLAN, FOE & U.S. PUB. INTEREST RES. GROUP, PLANT-MADE PHARMACEUTICALS: FINANCIAL RISK PROFILE 2, 4 (Jan. 2006), *available at* http://www.foe.org/camps/comm/safefood/biopharm/RiskyBusiness.pdf. Stine Seed (formerly Prodigene) has been approved for twenty-seven permits. *Id.* at 2, 4. Ventria has been approved for fourteen permits. *Id.* at 2. Large Scale Biology had eleven permits approved before filing for bankruptcy in 2005. *Id.* at 2, 5. Crop Tech had seven permits approved before filing for bankruptcy in 2003. *Id.* at 2.

greater protection.[29] As will be discussed, states, counties, and local communities have tried to take action to protect their farm products by opposing the production of pharma crops within their borders.[30]

III. GENETICALLY MODIFIED CROP CONCERNS

Concerns over containment, lack of foreign market support, health, and environmental effects are just some of the issues surrounding resistance to genetically engineered (GE) crop production.[31] Because of the possibility of cross-contamination into the food supply through seed dispersal by way of wind or birds, the need for containment is critical.[32] If pharma crop production is in close proximity to large-scale farming operations, the possibility of contamination could become a reality.[33] Long-grain rice constitutes over ninety-nine percent of all rice grown in Missouri, and approximately half of this long-grain rice is being consumed by foreign markets; therefore, the presence of Ventria production in this state

29. APHIS regulations sometimes appear to take the side of industry over the concerns of others. One example of this bias is Confidential Business Information (CBI) claims by APHIS. Under CBI, biotech corporations like Ventria are allowed non-disclosure protection giving them the right to withhold the size or the location of the proposed testing sites. *See* Letter from Ctr. for Food Safety, Docket Nos. 05-006-2 and 05-007-2, Comments on Two Environmental Assessments on Permit Application Nos. 04-302-01r & 05-117-01r, June 2, 2005, at 3, *available at* http://www.centerforfoodsafety.org/pubs/commentsVentriaNorthCarolinaEA6.2.2005.pdf.

30. In the future, the ability of local governments to do so may be very limited. According to House Bill 4167, the National Uniformity for Food Act of 2005 is set up to amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to provide uniform food safety regulations. H.R. 4167, 109th Congress (2d Sess. 2005) (the bill has not passed the Senate as of Jan. 23, 2007 and no action has been taken). The federal government's preemptive powers would supersede all state regulations, prohibiting local governments from regulating the planting of pharma crops. *See generally id.*; *see also* DONNA V. PORTER, CONGRESSIONAL RES. SERV., CRS REPORT FOR CONGRESS, FOOD SAFETY: NATIONAL UNIFORMITY FOR FOOD ACT (2007), *available at* http://www.nationalaglawcenter.org/assets/crs/RL3359.pdf. If this bill passes, concerns regarding contamination will persist unless federal regulation and enforcement is strengthened, and states and local governments will no longer be able to act where the legislation is silent. *See id.* at 6, 7-10.

31. FREESE, *supra* note 6. Human genes that are inserted into pharmaceutical plants to create proteins are different from the natural human protein. This difference may cause the immune system to perceive the plant protein as a foreign body, thereby creating an autoimmune disorder deactivating "the body's natural version of the protein," allowing humans to become more susceptible to disease. *See id.* at 7.

32. *Id.* at 2-3.

33. *Id.* at 3-4.

was problematic.[34] For example, when Japan was informed about Ventria's production plans in California, the Japanese Rice Association stipulated to the California Rice Commission its refusal to purchase rice from the state.[35] The European Union has also become leery of the U.S. food supply.[36] The additional issues of liability and manufacturing cost are also concerns.[37]

A. Early Incidents

Three incidents revealed initial problems with contamination from GE crops: Starlink, Syngenta, and Prodigene. Aventis CropScience was the first company to make major headlines. Approved in 1998 for feed purposes only, Aventis CropScience's Starlink corn contained Cry9C protein, a pesticide against insects that feed on corn and a potential food allergen for humans.[38] Due to this trait, the EPA opted not to approve Starlink for human consumption;[39] however in September 2000, Starlink was discovered in retail taco shells.[40] Three billion dollars were spent to remedy the contamination, 500 million bushels of corn were found to be contaminated, and 300 food products were recalled.[41] Also, the clean-up process may never end because the U.S. food supply may always contain the genetic remnants of Starlink.[42]

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34. *Id.* at 4.

