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PROTECTING THE INTEGRITY OF ORGANIC FOOD IN THE FACE OF
GENETIC ENGINEERING:
THE CASE OF ROUNDUP READY ALFALFA

By

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Bachelor of Arts, University of Wisconsin, La Crosse, Wisconsin 2002

Thesis

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Abstract

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Genetically engineered (GE) seeds are central to the debates around agricultural biotechnology, and continue to be rapidly adopted across the globe. At the same time that GE crops increase in acreage, the organic market has become one of the fastest growing sectors of the American food industry. While biotechnology companies claim there is a successful “coexistence” of GE crop technologies and organic crops, many organic producers are already challenged by keeping unwanted GE traits out of their fields. Still, little attention has been given to the role of regulations in the face of organic contamination by genetically engineered material. This paper looks at the National Organic Program (NOP) and Coordinated Framework for the Regulation of Biotechnology, and analyzes whether they are adequate for protecting the integrity of organic food in the face of genetic engineering, using a relatively new GE crop, Roundup Ready (RR) alfalfa, as a case study. Alfalfa is an essential component to the organic livestock industry, especially to organic dairy, where the demand has grown faster than the supply. This paper reveals that the organic alfalfa industry is at risk of contamination by RR alfalfa, and that part of the risk can be attributed to the inadequacy of the two regulatory frameworks, as both do not go far enough to keep GE crops contained and the integrity of organic products protected. These findings resulted from an extensive review of the pertinent laws and regulations, a review of the U.S.’s experience with GE crop technology, and research into the potential implications of introducing RR alfalfa. Recommendations include making changes to the two frameworks’ approach to regulation, including: making improvements to the regulation of GE crops both before and after they enter the marketplace; encouraging discussion within the organic industry about current threats to the integrity of organic, and the pros and cons of establishing a tolerance level and testing system; and taking a precautionary approach to RR alfalfa by performing a full Environmental Impact Statement (EIS), and pulling it from the market until all risks are addressed.

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INTRODUCTION

The advent of agricultural biotechnology in the mid-1980s was met by both enthusiasm and criticism, and continues to spark debate across the globe. Genetically engineered (GE) seeds are central to these debates, which have drawn attention to a variety of social and ecological issues that have as much to do with science as they do with cultural values and ethics. Even in light of these debates, GE seeds continue to be readily adopted. For instance, in 2000, 54 percent of soybeans planted in the U.S. were a GE variety; by 2006, this percentage was 89 percent.¹ More GE plantings are taking place abroad, too. In 2005, 21 countries planted GE crops on over 220 million acres, an 11 percent increase from 2004 (or 22 million acres).² The Grocery Manufacturers of America estimates that 70 percent of food on grocery shelves contains ingredients from GE crops.³

Genetic engineering differs tremendously from traditional breeding mechanisms. The National Research Council cites the general definition of a genetically engineered organism as “an organism that has been modified by the application of recombinant DNA technology.”⁴ Unlike other breeding methods, genetic engineering operates at the cellular and molecular level, and makes it possible to select and transfer a single gene, sometimes between unrelated species.⁵ For example, herbicide-tolerant plants are engineered to express a gene derived from a soil bacterium, and other examples (though not on the market) include tobacco and jellyfish genes in tomato plants and a soybean gene in

¹U.S. Department of Agriculture, Economic Research Service. (2006). Adoption of Genetically Engineered Crops in the U.S.: Soybeans, Retrieved May 2, 2006, from <http://www.ers.usda.gov/data/biotechcrops/extentofadoptiontable3.htm>

² International Service for the Acquisition of Agri-biotech applications. (2005). ISAAA Briefs No. 34-2005, Retrieved on May 3, 2006, <http://www.isaaa.org/kc/bin/briefs34/es/index.htm>

³ Barboza, David. (2000, June 4). Modified foods put companies in a quandary [Electronic version], *The New York Times*, Retrieved May 5, 2006, <http://www.nytimes.com/library/national/science/health/060400food-quandry-health.html>

⁴ National Research Council. (2004). *Biological Confinement of Genetically Engineered Organisms*, Washington, DC: The National Academies Press.

⁵ Ibid.; The process and products of recombinant DNA (rDNA) technology is referred to by several names, including “genetically engineered (GE),” “genetically modified (GM),” “genetically modified organism (GMO),” “bioengineered,” “biotech,” and “transgenic.” These labels are interchanged throughout this paper, but preference is given to “genetically engineered” and “transgenic.”

lettuce.⁶ Although agricultural biotechnology encompasses a host of organisms, including fish, insects, and animals, for the purposes of this paper, I will focus on the regulation of GE plants, specifically those engineered to tolerate the popular herbicide, Roundup (generic name of the active ingredient is glyphosate).

Almost all GE crops currently on the market fall under the “first generation” category of plants, which provide farmer-oriented traits, such as herbicide-tolerance, virus-resistance, and insect-resistance. The vast majority of these varieties involve corn, soybean, canola, and cotton plants. Few GE fruits and vegetables have been approved for commercial sale. In fact, many of these are no longer on the market despite regulatory approval. “Second generation” GE crops are engineered to express traits specific to nutritional and pharmaceutical composition—“consumer-oriented” traits. The first of these next generation plants is a soybean intended to reduce or eliminate trans fatty acid in a variety of food products.⁷

While biotechnology companies claim there is a successful “coexistence” of GE seed technologies and conventional⁸ (non-GE) seed, opponents of genetic engineering believe the technology poses serious challenges for organic producers,⁹ and, according to a leading agroecologist, is one of the main barriers to achieving a truly sustainable agriculture.¹⁰ At the same time that there is increased adoption of GE crops, the organic market has become one of the fastest growing sectors of the American food industry.¹¹ The United States Department of Agriculture (USDA) estimates it is growing by 20

⁶ Gene information taken from an overview of California field trial data at the Information Systems for Biotechnology website. (2006). “Field Test Releases in the U.S.,” Retrieved on November 16, 2006 from, (<http://www.isb.vt.edu/cfdocs/fieldtests1.cfm>)

⁷ USA: Kellogg moves to low linolenic oil to cut trans fats, (2005, December 9). Retrieved on May 2, 2006 from <http://www.organicconsumers.org/ge/soyoil121205.cfm>

⁸ Throughout this paper, I refer to seeds derived from traditional breeding methods as “conventional” or “non-GE.”

⁹ Numerous producers throughout the world farm organically and rightfully call themselves organic farmers, yet choose not to be certified. For purposes of this paper, “organic producer” or “organic farmer” generally refers to those who are certified and regulated under the NOP.

¹⁰ Altieri, Miguel A. (2001). *Genetic Engineering in Agriculture: The Myths, Environmental Risks, and Alternatives*, Oakland, CA: Food First Books.

¹¹ U.S. Department of Agriculture, Economic Research Service. (2006). Organic agriculture gaining ground [Electronic version], Retrieved on April 20, 2006 on www.ers.usda.gov/amberwaves/feb03/findings/organicagriculture.htm.

percent or more each year, with some individual sectors, such as organic dairy, growing by 60 percent in some parts of the country.¹² In 2003, the U.S. recorded over two million acres of certified organic farmland, a 63 percent increase from 1997.¹³ Because the USDA National Organic Program (NOP) does not allow GE seed and feed in certified organic systems, consumers rely on organic products as alternatives to food products that contain GE ingredients.¹⁴

Many organic producers are already challenged by keeping unwanted GE traits out of their fields, and feel coexistence is premised on the unfounded belief that non-GE markets will accept an increasing amount of GE material in products.¹⁵ In June 1999, the British government's Ministry of Agriculture, Fisheries, and Food released a report that showed wind-borne pollen and bees could carry GE genes for miles, raising concerns that it might become impossible to guarantee foods as GE-free.¹⁶ Several recent events validate this concern,¹⁷ including the discovery of an unapproved rice variety in the U.S. food supply, half of which is exported.¹⁸ This announcement in 2006 caused Japan to halt

¹² U.S. Department of Agriculture, Economic Research Service. (2006). Organic agriculture gaining ground [Electronic version], Retrieved on April 20, 2006 on

www.ers.usda.gov/amberwaves/feb03/findings/organicaagriculture.htm; Mack, S.K. (2005, July 23). Demand exceeds supply of organic milk in Maine [Electronic version], *Bangor Daily News*, Retrieved on April 12, 2006, from <http://pqasb.pqarchiver.com/bangor/access/871509821.html?dids=871509821:871509821&FMT=ABS&FMTS=ABS:FT&date=Jul+23%2C+2005&author=SHARON+KILEY+MACK&pub=Bangor+Daily+News&edition=&startpage=1&desc=Demand+exceeds+supply+of+organic+milk+in+Maine>

¹³ U.S. Department of Agriculture, Economic Research Service. (2006). Data Sets: Organic Production, Retrieved on October 5, 2006 (<http://www.ers.usda.gov/Data/organic/>)

¹⁴ In 1997, USDA received over 280,000 comments (mostly from consumers) opposing the agency's inclusion of genetically engineered organisms within its definitions of what constitutes "organic" in its proposed NOP rule.