35. *Id.* at 5.

36. FREESE, *supra* note 6, at 4.

37. *Id.* at 1-8.

38. StarLink, *StarLink History: What is StarLink and why was it used*, http://www.starlinkcorn.com/History/What%20is%20StarLink%20corn.htm (last visited Mar. 16, 2008) (discussing the pesticide effects of Cry9C); *see also* StarLink, *History: Why was StarLink corn not approved for food use?*, http://www.starlinkcorn.com/History/WhywasStarLinkcornnotapproved.html (last visited Mar. 16, 2008) (discussing the potential effects on humans).

39. StarLink, *History: Why was StarLink corn not approved for food use?*, *supra* note 38.

40. William Lin, Gregory K. Price & Edward Allen, *StarLink: Where no Cry9C corn should have gone before*, 16(4) CHOICES 31 (2002), *available at* http://www.choicesmagazine.org/2002-4/2002-4-05.pdf.

41. Stephanie Simon, *Fearing a Field of Genes,* LOS ANGELES TIMES, Dec. 23, 2002, at 1-1; *see also* Lin, *supra* note 40, at 31.

42. *See* Anthony Shadid, *Genetically Engineered Corn Appears in One-Tenth of Grain Tests*, BOSTON GLOBE, May 3, 2001. "Aventis CropScience has said it has contained 99 percent of StarLink grown in 2000, requiring 1.7 million tests and forcing the rerouting of more than 8,000 trucks, 15,000 rail cars and 285 barges. Even then, company officials say they won't completely remove it from the corn supply any time soon." *Id.*

About one year later in 2002, pharmaceutical compounds were found in soybean crops headed for the nation's food supply that were grown in Nebraska and Iowa.[43] Prodigene, the maker of the drugs, was under permitted authority to grow test plots of a pharmaceutical corn that was designed to prevent diarrhea.[44] Due to the power of wind, seeds from the pharma corn had blown over into neighboring soybean fields becoming mixed in with the soybean supply prior to harvest near the testing area at both sites in Nebraska and Iowa, resulting in cross-pollination.[45] Harvested before the entire pharma corn crop was removed, 500,000 bushels of beans had to be destroyed.[46] In addition, due to the same discovery in Iowa, 155 acres of corn had to be destroyed as well.[47]

After the Nebraska contamination was discovered by a USDA inspector, Prodigene was fined $3.75 million to cover all of the clean-up costs.[48] With the government covering all of the initial expenses,[49] the USDA's enforcement of the fine seemed to be more accommodating rather than punitive. According to the *Washington Post*, "buying, transporting and burning the beans ultimately cost $3.5 million. . . . The company [was] not required to begin making payments for a year, and it will have two years to pay the money in quarterly installments, owing the government no interest on either the fine or the cleanup—totaling $3.75 million."[50] According to APHIS, after the Prodigene incident, it improved its permit restrictions to include "comprehensive confinement procedures, performance standards, and required monitoring/auditing practices for ensuring that out-crossing or commingling with other seeds and commodities are prevented."[51]

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43. Christopher Doering, *ProdiGene to spend millions on bio-corn tainting*, REUTERS, Sept. 12, 2002, *available at* http://www.planetark.com/avantgo/dailynewsstory.cfm?newsed+18935. The crop contained trypsin, used to treat diabetes, and another compound used to treat diarrhea. *Id.*

44. *Id.*

45. Simon, *supra* note 41.

46. *Id*.

47. *Id*.

48. Justin Gillis, *U.S. Will Subsidize Clean up of Altered Corn*, WASH. POST, Mar. 26, 2003, at E1.

49. *Id.*

50. *Id*. The state of Iowa invested six million dollars in Prodigene development. Freese, *supra* note 6, at 8.

51. Press Release, APHIS, USDA Investigates Biotech Company For Possible Permit Violations (Nov. 13, 2002), *available at* http://www.aphis.usda.gov/lpa/news/2002/11/prodigene.html.

However, if APHIS compliance methods were better streamlined, arguably, untested seed from another company would not have been on the market illegally for over three years.[52] Void of U.S. approval, from 2001 to 2004 Syngenta, a Switzerland-based corporation, shipped and distributed untested Bt corn to the U.S. under a product name that had already received governmental approval.[53] According to Bill Freese, research analyst with Friends of the Earth, "Syngenta's genetically engineered Bt10 corn has not been tested or approved for human consumption anywhere in the world."[54] With 165,000 tons of the corn sold as food and feed,[55] the fact that Syngenta did not inform the USDA until December 2004 and that the unapproved sale was not publicly announced until March 2005[56] makes one question whether the USDA really learned its lesson from the Starlink and Prodigene fiascos.

With nearly one billion dollars spent on the Starlink debacle, the need for stringent regulations is essential.[57] Foreign markets are not the only ones reluctant to approve pharma crops for human consumption; the FDA has also established a zero tolerance standard for pharma crops.[58] Despite the fact that the FDA has set a zero tolerance standard, the USDA supports pharma crop production by permitting open-air field trials.[59] During the past decade, the USDA has approved around 200 permit applications.[60]

One group that has learned from these past incidences is the food industry. After the recall of 300 food products due to Starlink,

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52. *See* Press Release, Ctr. for Food Safety, *Recalls Urged for Illegal Biotech Corn* (May 11, 2005), *available at* http://www.centerforfoodsafety.org/press_release5.11.2005.cfm.

53. *Id.*

54. *See id.*; *see also* David Hamilton, *Biotech's Dismal Bottom Line: More Than $40 Billion in Losses*, WALL ST. J., May 20, 2004, at A1 (noting that between 1990 and 2003, publicly-traded U.S. biotechnology firms' investors lost more than $40 billion).

55. Press Release, Ctr. for Food Safety, *supra* note 52.

56. *See* Colin Macilwain, *U.S. launches probe into sales of unapproved transgenic corn*, 434 NATURE 423 (2005).

57. Stuart Smyth et al., *Liabilities and Economics of Transgenic Crops*, 20 NATURE BIOTECHNOLOGY 537-41 (2002).

58. FREESE, *supra* note 6, at 2.

59. USDA, BIOTECHNOLOGY REGULATORY SERVICES FACTSHEET (Feb. 2006), *available at* http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/BRS_FS_pharmaceutical_02-06.pdf.

60. Union of Concerned Scientists, *Pharmaceutical and Industrial Crops: Questions and Answers About a Growing Concern* (Dec. 2005), http://www.ucsusa.org/food_and_environment/genetic_engineering/faqs-pharmaceutical-and-industrial-crops.html (last visited Mar. 17, 2008).

many large food corporations that once supported the efforts of biotechnology became opposed to open-field testing of pharmaceutical crops once the possibility of cross pollination became a reality.[61] The Grocery Manufacturers of America (GMA) described the Prodigene incident as "a small but telling example of the potential consequences of inadequate containment."[62] In its comments to the FDA regarding the proposed regulations of pharmaceutical crops, the GMA described the regulations as a good effort but pointed out the need for more stringent restrictions, penalties, enforcement, and larger buffer zones to aid in containment.[63] Overall, the GMA stated that the "FDA and USDA need to draw a bright line between commodity agriculture and drug manufacturing."[64] With these horror stories in mind, and with great concern about the preservation of foreign markets for our commodities, local governments have attempted to step in to protect their interests, going far beyond what the federal government has done.

B. The California Experience

Since 1997, Ventria has conducted USDA-approved field trials on up to ninety-three acres of land in Central Valley, California, producing GM rice to generate pharmaceutical products.[65] By 2004, however, efforts to begin production on additional California acreage was blocked because many residents did not support the production of pharma rice mainly due to concerns over contamination.[66] Ranked as the second-largest rice producing state, California is the only rice producing state in 2006 whose acreage numbers were not predicted to decrease, but rather to increase by 25,000 acres.[67] According to the California Rice Commission, California produces two million tons of rice annually, generating a $500 mil-

61. Grocery Mfrs. of Am. (GMA), *Food Industry Comments on Proposed FDA Regulations for Plant-Made Pharmaceuticals*, http://www.gmabrands.com/publicpolicy/docs/Comment.cfm?docid=1068 (last visited Mar. 16, 2008).