¹⁵ Vermont Public Interest Research Group. (2003, December). *Blowing in the Wind, The Road to Extinction for Vermont's Organic Farms: Testing Confirms Genetic Pollution of Organically Grown Corn* [Electronic version], Montpelier, VT: Author, Retrieved on April 17, 2006, from www.gefreevt.org/images/downloads/blowing%20in%20the%20wind%20report.pdf

¹⁶ Waugh, P. (1999, June 16). Official Data Reveals GM Crop Risks [Electronic version], *UK Independent*, Retrieved on April 12, 2006, from http://www.intekom.com/tm_info/rw90620.htm#06

¹⁷ GeneWatch UK and Greenpeace International. (2005). *GM Contamination Report, A Review of Cases of Contamination, Illegal Planting, and Negative Side Effects of Genetically Modified Organisms*, Retrieved on April 1, 2006 from www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/gm_contamination_report.pdf

¹⁸ Weiss, Rick. (2006, November 6). Biotech rice saga yields bushel of questions for feds [Electronic version], *The Washington Post*, Retrieved on November 10, 2006, from <http://www.washingtonpost.com/wp-dyn/content/article/2006/11/05/AR2006110501092.html>; Transgenic rice discovery disrupts U.S. exports [Electronic version]. (2006, August 29). *Food Chemical News*,

rice imports from the U.S., and rice growers affected by the contamination wasted no time in filing a lawsuit against Bayer CropScience, the manufacturer of the rice variety.¹⁹

My research question is especially interesting and timely in light of a recently approved GE alfalfa variety. In June 2005, the U.S. Department of Agriculture (USDA) announced its approval of Roundup Ready (RR) alfalfa, a genetically engineered variety that tolerates glyphosate, the main ingredient in the Monsanto Company's trademark herbicide, Roundup. It is the first genetically engineered perennial plant to be commercialized for widespread planting in the U.S., and was produced by Monsanto in partnership with the largest alfalfa seed company, Forage Genetics International (a subsidiary of Land O'Lakes).²⁰

Alfalfa is an essential component to the organic livestock industry. Milk cows accounted for over half of the total number of certified animals in 2001, and the total number of certified organic livestock, including beef cattle, pigs, sheep and lambs, increased by 572 percent between 1997 and 2003.²¹ Several events show the demand for alfalfa-derived organic products is growing. For example, in 2005, California experienced a shortage in organic feed, and is looking to North Dakota to increase production of corn, soybeans, barley, peas and alfalfa.²² California currently has to import organic feed from China and South America to meet its rapidly growing demand for organic livestock and poultry markets. The U.S. is also experiencing a shortage in organic milk.²³ While the shortage is mostly attributed to a lack of certified organic cows, this demand is implicitly coupled with a need for more organic alfalfa hay.

Retrieved on November 10, 2006, from

<http://pewagbiotech.org/newsroom/summaries/display.php3?NewsID=1020>

¹⁹ Weiss, Rick. (2006, November 6). Biotech rice saga yields bushel of questions for feds [Electronic version], *The Washington Post*, Retrieved on November 10, 2006, from

<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/05/AR2006110501092.html>;

²⁰ Genetically engineered papaya, grown primarily in Hawaii, is also a USDA-approved perennial GE plant.

²¹ U.S. Department of Agriculture, Economic Research Service. (2006). Data sets: organic production [Electronic version], Retrieved on October 5, 2006, from <http://www.ers.usda.gov/Data/organic/>; (Total certified organic livestock equaled 18,513 in 1997, 74,435 in 2003.)

²² California organic farmers looking to North Dakota for feed. (2005, May 10). *Valley City Times-Record*.

²³ Weinraub, J. & Nicholls, W. (2005, June 1). Organic Milk Supply Falls Short [Electronic version], *Washington Post*, Retrieved on June 20, 2005, from <http://www.washingtonpost.com/wp-dyn/content/article/2005/05/31/AR2005053100363.html>

My interest in this topic stems from over five years of research and work in the non-profit sector on agricultural biotechnology issues. I developed an interest in the regulation of GE crops during a two-year position at the Center for Food Safety, a non-governmental organization headquartered in Washington, DC that encourages the U.S. government to take a precautionary approach to GE technologies, often through legal initiatives. I began researching RR alfalfa almost two years ago, when I began to follow the development of the new variety for a paper in a graduate course, and subsequently continued the research through a fellowship at the Western Organization of Resource Councils in Billings, MT. There, I researched the development of RR alfalfa; talked to organization members (ranchers who grew or were familiar with alfalfa production) about their perspectives on RR alfalfa; wrote newsletter articles and memos on the potential implications of introducing RR alfalfa; gave presentations on RR alfalfa to chapter groups around the West; and wrote a publication entitled *A Guide to Genetically Modified Alfalfa*.²⁴

While there are a lot of controversies around agricultural biotechnology and the organic standards, little attention has been given to the role of regulations in the face of organic contamination by genetically engineered material. An important exception is attorney Michelle Friedman's law review article on contamination issues in the context of the NOP: *You call that organic? The USDA's misleading food regulations*, which has been a valuable resource in my research. The purpose of this paper is to look at two regulatory frameworks—the NOP and Coordinated Framework—and identify if they protect the integrity of organic products in the face of genetic engineering, using RR alfalfa as a case study. That is, are the frameworks sufficient for keeping the two burgeoning industries separate in the field and marketplace?

This paper is divided into three chapters. Chapter one gives an overview of the NOP and Coordinated Framework, and describes how they address genetically engineered crops. In 2002, USDA introduced the NOP, the first federal standards to be implemented for the

²⁴ Hubbard, Kristina. (2006). *A guide to genetically modified alfalfa*, Western Organization of Resource Councils, www.worc.org/issues/art_issues/alfalfa_guide/alfalfa_guide.html.

purpose of providing a uniform organic standard given the previous patchwork of certification, and to protect the integrity of, and consumers' confidence in, certified organic food. When GE crops were introduced, no new laws were implemented to regulate them. Instead, three government agencies—USDA, Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA)—regulate GE crops under a patchwork of existing laws, most notably the Food, Drug, and Cosmetics Act; The Federal Insecticide, Fungicide, and Rodenticide Act; The Toxic Substances Control Act; and the Federal Plant Protection Act.

Chapter two explores the case of RR alfalfa by first describing the regulatory process that Monsanto and Forage Genetics went through to introduce it, followed by an analysis of the potential implications of introducing it, including agronomic, environmental, and economic effects. The analysis draws from examples of other RR crops that have been in the environment and marketplace for several years, such as RR corn and soybeans. RR alfalfa is a timely and important case study, as it is the first perennial crop to be approved for widespread planting, and is relatively new to the market. To the best of my knowledge, there has not been an effort to comprehensively examine the implications of introducing RR alfalfa for the organic industry. Using RR alfalfa as a case study in this analysis helps to fill this gap in literature.

Given the potential implications of introducing RR alfalfa, chapter three analyzes and assesses whether existing regulations are sufficient for protecting the integrity of organic alfalfa. Building on arguments laid out in chapters one and two, I flesh out the adequacy of the regulatory frameworks using RR alfalfa as a case study. This paper ends with a substantial conclusion that discusses the potential role of the judicial system and outlines policy recommendations. My hope is that these findings are useful to organic food producers, processors, and marketers, as well as non-governmental organizations and government officials interested in protecting the integrity of organic alfalfa seed and feed sources through advocacy and policy.

1.

THE NATIONAL ORGANIC PROGRAM & COORDINATED FRAMEWORK

*The organic food industry wanted to make sure that when people go out and see the word 'organic' that it has a clear set of standards. . .and we know that it clearly cannot include genetically engineered organisms.*²⁵

- Former U.S. Secretary of Agriculture, Dan Glickman

A Short History of Organic Agriculture Regulation

The national organic standards have received much attention in the agricultural arena, and have been the focus of many debates. Even before the new rules were in place, genetic engineering was one of the core issues in discussions involving the organic standards. Although genetic engineering has provoked countless controversies, few solutions to the challenges genetic engineering poses to organic production and regulation have surfaced.

Some of the debates around the organic standards focus on whether the organic label is accurate, whether consumers are getting what they expect and pay for when purchasing organic products.²⁶ Those who do not believe the organic label represents their personal ideals lament that a range of ecological, economic, and social concerns are not addressed by the NOP.²⁷ For example, recent reports uncover that labor conditions on large-scale organic farms are sometimes as bad as conventional operations.²⁸ One consumer advocate who pushed Congress to implement the NOP put it this way: "Organic is

²⁵ Food Fight [Electronic version]. (2000, March 7). PBS Online NewsHour, Retrieved on July 12, 2006, from http://www.pbs.org/newshour/bb/business/jan-june00/food_3-7.html

²⁶ Friedland, M. T. (2005). You call that organic? The USDA's misleading food regulations, 13 N.Y.U. Envtl. L.J. 379.

²⁷ Guthman, J. (2004). *Agrarian Dreams: The Paradox of Organic Farming in California*, California: The University of California.

²⁸ Mark, J. (2006, August 2). Workers on organic farms are treated as poorly as their conventional counterparts [Electronic version], *Grist*, Retrieved on August 3, 2006 from <http://www.grist.org/news/maindish/2006/08/02/mark/>

becoming what we hoped it would be an alternative to.”²⁹ While an analysis of the accuracy of the label in this context is outside the scope of this paper, understanding consumers’ perception of the organic label is an essential starting point for any discussion on the organic standards, as the consumers of organic products are the driving force of the market, whether the label is accurate or not.

It is clear that consumers who purchase organic foods expect these products be free of genetically engineered material; therefore, there exists an implied “zero tolerance” for GE material in organic products.³⁰ Polls show that the number of consumers who know that genetically engineered foods cannot be labeled “organic” under the organic standards is growing. In 2002, two polls showed that 68 percent of consumers who bought organics agreed they were purchasing products without genetically engineered organisms.³¹ In 2003, one of these polls showed that the number had grown to 76 percent.³²

Ironically, as this paper will show, GE material continues to turn up in crops and food intended for non-GE markets, including organic. Still, little attention has been given to the role of regulations in the face of GE contamination. The focus of this chapter is to outline the role of the organic standards and Coordinated Framework in keeping GE products contained and out of markets where they are not allowed. In chapter three, these regulatory issues will be fleshed out using the example of RR alfalfa.