62. *Id.*

63. *See id; see also* GMA, *Membership: General Members List*, http://www.gmaonline.org/membership/general/generalmemlist.cfm (last visited Mar. 16, 2008) (listing members including Kellogg, General Mills, Kraft, and Gerber).

64. GMA, *supra* note 61.

65. FREESE, *supra* note 6, at 1.

66. *Id.*

67. Cal. Rice Comm'n, *About California Rice: California's Rice Growing Region*, http://www.calrice.org/e7b_cas_rice_growing_region.htm (last visited Mar. 16, 2008); Elton Robinson, *Below 3 million in 2006? U.S. rice acreage expected to drop*, DELTA FARM PRESS, Jan. 6, 2006, at 34.

lion dollar per year industry.[68] As the largest producer of short- and medium-grain japonica rice, most of California's rice exports are geared toward Asia, the Middle East, and Mediterranean markets.[69] As a result of fears of contamination due to Ventria's close proximity to non-GM rice production, California and federal authorities banned Ventria's bid to increase its production to 120 acres in the state.[70] Based on a 2004 violation, the USDA cited Ventria for growing its rice within 100 feet of human food, which is not sufficient under the USDA's mandatory isolation distance.[71] Even Delia Bethall, the Vice President of Ventria, admitted that "the possibility of the inadvertent introduction of LF164 [one variety of the pharma rice] at low, adventitious levels into commercial rice varieties" is possible.[72] Lastly, there is also evidence that Ventria lied to the California Rice Commission in regard to its FDA permit approval, when in fact the FDA had not even responded to the company's petition at that time.[73]

In 2004, Mendocino County banned all GM crop production.[74] According to section two of the ordinance, "[i]t shall be unlawful for any person, firm, or corporation to propagate, cultivate, raise, or grow genetically modified organisms in Mendocino County."[75]

C. The Missouri Welcome and Opposition

In response to the Mendocino County ordinance banning all GM crops, Ventria decided to relocate its production operations to a more "welcoming" state. After soliciting eight states, Missouri won the favor of Ventria by offering significant incentives.[76] Offering a $30 million subsidy package "to fund construction of facilities at Northwest Missouri State University at Maryville" plus a $5 million incentive to contribute to finance costs, Missouri seemed to be eager

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68. Cal. Rice Comm'n, *supra* note 67.

69. *Id.*

70. FREESE, *supra* note 6, at 1.

71. *Id.* at 3-4.

72. *Id.*

73. *Id.*

74. Terri Somers, *For Mendocino County, Natural's the Only Way to Grow: Voters make quirky Northern California region first in nation to shun bioengineered foods, but not everyone favors shutting out science*, SAN DIEGO UNION-TRIBUNE, May 2, 2004, at A1; *see also* Campaign for a GMO Free Mendocino County, *Vote Yes to Measure H: County Ordinance Prohibiting growing of Genetically Modified Organisms*, http://www.gmofreemendo.com/moreh.html (last visited Mar. 15, 2008).

75. Campaign for a GMO Free Mendocino County, *supra* note 74.

76. FREESE, *supra* note 6, at 1.

to maintain its high status in the biotechnology field.[77] Ventria applied for three USDA permits to grow its pharma rice in southeastern Missouri.[78] It made plans for approximately 204 acres of production at the onset, with future plans to grow up to 28,000 acres.[79]

Without notice from the state, Missouri residents began to hear reports of Ventria's plans to produce pharma rice in the southeastern region of the state.[80] Many rice farmers, ranchers, and other residents were not as welcoming as the Missouri legislature.[81] Comprised of nine counties and known as the "boot heel," southeastern Missouri is the primary location for rice production in the state.[82] Ranked fourth in state rice production in 2006, Missouri produced 7.1% of U.S. rice that year.[83] With a $100 million per year industry in their backyard, many farmers were very concerned when Ventria's plans to grow pharma rice became more than just a rumor in January 2005.[84] By April, Ventria's anticipated plans to plant 150 acres of pharma rice only seven miles from where commercial rice was grown became a reality.[85]

The risk of cross-contamination was the driving force behind farmer's opposition.[86] Due to domestic and international market fears, even the very perception of pharma crop growth within close proximity to commercial food crop production could lead many purchasers to reject Missouri rice. According to Bob Papanos, Vice President of International Programs for the U.S. Rice Producers Association, "folks overseas don't pay attention to the Missouri/Arkansas border," and instead, they believe the entire U.S. rice supply could potentially be or become contaminated.[87] As Greg Yielding, a field representative with the U.S. Rice Producers Association, stated, "[w]hen it comes to making a living, farmers know what

77. *Id.*
78. *Id.*
79. *Id.*
80. Bennett, *supra* note 1.
81. *Id.*
82. FREESE, *supra* note 6, at 2.
83. NAT'L AGRIC. STATISTICS SERV., USDA, *Farm Facts: Missouri's Rank Among States, 2006*, http://www.nass.usda.gov/Statistics_by_State/Missouri/Publications/Farm_Facts/2006/Rank_Among_States.asp (last visited Mar. 16, 2008).
84. Bill Freese, FoE, *Friends of the Earth Helps Missouri Farm Block Biopharm Rice* (2005), http://www.foe.org/annualreport2005/biopharm.html (last visited Mar. 17, 2008); *see also* Bennett, *supra* note 1.
85. Bennett, *supra* note 1.
86. *Id.*
87. *Id.*

works. They don't want . . . some bureaucrat with a lobbyist in his ear making decisions on what can be planted next door."[88]

After months of protesting to various state representatives, many farmers were frustrated with the democratic process. In April 2005, the farmers' fears of market opposition became a reality when Anheuser-Busch announced its threat of a boycott on all Missouri rice due to the presence of Ventria's pharma rice crops.[89] According to Busch's executives, there is a difference between herbicide-tolerant crops and pharma crops—"it's not regarded as safe, Busch would have to recall products if this [plant-made pharmaceutical] rice accidentally found its way [into food-grade rice]."[90] As a purchaser of six to ten percent of the annual U.S. rice supply,[91] Anheuser-Busch is reported to be the largest purchaser of domestic rice.[92]

Due to the enormity of Busch's purchasing power, within a week of the announced boycott, the Missouri Department of Agriculture announced a "compromise" that would exclude Ventria's plans of production.[93] As a result of this compromise, Ventria agreed to relocate its site 120 miles outside of the Bootheel area.[94] In measures to maintain its image and reduce any potential recall expense, Busch's opposition carried the weight of the farmers, allowing relief that would not have come without market opposition. Many farmers and advocates like Sonny Martin, chairman of the Missouri Rice Research and Merchandising Council, believe that "[Missouri's] decision wasn't based on what the producers wanted. The decision to move out of the Bootheel, in the end was based on what an end user, Busch wanted."[95] The fact that corporations like Busch believe that pharma crops are not considered to be safe is not an unsubstantiated claim, but now is a reality.

In early 2006, due to market pressures and a lack of state funding, Ventria decided to terminate its contract to move its operation

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88. *Id.*

89. David Bennett, *Missouri GMO Bill Pushed Back Agriculture Interests*, DELTA FARM PRESS, June 2, 2006, at 8.

90. Bennett, *supra* note 1.

91. Press Release, Greenpeace Int'l, Anheuser-Busch using experimental genetically-engineered (GE) rice to brew Budweiser (Oct. 8, 2007), *available at* http://www.greenpeace.org/international/press/releases/anheuser-busch-using-experimen.