The National Organic Program

In just decades, the organic agriculture industry grew from a grassroots movement into a

²⁹ Pollan, M. (2001, May 13). Behind the organic-industrial complex [Electronic version], *The New York Times*, Retrieved on July 30, 2006, from <http://www.mindfully.org/Food/Organic-Industrial-Complex.htm>

³⁰ Ronald, P. & Fouche, B. (2006). Genetic engineering and organic production systems, Retrieved on August 12, 2006, from www.indica.ucdavis.edu/publication/reference/r0602.pdf

³¹ Carolyn R. & Grobe, D. (2005). Consumer knowledge and perceptions about organic food [Electronic version], *Journal of Extension*, 43(4), Retrieved on October 14, 2005 from <http://www.joe.org/joe/2005august/rb3.shtml>; Whole Foods Market. (2003). One year after USDA organic standards are enacted more Americans are consuming organic food [Electronic version]. Retrieved on August 14, 2006 from http://www.wholefoods.com/company/pr_10-14-03.html

³² Whole Foods Market. (2003). One year after USDA organic standards are enacted more Americans are consuming organic food [Electronic version]. Retrieved on August 14, 2006 from http://www.wholefoods.com/company/pr_10-14-03.html

\$14 billion industry.³³ As the organic industry grew, many believed that this rapid growth warranted uniform production standards at the federal level. On October 21, 2002, the United States Department of Agriculture (USDA) implemented the country's first National Organic Program (NOP). The standards were the product of a decade-long effort to develop uniform organic production standards, which, in the end, were met with both praise and apprehension. Proponents of the new rules celebrated a uniform labeling regime after years of confusion in the marketplace regarding what constituted "organic."³⁴ By contrast, opponents of the rules saw the new government label as a federal usurpation of the word "organic," because once the NOP was established, it became illegal for anyone to label products as "organic" unless he or she was certified under the federal program.

For decades, organic agriculture was regulated by state and private agencies. The industry's growth, however, created confusion in the marketplace, evidence for mislabeling, and problems with interstate commerce.³⁵ Members of the organic industry began petitioning Congress for federal standards that they hoped would reduce consumer confusion over the various state and private labeling rules. Congress responded. Oregon Representative Peter DeFazio introduced a bill (H.R. 4165) with the main purpose of promoting "the production of organically produced foods through the establishment of a national standard production for organically produced products and providing for the labeling of organically produced products, and for other purposes"—it had twenty-two co-sponsors.³⁶ The staff of Vermont Senator Patrick Leahy ultimately penned the final act, the Organic Foods Production Act of 1990 (OFPA), which Congress passed as part of the 1990 Farm Bill.³⁷

³³ Organic Trade Association. (2006, May 7). Organic sales continue to grow at a steady pace [Electronic version], Retrieved on August 12, 2006, from

http://www.organicnewsroom.com/2006/05/organic_sales_continue_to_grow.html

³⁴ Nichols, A.J. (2003). As the organic food industry gets its house in order, the time has come for national standards for genetically modified foods, 15 Loy. Consumer L. Rev. 277.

³⁵ Friedland, M. T. (2005). You call that organic? The USDA's misleading food regulations, 13 N.Y.U. Evtl. L.J. 379; (See note 14)

³⁶ H.R. 4156, Retrieved on June 1, 2006, from <http://thomas.loc.gov/cgi-bin/bdquery/D?d101:44:./temp/~bdmssF>:

³⁷ Carroll, C. S. (2004). What does organic mean now? Chickens and wild fish are undermining the Organic Foods Production Act of 1990, 14 S.J. Agri. L. Rev. 117; Clark, J.B. (1995). Impact and Analysis of the

The National Organic Program: Proposed Rule The Organic Foods Production Act (OFPA) authorized the Secretary of Agriculture to create a certification program that would meet the Act's goals. It would be a "comprehensive statutory and regulatory framework governing all stages of organic production and handling," what is now the NOP.³⁸ To develop the standards, the Secretary of Agriculture appointed a National Organic Standards Board (NOSB), which reviewed existing state, foreign, and private organic certification programs. The NOSB was "to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of [organic certification]."³⁹ The fifteen NOSB members represent several categories in agriculture, including: farmer (4), handler/processor (2), retailer (1), consumer/public interest (3), environmentalist (3), scientist (1), and certifying agent (1).⁴⁰

Significantly, the NOSB was not meant to be just another advisory committee. Many people were skeptical of the federal government's ability to draft organic standards that reflected the inherent values of organic agriculture. In fact, "the organic community agreed to agree to USDA's primary role in setting organic standards only if the authority of USDA was balanced by that of the [NOSB]."⁴¹ Thus, the NOSB was to serve as USDA's partnership with the organic community.⁴²

When OFPA was passed, 21 states already had existing laws regulating organic product labeling.⁴³ By the time the National NOP was fully implemented in 2002, the number of

U.S. Federal Organic Food Production Act of 1990 with particular reference to the Great Lakes, 26 U. Tol. L. Rev. 323.

³⁸ Rawson, J. M. (2005). Organic agriculture in the U.S.: Program and policy issues [Electronic version], Congressional Research Service Report for Congress, Washington, DC: Congressional Research Service, Retrieved on August 16, 2006, www.fpc.state.gov/documents/organization/57848.pdf

³⁹ 7 U.S.C. 6518 (a),(b)

⁴⁰ 7 U.S.C. 6518 (b)

⁴¹ Sligh, Michael. 2002. Organics at the crossroads: The past and the future of the organic movement, In Kimbrell, A. (Ed.), *Fatal harvest: The tragedy of industrial agriculture* (p. 343). San Francisco, CA: Island Press.

⁴² Ibid.

⁴³ Friedland, M. T. (2005). You call that organic? The USDA's misleading food regulations, 13 N.Y.U. Evtl. L.J. 379.

states had grown to 33.⁴⁴ Existing state regulatory frameworks were more stringent than the proposed rule (especially California), and prohibited genetically engineered products from products certified as organic.⁴⁵ Although USDA reviewed California's and other state laws governing organic production, the agency failed to incorporate some of the most basic tenets of these regulatory frameworks into its proposed rule.

When the USDA published its proposed rule for the NOP in 1997, the rule allowed for the use of many controversial inputs, including genetically engineered (GE) organisms. Members of the organic industry, and largely consumers, were outraged by the proposed rule. To date, the USDA has never received more comments on a proposed rulemaking than it did on its first proposed NOP rule.⁴⁶ The agency received 275,603 comments in opposition of the rule, most of which abhorred the inclusion of GE organisms on the National List of Active Synthetic Substances Allowed.⁴⁷ When asked in an interview about the public's response to the proposed rule, former Secretary of Agriculture Dan Glickman replied: "There was an absolute firestorm."⁴⁸ Speaking to the more than 270,000 comments, Glickman said: "It was the most this department has ever received on any rule and maybe one of the most the government has received in modern history."⁴⁹ This large consumer outcry showed how important sound organic principles were to the public, and that among other controversial practices, genetic engineering held no place in the organic movement's collective vision of what constituted an organic production system.

⁴⁴ Carroll, C. S. (2004). What does organic mean now? Chickens and wild fish are undermining the Organic Foods Production Act of 1990, 14 S.J. Agri. L. Rev. 117; (See Note 54).

⁴⁵ Howe, K. (1997, December 16). Organic food proposals criticized [Electronic version], *San Francisco Chronicle*, Retrieved on June 3, 2006, from <http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/1997/12/16/BU17287.DTL>

⁴⁶ 65 Fed. Reg. (March 13, 2000); Cummings, Claire. Undermining organic: How the proposed USDA organic standards will hurt farmers, consumers, and the environment. *Pesticides and You*, Vol. 17 No. 4, Winter 1997-1998.

⁴⁷ 65 Fed. Reg., (March 13, 2000).

⁴⁸ Lambrecht, B. (1999, June 6). A biotech warrior stresses subtlety [Electronic version], *Post-Dispatch Washington Bureau*, Retrieved on November 1, 2006, from <http://www.cnr.berkeley.edu/~steggall/24Apr99-22Jul99.html>

⁴⁹ Ibid.

The crux of many of the controversies surrounding the proposed rule was that USDA had ignored many of the NOSB's recommendations, including the Board's recommendation to exclude the "big three," as they came to be known: genetically engineered organisms, sewage sludge, and irradiation.⁵⁰ In fact, many of the comments "angrily called on the agency to obey the NOSB."⁵¹ Today, the USDA continues to be criticized for not responding to NOSB recommendations.⁵²

Why was USDA permissive of genetic engineering under the organic standards to begin with? In an internal memo acquired by *Mother Jones* magazine, USDA highlights its concern about excluding genetically engineered material from organics: "The Animal and Plant Health Inspection Service and the Foreign Agricultural Service are concerned that our trading partners will point to a USDA organic standard that excludes GMOs as evidence of the Department's concern about the safety of bioengineered commodities."⁵³ Still, USDA could not ignore the huge public response it received against the proposed rule.

The National Organic Program: The Final Rule In the end, the final rule better reflected consumer and organic industry preferences.⁵⁴ USDA issued new proposed rules on March 13, 2000, which went through another public comment period. The final rule was published on December 21, 2000.⁵⁵ The NOP became effective on February 21, 2001, but the program itself was not fully implemented until October 21, 2002 (codified

⁵⁰ NCSA urges Gore to insure 'strong, credible' organic rule. (1998, September). ATTRAnews Digest, Retrieved on November 20, 2006, from <http://www.attra.org/attradigest/news0998.html>

⁵¹ Sligh, Michael. 2002. Organics at the crossroads: The past and the future of the organic movement, In Kimbrell, A. (Ed.), *Fatal harvest: The tragedy of industrial agriculture*. San Francisco, CA: Island Press.

⁵² Center for Food Safety. (2004). Threats to the National Organic Standards, Retrieved on September 7, 2006 from <http://centerforfoodsafety.org/ProtectingNOS.cfm>; Scott, C. (2006, April 26). Organic milk goes corporate [Electronic version], *Mother Jones*, Retrieved on August 3, 2006, from http://www.motherjones.com/news/update/2006/04/organic_milk.html

⁵³ Schmelzer, P. (1998, May). Label loophole: When organic isn't—organic foods labeling [Electronic version], *The Progressive*, Retrieved on November 3, 2006, from http://www.findarticles.com/p/articles/mi_m1295/is_n5_v62/ai_20527633

⁵⁴ Guthman, J. (2004). *Agrarian dreams: The paradox of organic farming in California*, Berkeley and London: University of California Press.

⁵⁵ 65 Fed. Reg. (December 21, 2000)

at 7 C.F.R. 205).⁵⁶

In a Research Service Report for Congress, it was clearly stated that the NOP's purpose is "to give consumers confidence in the legitimacy of products sold as organic, permit legal action against those who use the term fraudulently, increase the supply and variety of available organic products, and facilitate international trade in organic products."⁵⁷

Unlike the OFPA, the final rule provided a definition for "organic production," defining it as "a production system that is managed in accordance with the [OFPA] and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."⁵⁸ (The OFPA only states that "organically produced" means an agricultural product that is produced and handled in accordance with this title.)⁵⁹

To meet the goals of the OFPA and NOP, USDA accredits private and state certification agents to oversee compliance with the rules, largely by monitoring a farmer's "organic system plan." The "organic system plan" is "a plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling," as described in the act and regulations.⁶⁰ Certified organic producers must submit this plan to their certifying agent for the purpose of creating "a forum through which the producer or handler and certifying agent collaborate to define, on a site-specific basis, how to achieve and document compliance with the requirements of certification."⁶¹

Most certifying agents are private. As of August 2006, only nineteen states and counties

⁵⁶ Rawson, J. M. (2005). Organic agriculture in the U.S.: Program and policy issues [Electronic version], Congressional Research Service Report for Congress, Washington, DC: Congressional Research Service, Retrieved on August 16, 2006, www.fpc.state.gov/documents/organization/57848.pdf

⁵⁷ Ibid.

⁵⁸ 7 CFR § 205.2

⁵⁹ 7 U.S.C. 6502(14)

⁶⁰ 7 C.F.R. § 205.2

⁶¹ 65 Fed. Reg. 80,547, 80,558 (December 21, 2000)

have established certifying entities. The remaining thirty-six are private companies.⁶² These agents visit producers, processors, and handlers to conduct annual reviews of crop management practices, handling, and inputs, and to verify continued compliance.⁶³ States are permitted to adopt their own organic labeling requirements with USDA approval. State requirements must be as or more stringent than USDA standards and are allowed to label their products with a separate logo in addition to the USDA label (as are private organic certifying organizations).⁶⁴

Perhaps the most important aspect to remember about the NOP is that it provides production standards only, and does not serve as a certification of the end product.⁶⁵ In the same vein, USDA is clear in pointing out that NOP regulations are not intended to address food safety or nutrition. In other words, USDA does not claim that organic foods are more nutritious or safer than conventionally produced foods.⁶⁶ Because the regulations are process-based and not product-based (often referred to as the “process-product distinction”),⁶⁷ they focus on how a product is grown, harvested and prepared, rather than characteristics of the end product. Interestingly, most of the state laws that governed organic production before OFPA were not exclusively process-based.⁶⁸

How Does the NOP Address Genetic Engineering?

As mentioned earlier, the final rule does not allow for the use of products derived from genetic engineering in certified organic systems. Section 205.105 of the NOP specifically

⁶² Agricultural Marketing Service. (2006). The National Organic Program: Accredited certifying agents [Electronic version], Retrieved August 1, 2006, from <http://www.ams.usda.gov/NOP/CertifyingAgents/Accredited.html>

⁶³ Rawson, J. M. (2005). Organic agriculture in the U.S.: Program and policy issues [Electronic version], Congressional Research Service Report for Congress, Washington, DC: Congressional Research Service, Retrieved on August 16, 2006, www.fpc.state.gov/documents/organization/57848.pdf; Baier, A. (2005). Organic certification process [Electronic version], Retrieved on May 29, 2006 from http://attra.ncat.org/attra-pub/organic_certification.html

⁶⁴ 7 C.F.R. § 205.620(a),(c).

⁶⁵ 65 Fed. Reg. 80,549 (December 21, 2000), (“The emphasis and basis of these standards is on process, not product.”)

⁶⁶ 65 Fed. Reg. 80,548 (December 21, 2000), (“The seal does not convey a message of food safety or more nutritional value.”)

⁶⁷ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. Evtl. L.J. 379.

⁶⁸ Ibid.

prohibits GE crops from certified organic production systems: “To be sold or labeled as ‘100 percent organic’ . . . the product must be produced and handled without the use of excluded methods. “Excluded methods” are “methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production.”⁶⁹ Such methods include “cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology).”⁷⁰

The rules extend the prohibition of GE organisms to animal feed by requiring certified organic livestock be fed certified organic feed: “The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled.”⁷¹

The NOP provides strict certification standards that organic farmers must adhere to in order to label their products as “organic.” On the surface it may seem that the NOP clearly addresses agricultural biotechnology by not allowing the use of GE seeds and feed in certified operations. However, as explained below, GE material can enter a farmer’s field and products through means completely out of the farmer’s control, complicating the issue of “excluded methods” as they pertain to the NOP. Because genetic engineering is listed as an “excluded method,” how do the rules address the unwanted and unintended presence of GE material in organic products?

Genetically Engineered Seeds and Crops: Genetic Drift Organic farmers have long been concerned with pesticide drift, where residues of chemicals applied in their

⁶⁹ 7 C.F.R. § 205.2

⁷⁰ 7 C.F.R. § 205.2

⁷¹ 7 C.F.R. §205.237(a)

area show up in their organic products.⁷² Pesticide drift occurs unavoidably with ground and aerial methods of pesticide application; in fact, 10 percent to 35 percent of pesticides applied with ground application equipment misses the target area, and 50 percent to 75 percent of pesticides applied with aircraft misses the target area.⁷³

Now, in addition to chemicals transported across field borders, organic producers are experiencing a new drift—“genetic drift”—from neighboring fields. The rules define “drift” as “the physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.”⁷⁴ A “prohibited substance” is the use of a substance “of which in any aspect of organic production or handling is prohibited or not provided for” in the Act or regulations.⁷⁵ Thus, “prohibited substances” include “excluded methods,” including genetically engineered material.

The transfer of genes from GE crops to organic crops poses many problems to organic farmers.⁷⁶ Should a farmer’s crop acquire unwanted GE material, he or she risks losing premium prices afforded by organic markets, including organic, as well as export markets that shun GE crops and food. Farmers also risk losing the genetic integrity of seeds that took years to develop through careful breeding. The issue of liability associated with patented genetic traits is of great concern, as companies effectively own crops that contain their patented traits, even if those traits entered the crop through inadvertent cross-pollination, as will be discussed at the end of this paper.

While the NOP prohibits the intentional use of GE material in organic systems, the rules do not address the unintended presence of GE material—there is no set tolerance for

⁷² 65 Fed. Reg. 80,556 (December 21, 2000) (“Organic operations have always had to worry about the potential for drift from neighboring operations, particularly drift of synthetic chemical pesticides.”)

⁷³ Altieri, M. A. (2005). The myth of coexistence: Why transgenic crops are not compatible with agroecologically based systems of production [Electronic version], *Bulletin of Science, Technology & Society*, 25(4), pp. 361-371, Retrieved on May 12, 2006 from www.bst.sagepub.com/cgi/reprint/25/4/361.pdf

⁷⁴ 7 C.F.R. § 205.2

⁷⁵ 7 C.F.R. § 205.2

⁷⁶ Altieri, M. A. (2005). The myth of coexistence: Why transgenic crops are not compatible with agroecologically based systems of production [Electronic version], *Bulletin of Science, Technology & Society*, 25(4), pp. 361-371, Retrieved on May 12, 2006 from www.bst.sagepub.com/cgi/reprint/25/4/361.pdf

“contamination” of GE material in organic products.⁷⁷ Several countries have set tolerance levels for GE material in conventional (non-GE) crops and food. These vary widely, from the European Union (EU) (0.9 percent) and Japan (5 percent).⁷⁸ A GE crop must be approved in the country in order for any level of tolerance to be acceptable. For example, if a GE corn variety not approved for import by the EU is discovered in a large shipment of corn that is approved for import, the whole shipment would likely be rejected because there is zero tolerance for an unapproved GE product.