92. Bennett, *supra* note 1.

93. Alexei Barrionuevo, *Biotech Plan in Missouri Suffers Setback*, N.Y. TIMES, Jan. 6, 2006, at C3.

94. *Id.*

95. *Id.*

to the anticipated Northwest Missouri State University facilities.[96] In a joint statement with the University, Ventria stated that its business objectives required setting up its "processing facilities in place sooner than possible."[97] Due to legislative hesitancy resulting in a failure to approve the original $10 million contribution, the University reduced its building projections which led Ventria to back out of the deal.[98] Whatever the reason, Ventria has now sought refuge in the state of North Carolina.[99] On March 7, 2006, the USDA approved Ventria's permit to plant up to seventy acres of pharma rice in North Carolina.[100]

Unfortunately for the farmers and concerned citizens, the battle against the Missouri legislature did not end with Ventria. During the spring of 2006, the Missouri Senate Agriculture Committee approved a bill that would prohibit the state and local municipalities from passing laws that would exceed the federal provisions.[101] In addition, the law also proposed giving the state total control over "the registration, labeling, sale, storage, transportation, distribution, notification of use, use, and planting of seeds and other propagules" to the exclusion of any local ordinance or regulation.[102] According to Rhonda Perry, the program director for the Missouri Rural Crisis Center, "[w]e, as local citizens, will be giving up all our rights."[103] Once again, after opposition from Busch, other companies, farmers, and ranchers, the legislature decided to exclude the preemptive language that would restrict local municipalities from passing laws that would regulate above the federal standards.[104]

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96. *Id.*

97. *Id*.

98. Barrionuevo, *supra* note 93.

99. *Id*.

100. APHIS, Biotechnology Regulatory Servs., *Applications Recently Submitted to North Carolina*, http://www.aphis.usda.gov/brs/status/cata_sta_nc.html (last visited Mar. 16, 2008); *see also* Hope Shand, *A growing stake in the biotech crops debate*, NEWS & OBSERVER (Raleigh, N.C.), May 19, 2005, at A15.

101. *See* Missouri Seed Law, S.B. 1009, 93rd Gen. Assem., 2d Reg. Sess. (Mo. 2006).

102. *Id.*

103. Chris Blank, Associated Press, *Senate Considers ban on Regulations for GM Crops*, Mar. 17, 2006, *available at* http://www.thecampaign.org/forums/archive/index.php/t-262.html.

104. *See* Bennett, *supra* note 89. Unfortunately, the same cannot be said for fifteen other states that, since 2004, have passed laws that prohibit local control over GMO crops. David Eggert, Associated Press, *Heated Debate Over Law That Would Prohibit Local GMO Bans in Michigan*, Jan. 29, 2006, *available at* http://www.organicconsumers.org/ge/michigan013106.cfm.

D. The Bayer Lawsuit

On August 18, 2006, Missouri farmers' fears came true when the USDA announced that a genetically engineered strain of Liberty Link 601 (LL601) had been detected in the rice supply at a Riceland mill in Arkansas.[105] Known as the world's largest rice mill and marketer, Riceland serves over 9,000 farmer-members in all the major rice states including Missouri, Louisiana, Mississippi, and Texas.[106] Located in northeast Arkansas, Riceland's location accommodates Missouri rice farmers. The strain was discovered by Riceland in January 2006 and was supposed to have been restricted to laboratory and field testing by Bayer.[107] Traced back to Arkansas, Missouri, Louisiana, and Texas as the source,[108] the minuscule amount of six grains in a thousand indicates how contamination can persist beyond the life of the GMO crop.[109] Designed to resist herbicides, LL601 was grown in test plots from 1998 to 2001 by Aventis CropScience, which was later taken over by Bayer in 2002.[110] According to a press release by Bayer on September 19, 2006, the protein that is contained within the rice had already been pre-approved by several countries in the European Union prior to this incident.[111] However, Bayer did admit that a similar incident in 2003 had taken place in Louisiana when trace amounts of LL601 were found in seed grown at a research station at Louisiana State University.[112] Commenting on its actions, Bayer stated it "believes that the company acted responsibly and in compliance with all applicable laws and regulations in this matter."[113] Bayer also stated it would "vigorously defend itself

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105. *Id.*; *see also* A. Bryan Endres & Justin G. Gardner, *Genetically Engineered Rice: A Summary of the LL Rice 601 Incident*, 06-04 AGRIC. LAW & TAX'N BRIEFS 1 (2006).