The organic rules do, however, establish a tolerance level for pesticide residue. “Residue testing” is defined as “an official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradations products in or on raw or processed agricultural products.”⁷⁹ “Tolerance” is “the maximum legal level of a pesticide chemical residue in or on a raw or processed agricultural commodity or processed food.”⁸⁰ When organic products test for more than 5 percent residue of the Environmental Protection Agency’s (EPA) tolerance for a specific contaminant, the agricultural product cannot be sold, labeled or represented as organic.⁸¹

Because the regulation does not establish a tolerance or threshold level for GE material in organic products, the rules governing the exclusion of products exceeding tolerance levels from organic sale do not apply to GE contamination, as it only applies to contaminants for which there is an established EPA or FDA tolerance. In the Federal Register notice announcing the final rule, USDA explains why a tolerance was not established in response to comments regarding setting a “threshold” for GE material in organic products:

We do not believe there is sufficient consensus upon which to establish such a standard at this time. Much of the basic, baseline information about the prevalence of genetically engineered products in the conventional agricultural marketplace that would be necessary to set

⁷⁷ For purposes of this paper, “contamination” refers to the unwanted presence of GE material in organic and conventional crops.

⁷⁸ Ronald, P. & Fouche, B. (2006). Genetic engineering and organic production systems, Retrieved on August 12, 2006, from www.indica.ucdavis.edu/publication/reference/r0602.pdf

⁷⁹ 7 C.F.R. § 205.2

⁸⁰ 7 C.F.R. § 205.2

⁸¹ 7 C.F.R. § 205.671

such a threshold—e.g., the effects of pollen drift where it may be a factor, the extent of mixing at various points throughout the marketing chain, the adventitious presence of genetically engineered seed in nonengineered seed lots—is still largely unknown. Our understanding of how the use of biotechnology in conventional agricultural production might affect organic crop production is even less well developed.⁸²

This response points to a lack of data regarding the presence of transgenes in organic and conventional fields and products. However, as this paper will show, contamination is a real threat to many organic producers. USDA’s inaction on the issue proves to be a large gap in the NOP, especially when farmers can become contaminated via environmental factors completely out of their control.

GE material can enter a farmer’s field through several routes, unlike pesticide drift, which is largely attributed to wind. First, transgenic pollen can travel from a neighboring farm via wind or pollinating insects (i.e. bees). Second, transgenic and conventional seed can get mixed through shared harvesting and storage equipment. Third, volunteer plants—crop plants that persist without deliberate cultivation—show up in fields a year or more after the original crop was grown as a result of seed being shed from the crop and remaining dormant in the soil.⁸³ Some volunteer plants germinate several years after the original seed was shed.⁸⁴

Within a farmer’s “organic system plan” are measures to ensure the genetic integrity of the organic product, including the process for locating commercially available, organically produced seed.⁸⁵ Although it is a general rule that producers must use organically grown seeds, annual seedlings, and planting stock in their operations,⁸⁶ there

⁸² 65 Fed. Reg. 80632 (December 21, 2000)

⁸³ The Royal Society. (1998). Genetically modified plants for food use [Electronic version], Retrieved on August 4, 2006, from <http://genaction-kr.jinbo.net/archive/roysoc.htm#enviro>; Definition of “volunteer plant” taken from The Pew Initiative on Food and Biotechnology. (2006). Glossary, Retrieved on August 4, 2006, from www.pewagbiotech.org/resources/glossary

⁸⁴ The Royal Society. (1998). Genetically modified plants for food use [Electronic version], Retrieved on August 4, 2006, from <http://genaction-kr.jinbo.net/archive/roysoc.htm#enviro>; (See note 11)

⁸⁵ 65 Fed. Reg. 80,558 (December 21, 2000)

⁸⁶ 7 C.F.R. § 205.204(a)

are five exceptions to this rule.⁸⁷ If “an equivalent organically produced variety is not commercially available,” a producer may use nonorganically produced, untreated seeds and planting stock.⁸⁸ This exception does not extend to seeds used for edible sprouts, such as alfalfa seed used for sprouting. All seeds used for producing edible sprouts under the NOP must be organically produced.⁸⁹ None of the exceptions allow for the use of GE seeds.

The plan must also include a description of the management practices that a producer or handler will implement to “prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances.”⁹⁰ For example, the NOP requires farms to “have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.”⁹¹

A “buffer zone” is defined as:

an area located between a certified production operation or portion of a production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.⁹²

Even with guidelines to prevent commingling and drift in place, the regulations do not require mandatory testing of products to ensure these measures are successful.⁹³ This differs from many of the state laws that governed organic production before OFPA, as

⁸⁷ For a description of all the exceptions, see Pittman, Harrison M. (2004). A legal guide to the National Organic Program [Electronic version], Retrieved on July 2, 2006, from <http://www.nationalaglawcenter.org/research/#organic>

⁸⁸ 7 C.F.R. § 205.204(a)(1)

⁸⁹ 7 C.F.R. § 205.204(a)(1)

⁹⁰ 7 C.F.R. § 205.201(a)(5)

⁹¹ 7 C.F.R. § 205.202(c)

⁹² 7 C.F.R. § 205.2

⁹³ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. Evtl. L.J. 379.

many required residue testing.⁹⁴ The NOP requires certifiers' on-site inspections to verify:

That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, *may* include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. [emphasis added]⁹⁵

Therefore, testing for GE material is not mandatory, even when there is reason to believe that prohibited substances have entered an organic product:

The Administrator, applicable State organic program's governing State official, or the certifying agent *may* require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold [organic] . . . when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. [emphasis added]⁹⁶

Moreover, testing is unlikely to occur, because: "Such tests must be conducted . . . at the official's or certifying agent's *own expense*." [emphasis added]⁹⁷

As mentioned above, the NOP does not provide a tolerance level for transgenic material. Some comments submitted in response to USDA's proposed rule argued that without a threshold for GE material in organic products the rules set a "zero tolerance" standard for contamination.⁹⁸ Yet USDA states otherwise:

. . .these regulations do not establish a 'zero tolerance' standard. As with other substances not approved for use in organic production systems, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred.⁹⁹

⁹⁴ Friedland, M. T. (2005). You call that organic? The USDA's misleading food regulations, 13 N.Y.U. Env'tl. L.J. 379: 6.

⁹⁵ 7 C.F.R. §205.403(c)(3)

⁹⁶ 7 C.F.R. § 205.670

⁹⁷ 7 C.F.R. §205.670(b)

⁹⁸ 65 Fed. Reg. 80,632 (December 21, 2000)

⁹⁹ 65 Fed. Reg. 80, 632 (December 21, 2000)

If GE material is detected in an organic product, the finding does not automatically point to a violation of organic standards, as the standards only govern intentional actions, and the “presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards.”¹⁰⁰ So, not only is it unlikely that testing to identify excluded material in organic products will occur, in the event that contamination is revealed in an organic product, the regulations do not prohibit this product from being sold as organic.

Still, it might be assumed that organic farmers risk losing certification if residues of an excluded method turn up in their products. Interestingly, according to a letter from the USDA to the National Association of State Departments of Agriculture, no farmer has ever lost certification due to the presence of GE material in his or her certified organic products.¹⁰¹ But it is likely that organic producers will have difficulty selling their crops to non-GE markets if GE material is found in their products. They might be forced to sell in a conventional market, thus “forfeiting the organic premium price that they would otherwise have received for their product.”¹⁰²

As mentioned before, regulations do not specify a threshold level for the unintended presence of GE material in an organic product, unlike the tolerance levels set for pesticide residue. The regulations do not even mention contamination by transgenic pollen or seed. Because there is no requirement to test for the unwanted presence of transgenic material, it is highly unlikely that certifiers and/or producers will test products under the current rule, especially when testing is conducted at the certifying agent’s or farmer’s own expense. Moreover, there is no EPA tolerance level for the products of genetic engineering, so “as weak as the USDA production standards are with regard to pesticide contamination, they are even weaker with regard to biotech contamination—the regulation do not establish any limit whatsoever on contamination by genetically

¹⁰⁰ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. Envtl. L.J. 379; 65 Fed. Reg. 80548 (December 21, 2000)

¹⁰¹ Ronald, P. & Fouche, B. (2006). Genetic engineering and organic production systems, Retrieved on August 12, 2006, from www.indica.ucdavis.edu/publication/reference/r0602.pdf; (“The USDA indicated in a December 2004 letter to the National Association of State Departments of Agriculture that no grower has ever lost certification due to the presence of GE products in their organic product.”)

¹⁰² Ibid.

engineered materials.”¹⁰³ This means the regulations allow a product to be sold as organic even if contamination is revealed, as long as the producer did not intentionally use an excluded method.

Of course, organic foods grown and handled according to the NOP will contain less pesticide residue and GE material than their conventional counterparts, because producers who adhere to the standards do not intentionally apply pesticides or use GE seeds or feed.¹⁰⁴ But will consumers tolerate any contamination of their organic food products? Do they even know that accidental contamination occurs?

Consumer Perception

The organic food industry continues to grow, and remains an alternative to GE ingredients for many consumers. In 2005, organic foods accounted for the largest share of the organic industry, with over \$13 billion in sales.¹⁰⁵ Sales of organic food in the U.S. are projected to more than double by 2009.¹⁰⁶ The FDA believes that “the practices and record keeping that substantiate the ‘certified organic’ statement would be sufficient to substantiate a claim that a food was not produced using bioengineering.”¹⁰⁷ But GE material continues to turn up in crops and food intended for non-GE markets, even when the “food was not produced using bioengineering,” as the FDA statement just read. Because it is clear that consumers who purchase organic foods expect these products be free of GE material, there exists an implied “zero tolerance” for GE material in organic

¹⁰³ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations [Electronic version], 13 N.Y.U. Envtl. L.J. 379.

¹⁰⁴ Consumers Union. (2002). Consumers Union research team shows: Organic foods really do have less pesticides [Electronic version], Retrieved on September 4, 2006, from <http://www.consumersunion.org/food/organicpr.htm>

¹⁰⁵ Organic Trade Association. (2006). 2006 manufacturer survey, Retrieved on September 23, 2006, from www.ota.com/pics/documents/short%20overview%20MMS.pdf

¹⁰⁶ When it pays to buy organic [Electronic version]. (2006, February). *Consumer Reports*, Retrieved on September 8, 2006, from <http://www.consumerreports.org/cro/food/organic-products-2006/overview/index.htm>

¹⁰⁷ U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition. (2001, January). Voluntary labeling indicating whether foods have or have not been developed using bioengineering [Electronic version], (Draft Guidance) Retrieved on September 4, 2006, from <http://www.cfsan.fda.gov/~dms/biolabgu.html>

products.¹⁰⁸ It is unclear whether the organic industry will set a threshold in the future for GE material in organic foods.

The organic standards remain controversial, and how they are implemented determines their impact on organic integrity, according to Michael Sligh, founding chair of the NOSB.¹⁰⁹ Even if a tolerance level is established, testing remains a voluntary tool for measuring the effectiveness of the NOP. The next chapter reveals a disturbing pattern of contamination events that threaten the integrity of the organic industry. Because testing is unlikely to occur, the extent of this contamination is largely unknown, making it difficult to gauge what a realistic and enforceable tolerance level would be. Furthermore, the introduction of RR alfalfa creates new challenges to organic producers, as will be explored in the next chapter. The role of the government in regulating GE plants is explored next. What responsibility does the federal government and biotechnology industry share in keeping GE traits contained?

A Short History of Genetically Engineered Crop Regulation

The regulatory framework for GE crops and food differs tremendously from that governing certified organic production. Although GE crops garnered much controversy when they were first introduced, and continue to do so today, no new laws were ever created to regulate the new technology. Instead, a patchwork of approximately a dozen existing laws, and primarily three agencies, governs the testing and introduction of GE crops and food.

The framework is outlined below, and includes only those laws and regulations that govern GE plants. Segregation and containment issues are discussed at the end of this chapter, including assessments by scientists and government officials of their adequacy in containing transgenic crops in the environment and marketplace. What we see is a

¹⁰⁸ Ronald, P. & Fouche, B. (2006). Genetic engineering and organic production systems, Retrieved on August 12, 2006, from www.indica.ucdavis.edu/publication/reference/r0602.pdf

¹⁰⁹ Sligh, Michael. 2002. Organics at the crossroads: The past and the future of the organic movement, In Kimbrell, A. (Ed.), *Fatal harvest: The tragedy of industrial agriculture* (p. 344). San Francisco, CA: Island Press.

regulatory system largely dependent upon voluntary compliance and risk assessments produced by the manufacturers of the products being regulated.

Discussions about risk assessment and regulation of GE organisms began in the 1970s, but the federal government did not complete the “Coordinated Framework for Regulation of Biotechnology” (hereinafter the “Coordinated Framework”) until 1986, which was published by the Office of Science and Technology, and still applies to new agricultural biotechnology products today.¹¹⁰ The federal government established a policy to regulate products of biotechnology based on composition and intended use rather than by the method used to produce them.¹¹¹ Therefore, the regulatory system for GE crops is product-based, unlike the NOP’s process-based approach.

This policy decision was largely based on scientific reports that concluded the risks posed by genetically engineered products do not differ in kind from the risks posed by their conventional counterparts.¹¹² Specifically, the National Research Council argued assessment of risks should be based on the nature of the organism and the environment into which it is introduced, not on the method by which it is produced.¹¹³ Therefore, a central premise of the Coordinated Framework is that the process of genetic engineering poses no new unique risks, and should not only be regulated by the same laws as conventionally produced products, but that these existing laws are adequate.¹¹⁴ The adequacy of the Coordinated Framework has been debated since its inception—from those arguing it is not stringent enough, to those arguing that it over-regulates.¹¹⁵

Regulatory authority of GE crops and food is primarily given to three federal agencies: United States Department of Agriculture (USDA), Environmental Protection Agency

¹¹⁰ Uchtmann, D.L., (2002). Starlink TM—A case study of agricultural biotechnology regulation, 7 Drake J. Agric. L. 159. (This article gives an excellent overview of the discussions in around regulating biotechnology in the 1970s.)

¹¹¹ 51 Fed. Reg. 23302 (June 26, 1986)

¹¹² National Research Council. (1989). Field testing genetically modified organisms: Framework for decision. Washington, DC: National Academy Press.

¹¹³ Ibid.

¹¹⁴ The Pew Initiative on Food and Biotechnology. (2004). *Issues in the regulation of genetically engineered plants and animals* [Electronic version]. Washington, DC: Author, Retrieved on August 24, 2006, from <http://pewagbiotech.org/research/regulation/Regulation.pdf>

¹¹⁵ Ibid.

(EPA), and Food and Drug Administration (FDA). Below is an overview of these agencies' role in the Coordinated Framework, including the source(s) of their legal authority and process for regulating GE plants and GE plant-derived food and feed. As will be discussed, some GE products are regulated by more than one agency. Because no laws specifically address genetic engineering, and the laws incorporated into the Coordinated Framework were enacted for other purposes, they are more general in nature.¹¹⁶ Furthermore, these agencies have depended on creative interpretations of their roles and authority to develop regulations and guidelines that apply existing laws to products derived from genetic engineering.¹¹⁷

Table 1		
Major Laws that Give Federal Agencies Power to Regulate Biotechnology		
LAWS & REGULATIONS	AGENCY	CODIFIED
<p>The Plant Protection Act</p> <ul style="list-style-type: none"> • Gives USDA authority for GE plants, seeds, and other GE organisms containing genetic material from plant pests, and prohibits unauthorized movement of plant pests 	USDA	7 C.F.R. §340
<p>The Federal Insecticide, Fungicide, and Rodenticide Act</p> <ul style="list-style-type: none"> • Requires all pesticides sold or distributed in the U.S. to be registered by EPA 	EPA	40 C.F.R. §§152 and 174
<p>The Food, Drug, and Cosmetics Act</p> <ul style="list-style-type: none"> • Requires EPA to set pesticide tolerances for all pesticides used in or on food • Authorizes FDA to regulate “adulterated foods” and “food additives,” and to govern food labeling 	FDA, EPA	40 C.F.R. §§152 and 174 (N/A for FDA)
<p>The National Environmental Policy Act</p> <ul style="list-style-type: none"> • Requires all federal agencies to consider the consequences of their proposed actions on the human environment prior to making decisions, including performing Environmental Assessments 	USDA, EPA, FDA	40 C.F.R. §§1501.3; 1508.9

¹¹⁶ The Pew Initiative on Food and Biotechnology. (2004). *Issues in the regulation of genetically engineered plants and animals* [Electronic version]. Washington, DC: Author, Retrieved on August 24, 2006, from <http://pewagbiotech.org/research/regulation/Regulation.pdf>

¹¹⁷ Bratspies R. M. (2005). Glowing in the dark: How America's first transgenic animal escaped regulation, 6 Minn. J.L. Sci. & Tech. 457.

United States Department of Agriculture

Legal Authority The Plant Protection Act (PPA) of 2000 gives USDA authority for oversight of GE plants, seeds, and other genetically engineered organisms containing genetic material from plant pests.¹¹⁸ The PPA prohibits unauthorized movement of plant pests or potential plant pests, including plants derived from genetic engineering.¹¹⁹ Because the PPA was enacted in 2000, on the surface it “appears to deviate from the trend of regulating biotechnology under ancient statutes.”¹²⁰ However, the new law is basically an amalgamation of older statutes. The Federal Plant Pest Act (FPPA) of 1957 and the Plant Quarantine Act (PQA) of 1912 originally governed USDA’s role in agricultural biotechnology, before repeal by the Agricultural Risk Protection Act (ARPA), and incorporated into what is now the PPA.¹²¹ The FPPA and PQA were enacted well before modern biotechnology and were intended to regulate the introduction of non-native plant species, not GE organisms.¹²² USDA developed and still follows regulations under the FPPA and PQA to review the agricultural safety of GE organisms,¹²³ and has not proposed new or different regulations under the PPA, according to the Office of the Inspector General.¹²⁴

¹¹⁸ 7 C.F.R. § 340.0 (2)

¹¹⁹ Plant Protection Act of 2000, 7 U.S.C. § 7711(a)

¹²⁰ Mandel, G. N. Gaps. (2004). Inexperiences, inconsistencies, and overlaps: Crisis in the regulation of genetically modified plants and animals, 45 Wm and Mary L. Re.

¹²¹ 7 U.S.C. §§ 7701-7772

¹²² Mandel, G. N. Gaps. (2004). Inexperiences, inconsistencies, and overlaps: Crisis in the regulation of genetically modified plants and animals, 45 Wm and Mary L. Re.

¹²³ 7 U.S.C. § 7758 (repeals former laws and states: “Regulations issued under the authority of a provision of law repealed by subsection (a) shall remain in effect until such time as the Secretary issues a regulation under section 434 that supersedes the earlier regulation.”)

¹²⁴ 66 Fed. Reg. 51,340 (October 9, 2001); U.S. Department of Agriculture, Office of Inspector General. (2005, December). *Audit report: Animal and Plant Health Inspection Service controls over issuance of genetically engineered organism release permits*, Retrieved on April 13, 2006, from www.usda.gov/oig/webdocs/50601-08-TE.pdf (“Even if APHIS improves its inspection process, we found that APHIS has not updated its regulations to reflect the Plant Protection Act of 2000, under which APHIS carries out its biotechnology oversight duties.”)