106. Riceland Foods, *About Riceland*, http://www.riceland.com/about (last visited Mar. 16, 2008).

107. Nancy Cole, *State's farmers want answers on tainted rice Harmed by export discovery, they say at Stuttgart meeting*, ARK. DEMOCRAT-GAZETTE, Aug. 24, 2006; *Thai Rice Exporters to Benefit on EU ban on Importing Genetically Modified Rice*, THAI PRESS REP., Oct. 24, 2006 [hereinafter *Thai Rice Exporters*].

108. *Thai Rice Exporters*, *supra* note 107.

109. Richard Burgess & Acadiana Bureau, *Company Accused of Letting Rice Strains into Commercial Fields*, BATON ROUGE ADVOCATE, Sept. 22, 2006, at B1.

110. Press Release, Bayer CropScience, Comments of Bayer CropScience on LLRICE601 as of September 19, 2006 (Sept. 19, 2006), *available at* http://www.bayercropscience.com/bayer/cropscience/cscms.nsf/id/20061004_EN?open&ccm=400.

111. *Id.*

112. *Id.*

113. *Id.*

against" the various class action suits that have been brought against it by rice farmers.[114]

In early September, rice farmers in all six rice-producing states—Arkansas, Missouri, Louisiana, Texas, Mississippi, and California—filed three different class actions suits against Bayer seeking damages.[115] The first lawsuit was filed in the Eastern District Federal Court in Arkansas where Riceland is located.[116] The second lawsuit was filed in St. Louis, Missouri, listing 229 plaintiffs who represent more than 125,000 acres of farmland.[117] The third lawsuit represents forty to fifty farmers who allege that Riceland failed to disclose the contamination when it was initially discovered, thereby failing to take proper preventive measures along with Bayer.[118] The first suit seeks compensatory and punitive damages against Bayer, including an injunction requiring Bayer to cover the cost of testing and clean-up.[119] Presumably, the second lawsuit seeks several million dollars in damages.[120] The third suit seeks $5 million in damages to compensate the farmers for the alleged resulting drop in the market price.[121] A complaint proposing to consolidate all three suits was filed on May 17, 2007, in the U.S. District Court for the Eastern District of Missouri; however, class certification has not yet been approved placing farmers in legal limbo.[122] In May 2008, the court will decide on certification, leaving the trial date set to begin in early 2009.[123]

Based on the USDA's lack of findings, Bayer will not be held federally liable leaving the pending civil action as the only means of recourse for U.S. farmers.[124] Unfortunately, U.S. farmers were not

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114. *Id.*

115. Lance Turner, *Six States, Arkansas farmers Sue Over Modified Rice*, 23(35) ARK. BUS. & ECON. REV. 10 (2006); *see also* Allison Retka, *Contaminated Rice Crops Spur Twin Class Action Suits in Missouri*, ST. LOUIS POST-DISPATCH, Sept. 19, 2006.

116. Turner, *supra* note 115.

117. Retka, *supra* note 115.

118. *Id.*

119. Turner, *supra* note 115.

120. *See* Kerri Walsh, *USDA Declares Bayer CropScience's Rice Safe*, CHEMICAL WEEK, Dec. 2006, at 34.

121. Robert Patrick, *Three Missouri Farmers Sue Bayer CropScience Over Genetically Modified-Rice Contamination*, ST. LOUIS POST-DISPATCH, Sept. 7, 2006, at E2.

122. David Bennett, *GM rice class co-counsels warn against quick decisions*, DELTA FARM PRESS, Aug. 17, 2007, at 10; *see also* David Bennett, *GM rice contamination leads to proposed class action*, DELTA FARM PRESS, May 25, 2007, at 6.

123. *Id.*

124. Press Release, FoE, US Investigation over GM rice Contamination lets Bayer off the Hook, (Oct 8, 2007), *available at* http://www.foe.co.uk/resource/press_releases/us_investigation_over_gm_r_09102007.html.