Key Roles and Process for Regulation The Animal and Plant Health Inspection Service (APHIS) is the primary entity in USDA that regulates biotechnology.¹²⁵ Through a notification and permit process, APHIS regulates field testing of GE crops in the environment, interstate movement, and importation of GE organisms.¹²⁶ APHIS considers each GE plant a “regulated article,” and each DNA segment inserted using rDNA methods an “event.”¹²⁷ Most field trials are conducted under APHIS’ notification system, a streamlined process that replaced the permit process for more than 85 percent of the crops in field trials, beginning in 1993.¹²⁸ In 2004, about 97 percent of the plants in field trials were regulated under notifications.¹²⁹ Permits are now only required for plants that do not fit the six criteria listed for notifications, such as plants engineered to produce pharmaceutical proteins or industrial chemicals.¹³⁰

Field trials of GE organisms began in 1986, the same year the Coordinated Framework was published. Before a person or institution (hereinafter “applicant”) can field test a GE organism, they must notify APHIS of the planting (unless a permit is needed). APHIS is required to evaluate the notification information and acknowledge within ten days of receipt that the planting is “appropriate.”¹³¹ Following field tests, applicants can petition APHIS to obtain a “nonregulated” status for their product. APHIS evaluates petitions submitted by the applicant of the organism being field tested, and after assessing the agricultural and environmental safety of the organism, publishes a document explaining whether the organism poses a plant pest risk or not, as well as an Environmental

¹²⁵ Roles of U.S. Agencies. United States regulatory agencies unified website. Retrieved on September 15, 2006 from <http://usbiotechreg.nbio.gov/roles.asp>

¹²⁶ Animal and Plant Health Inspection Service. (2006.) About Biotechnology Regulatory Service, Retrieved on September 16, 2006 from http://www.aphis.usda.gov/brs/about_brs.html (In 2002, a unit within APHIS, the Biotechnology Regulatory Services (BRS), was created to focus on APHIS’ role in regulating agricultural biotechnology.)

¹²⁷ 7 C.F.R. § 340.1 (1987) (definition “regulated article”); McHughen, A. (2006). Plant genetic engineering and regulation in the United States [Electronic version], Retrieved on September 14, 2006 from www.anrcatalog.ucdavis.edu/pdf/8179.pdf (definition “event”)

¹²⁸ 58 Fed. Reg. 17044-17059 (March 31, 1993) (“Eighty-five percent of current field tests could be conducted under the notification procedure.”)

¹²⁹ U.S. Department of Agriculture, Office of Inspector General. (2005, December). *Audit report: Animal and Plant Health Inspection Service controls over issuance of genetically engineered organism release permits*, Retrieved on April 13, 2006, from www.usda.gov/oig/webdocs/50601-08-TE.pdf

¹³⁰ 7 C.F.R. § 340.3

¹³¹ 7 C.F.R. § 340.3(e)(4)

Assessment (EA) that addresses the potential environmental impact of no longer regulating the organism.¹³²

If the petition is approved, the product is no longer regulated by APHIS and can be grown for commercial sale. APHIS no longer has oversight over the deregulated crop, including requests for new or follow-up testing.¹³³ APHIS reviews approximately 1,000 field test notifications per year for GE crops.¹³⁴ Since 1986, USDA has approved over 10,600 applications for more than 49,300 field sites,¹³⁵ and has deregulated over 60 different GE crops.¹³⁶ The first GE food crop, the Flavr Savr tomato, a variety engineered to sustain longer shelf life, entered the marketplace in 1994.¹³⁷

The Environmental Protection Agency

Legal Authority EPA is charged with the responsibility to regulate the manufacture, sale, and use of pesticides to ensure that human health and the environment are protected.¹³⁸ The 1947 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the 1938 Federal Food, Drug and Cosmetic Act (FFDCA), both amended most recently by the Food Quality Protection Act of 1996, give EPA authority to regulate pesticides.¹³⁹ FIFRA requires all pesticides sold or distributed in the U.S. to be registered by EPA, and FFDCA requires EPA to set pesticide tolerances for all pesticides used in or

¹³² 7 C.F.R. § 340.6 (Petition for determination of nonregulated status); 7 C.F.R. § 372 (National Environmental Policy Act Implementing Procedures)

¹³³ Tokar, B. (2006, June). *Deficiencies in federal regulatory oversight of genetically engineered crops*, Retrieved on June 1, 2006 from <http://environmentalcommons.org/RegulatoryDeficiencies.html> (www.environmentalcommons.org/RegulatoryDeficiencies.html)

¹³⁴ Vines, R. (2002, May). The regulation of biotechnology [Electronic version], Retrieved on October 2, 2006, from www.ext.vt.edu/pubs/biotech/443-006/443-006.html

¹³⁵ U.S. Department of Agriculture, Office of Inspector General. (2005, December). *Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits*, Retrieved on April 13, 2006, from www.usda.gov/oig/webdocs/50601-08-TE.pdf

¹³⁶ Animal and Health Inspection Service. (2006). Petitions of nonregulated status granted or pending by APHIS as of September 2006, Retrieved on September 12, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

¹³⁷ The Flavr Savr tomato is now obsolete in the marketplace. Some speculate that it failed in grocery stores because it was explicitly labeled as “GE,” while others speculate that the product did not meet consumers’ expectations regarding quality.

¹³⁸ 7 U.S.C. § 136 (a)

¹³⁹ U.S. Environmental Protection Agency. (2006). Pesticide Registration Program, Retrieved on September 10, 2006 from <http://www.epa.gov/pesticides/factsheets/registration.htm>

on food.¹⁴⁰ When first enacted, FIFRA was intended to regulate chemical and biological substances designed to kill, damage, or repel unwanted organisms, not products derived from biotechnology. Although FIFRA has been amended several times, one article points out that it was enacted prior to Watson and Crick’s discovery of the DNA molecule.¹⁴¹

Key Roles and Process for Regulation Some plants derived from biotechnology are engineered to produce their own pesticides. EPA refers to these plants as “plant incorporated protectants.”¹⁴² Early on, EPA exempted plants and microorganisms with pesticidal properties from FIFRA requirements.¹⁴³ However, the pesticidal properties of the genetic material falls under FIFRA’s definition of a “pesticide.”¹⁴⁴ Therefore, EPA does not regulate GE plants themselves, only the genetic material inserted into a pesticide-producing plant, along with the products it produces.

Examples of pesticide-producing (often called insect-resistant) plants include crops engineered to produce a natural-occurring soil bacterium called *Bacillus thuringiensis* (*Bt*), which creates proteins that are toxic to certain insects, so that the entire plant effectively becomes a living insecticide.¹⁴⁵ *Bt* crops are some of the most frequently deregulated crop varieties in the United States, including *Bt* cotton and corn.¹⁴⁶

Pursuant to the FFDCFA, EPA establishes a “tolerance” for the allowable amount of pesticide residue on food products.¹⁴⁷ All pesticide-producing plants are exempt from tolerance level requirements.¹⁴⁸ The regulation “eliminates the need to establish a

¹⁴⁰ U.S. Environmental Protection Agency. (2006). Pesticide Registration Program, Retrieved on September 10, 2006 from <http://www.epa.gov/pesticides/factsheets/registration.htm>

¹⁴¹ Mandel, G. N. Gaps. (2004). Inexperiences, inconsistencies, and overlaps: Crisis in the regulation of genetically modified plants and animals, 45 Wm and Mary L. Re.

¹⁴² 40 C.F.R. § 152.20(a)(4)

¹⁴³ 40 CFR § 152.20 (2001); 53 FR 15,952, 15,975 (May 4, 1988)

¹⁴⁴ 66 Fed. Reg. 37,772-37,773 (July 19, 2001)

¹⁴⁵ Mendelsohn, M., Kough, J., Vaituzis, Z. & Matthews, K. (2003, September). Are *Bt* crops safe? [Electronic version] *Nature Biotechnology*, 21(9), Retrieved on October 5, 2006, from www.epa.gov/pesticides/biopesticides/pips/are_bt_crops_safe.pdf

¹⁴⁶ Animal and Health Inspection Service. (2006). Petitions of nonregulated status granted or pending by APHIS as of September 2006, Retrieved on September 12, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

¹⁴⁷ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 408

¹⁴⁸ 40 C.F.R. § 180.1155

maximum permissible level for residues of this plant-pesticides in or on all raw agricultural commodities,”¹⁴⁹ because “there is a reasonable certainty that no harm will result from aggregate exposure to the U.S. population.”¹⁵⁰

The Food and Drug Administration

Legal Authority FDA’s statutory authority for regulating genetically engineered food stems from the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA).¹⁵¹ There are no statutory provisions for food derived from genetic engineering, and FDA has never promulgated regulations that expressly cover genetically engineered food.¹⁵² Coupled with FDA’s largely voluntary approach to regulating genetically engineered food, FDA arguably practices the least amount of oversight over agricultural biotechnology products.