the only parties affected by the contamination; many United Kingdom grocers found traces of GE rice in their stores.[125] Ironically, despite its initial opposition, Anheuser-Busch is reportedly using the contaminated rice for production of Budweiser according to a Greenpeace report released in October 2007.[126] An independent laboratory study sponsored by Greenpeace, a non-profit environmental advocacy organization, found the presence of the illegal GE rice strain in three out of four samples taken from a mill used in production of Budwiser and operated by Anheuser-Busch,[127] the same company that threatened to boycott Missouri rice if Ventria production proceeded. With thirty percent of the U.S. rice crop containing the contaminated rice strain,[128] Busch's use of GE rice does not improve the public perception of US rice which "supposedly" was Busch's sole reason behind its initial opposition to Ventria. In response to the findings, Busch stated that the GE rice is only used in domestic, not export, production.[129] Whether Busch's actions are seen as hypocritical or profit saving, the fact remains that this incident has internationally ostracized the U.S. rice industry despite the government's failure to assign fault.[130]

Ranked as the number one district in "rice production, number four in cotton, and among the top ten in soybeans," the Eastern District of Arkansas is losing billions of dollars due to Europe's overreaction according to Representative Marion Berry.[131] Whether described as an overreaction or a reasonable response, the countries of the European Union have not taken the matter lightly, and their response is illustrative of the European belief that the U.S. has not taken the matter seriously enough. Two days after the USDA's announcement, experts estimated that farmers lost $150 million in trading.[132] Even after a month, the market price for rice was at $9.26 per 100 pounds at the Chicago Board of Trade, compared to $10.38 per 100 pounds prior to the incident.[133] With more than 100 rice

125. *Id.*
126. Press Release, Greenpeace Int'l, *supra* note 91.
127. *Id.*
128. *Id.*
129. *Id.*
130. *Id.*
131. Press Release, Marion Berry (1st Dist. Ark.), Berry Calls for Investigation into Ban on U.S. Long Grain Rice Imports (Aug. 24, 2006), *available at* http://www.house.gov./berry/pressreleases/archive/2006/riceinvestigation.html.
132. David Bennett, *Industry Leaders Address GM Rice Imbroglio*, SOUTHWEST FARMPRESS, Sept. 21, 2006, at 9.
133. *See* Retka, *supra* note 118.

varieties grown primarily in six states and estimates of the 2006 rice crop valued at $1.88 billion,[134] the reaction from farmers is understandable. The U.S. represents twelve percent of the world's rice trade, and eighty percent of U.S. rice consists of the contaminated long-grain rice.[135] Sixteen European countries, the Philippines, and Japan have banned the import of U.S. GE rice.[136] Thailand has reaped much of the benefit. According to Wanlop Pitchyapongsa of Capital Rice, a major exporter in Thailand, "[w]e've got more orders from Europe to replace those which would otherwise have gone to the US."[137] Annually, Thailand ships around 7.5 million tons of rice per year, which has an estimated value of $80 billion.[138] Priding itself on having no GE rice research facilities, Thailand's status will undoubtedly continue to flourish in Europe as the U.S. continues to experiment with genetic modifications such as pharma crops without having adequate controls in place.[139]

IV. CONCLUSION

With the need for present regulations to become more restrictive and the urgency to create additional regulations, the federal government's insufficient role in regulating genetically engineered crops is not only publicly obvious but dire. Unfortunately, incidents such as the Starlink and Prodigene scandals are just a few examples of what can happen when the federal government negligently regulates an industry. Allowing companies like Ventria to hopscotch from state to state under permit approval to plant pharmaceutical-producing organisms near commercial food supplies is frightening but yet acceptable under the current federal regulations. The label of "government approved" no longer symbolizes a sense of safety, but instead reflects corporate interests, which often seem to be the U.S. priority.

Since 1997, Ventria has persisted in its quest to radicalize grain rice into a pharmaceutical tool that it anticipates will save both

134. USDA, *Fact Sheet: Genetically Engineered Rice* (Aug. 2006), http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2006/08/0306.xml (last visited Mar. 16, 2008).

135. *Id.*

136. *Thai Rice Exporters*, *supra* note 107.

137. *Id.*

138. *Id.*

139. *See id.*

money and lives.[140] Sadly, knowing that experimentation with human genetics could lead to immune deficiencies, allergic reactions, and environmental defects has not deterred Ventria and others in their efforts, forcing the public to face a future with unknown side effects.

140. *See* Mark Gunther, *Attack of the Mutant Rice*, FORTUNE, July 9, 2007, at 74, 77-78.