Key Roles and Process for Regulation FDA is responsible for ensuring the safety and proper labeling of plant-derived foods and feeds, including those that have been genetically engineered.¹⁵³ FDA is authorized under the FFDCA to regulate “adulterated foods,” food that “bears or contains any poisonous or deleterious substance which may render it injurious to health.”¹⁵⁴ FDA also regulates “food additives,” which is any substance intended to become a component, or affecting the characteristics, of any food.¹⁵⁵ A “food additive” requires FDA approval unless deemed “generally recognized as safe” (GRAS).¹⁵⁶ Notably, the manufacturer of a “food additive,” of a GE ingredient, makes an “independent determination” as to whether the substance is GRAS.¹⁵⁷ Moreover, manufacturers are not required to report a GRAS determination.¹⁵⁸ The FDA has never formally “approved” a GE food or feed as safe to eat; it has only determined

¹⁴⁹ 62 Fed. Reg. 17720 (April 11, 1997)

¹⁵⁰ 62 Fed. Reg. 17721 (April 11, 1997)

¹⁵¹ 21 U.S.C. §§ 301-399

¹⁵² Mandel, G. N. Gaps. (2004). Inexperiences, inconsistencies, and overlaps: Crisis in the regulation of genetically modified plants and animals, 45 Wm and Mary L. Re.

¹⁵³ The Food and Drug Administration. Roles of U.S. agencies, Retrieved on September 24, 2006 (<http://usbiotechreg.nbi.gov/roles.asp>)

¹⁵⁴ 21 U.S.C. 342(a)(1)

¹⁵⁵ 21 U.S.C. 321(s)

¹⁵⁶ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,985 (May 29, 1992)

¹⁵⁷ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22989 (May 29, 1992)

¹⁵⁸ Ibid.

them to be similar to their conventional counterparts.¹⁵⁹ Therefore, FDA has decided that most components of food derived from genetic engineering (both the inserted gene into a GE plant and the product itself) do not need approval: “In most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food, such as proteins, fats and oils, and carbohydrates.”¹⁶⁰

Critics of FDA’s policy argue that the differences between a GE food and its conventional counterpart have never been defined, and view the concept of “substantial equivalence” as being a barrier to research into potential risks of eating GE foods.¹⁶¹ According to one source, there is but one somewhat official definition of “substantial equivalence,” that by the Organization for Economic Cooperation and Development (OECD): “The concept of substantial equivalence embodies the idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new.”¹⁶² Using this definition, GE food “can be characterized as substantially equivalent to its natural antecedent, it can be assumed to pose no new health risks and hence to be acceptable for commercial use.”¹⁶³

FDA also has authority over food labeling,¹⁶⁴ but stands by its product-based policy that GE foods must only be labeled if they differ “significantly” from their conventional counterparts. A change is “significant” when there is an alteration of the nutritional

¹⁵⁹ Jaffe, G. (2003, May). *Current regulation of biopharming: Is it adequate?* [Electronic version] Retrieved on October 3, 2006 from www.cspinet.org/biotech/ABAFinal.pdf

¹⁶⁰ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22988 (May 29, 1992)

¹⁶¹ Ho, M.W. and Steinbrecher, R. (1998). *Fatal flaws in food safety assessment: Critique of the joint FAO/WHO biotechnology and food safety report*, Retrieved on November 1, 2006, from <http://www.psra.org/fao96.htm>

¹⁶² Organization of Economic Cooperation and Development. (1993). *Safety evaluation of foods derived by modern biotechnology: Concepts and principles*, cited In Millstone, E., Brunner, E., and Mayer, S. (1999). Beyond ‘substantial equivalence’ [Electronic version], *Nature*, 401: 525-526, Retrieved on October 5, 2006 from http://www.biotech-info.net/substantial_equivalence.html

¹⁶³ Millstone, E., Brunner, E., and Mayer, S. (1999). Beyond ‘substantial equivalence’ [Electronic version], *Nature*, 401: 525-526, Retrieved on October 5, 2006 from http://www.biotechinfo.net/substantial_equivalence.html

¹⁶⁴ Federal Food, Drug, and Cosmetic Act, 21 C.F.R. § 101.22

content of the food or if a potential allergen is present.¹⁶⁵ Because FDA believes GE food does not differ from conventional food, labeling of GE foods is not required.¹⁶⁶

Consumers and food industry players alike have expressed concern about FDA's voluntary approach to regulating genetically engineered food. In response, FDA proposed an amendment to its voluntary consultation policy in 2001.¹⁶⁷ To date, the new rule has not been finalized. Therefore, it is up to the applicant to decide whether to notify FDA prior to putting GE foods and animal feeds on the market. Those who do notify FDA before a new GE ingredient is placed on the market go through a consultation with the agency, after which FDA publishes a memo.¹⁶⁸ Although "FDA believes that, to date, all developers of bioengineered foods commercially marketed in the United States have consulted with the agency prior to marketing the food,"¹⁶⁹ developers of a new GE food could legally place it on the market without FDA's knowledge.¹⁷⁰ FDA does not require mandatory safety testing for GE foods either,¹⁷¹ and has only conducted one safety review for a GE food: the first deregulated food product mentioned earlier, the Flavr Savr tomato.¹⁷²

The National Environmental Policy Act

All three agencies are subject to the National Environmental Policy Act (NEPA), a law that requires all federal agencies to consider the consequences of their proposed actions

¹⁶⁵ Vines, R. (2002, May). The regulation of biotechnology [Electronic version], Retrieved on October 2, 2006, from www.ext.vt.edu/pubs/biotech/443-006/443-006.html

¹⁶⁶ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,989 (May 29, 1992)

¹⁶⁷ 66 Fed. Reg. 4706-4738 (January 18, 2001)

¹⁶⁸ U.S. Food and Drug Administration. (2004, December 8). Biotechnology Consultation Note to the File: BNF No. 000084, Retrieved August 8, 2006, from <http://www.cfsan.fda.gov/~rdb/bnfm084.html>

¹⁶⁹ 66 Fed. Reg. 4708 (January 18, 2001)

¹⁷⁰ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,989 (May 29, 1992) (stating that "consultation is not legally required" before an ingredient is placed on the market)

¹⁷¹ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,989 (May 29, 1992) ("FDA has not found it necessary to conduct, prior to marketing, routine safety reviews of whole plants derived from plants.")

¹⁷² Pusztai, A. (2001). Genetically modified foods: Are they a risk to human/animal health? *American Institute of Biological Sciences*, Retrieved on September 20, 2006 from <http://www.actionbioscience.org/biotech/pusztai.html>

on the human environment prior to making decisions.¹⁷³ NEPA provides procedures for environmental review, which comes into play for some agency decisions regarding agricultural biotechnology, especially the USDA.¹⁷⁴ For example, APHIS' Environmental Assessments stem from NEPA process, and are used to determine whether a full Environmental Impact Statement (EIS) is required.¹⁷⁵

Segregation and Containment Measures

Segregation The U.S. currently does not require the segregation of GE crops from non-GE crops in the food supply chain, but may propose a system in the future.¹⁷⁶ As will be explained in the following chapter, segregating GE and non-GE crops, including organic, has proven extremely difficult, and has proven to be an expensive process—both to establish segregation measures and to fix mistakes involving unintended mixing of GE and non-GE products. Segregating GE and non-GE products throughout the planting, processing, transportation, and exporting stages is a complicated and expensive procedure. As illustrated by Dr. Susan Harlander, former vice president of Pillsbury Company: a food company can have more than 6,000 products that contain 8,000 ingredients from 1,000 suppliers that move through 30 processing plants on their way to being exported to as many as 100 countries.¹⁷⁷ The presence of unapproved varieties of GE crops in the food system poses even greater challenges. According to some experts, “it may be simply impossible to prevent all mixing and thus ensure the regular absence of unapproved transformation events,” especially in the case of crops that cross-pollinate.¹⁷⁸

¹⁷³ 42 U.S.C. 4332

¹⁷⁴ The Pew Initiative on Food and Biotechnology. (2004). *Issues in the regulation of genetically engineered plants and animals* [Electronic version]. Washington, DC: Author, Retrieved on August 24, 2006, from <http://pewagbiotech.org/research/regulation/Regulation.pdf>

¹⁷⁵ 7 C.F.R. § 372

¹⁷⁶ Fabi, R. (2006, August 6). USDA mulls program verifying bio-free US crops [Electronic version], *Reuters*, Retrieved on September 30, 2006, from <http://www.organicconsumers.org/gefood/segregation080802.cfm>

¹⁷⁷ Vines, R. (2002, May). The regulation of biotechnology [Electronic version], Retrieved on October 2, 2006, from www.ext.vt.edu/pubs/biotech/443-006/443-006.html

¹⁷⁸ Bullock, D.S. & Desquilbet, M. (2002). The economics of non-GMO segregation and identity preservation, *Food Policy* 27, 81–99.

Containment Efforts to keep GE products segregated from non-GE products begin in the field. Institutions that submit notifications to APHIS for field trials are required to follow performance standards, including important containment measures for reducing the crops' effect on the environment and surrounding crops. Some of the performance standards that must be met for introductions under the notification procedure include:¹⁷⁹

1. Regulated plants or plant material must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.
2. Regulated plants released into the environment must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species that are not part of the environmental release.
3. Regulated plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.
4. The field trial must be conducted such that the regulated article will not persist in the environment, and no offspring can be produced that could persist in the environment.
5. Upon termination of the field test no viable material shall remain which is likely to volunteer in subsequent seasons, or volunteers shall be managed to prevent persistence in the environment.

As for permits, “conditions” are set for anyone issued a permit to “prevent the dissemination and establishment of plant pests.”¹⁸⁰ Not surprisingly, many of the conditions under permits overlap with the performance standards required for notifications; however, permits require more government involvement and stricter containment and disposal measures. For example, anyone issued a permit must submit a field test report within six months after the termination of the field test, including an analysis of all deleterious effects on plants, nontarget organisms, or the environment.¹⁸¹

¹⁷⁹ 7 C.F.R. § 340.3(c)

¹⁸⁰ 7 C.F.R. § 340.4(f)

¹⁸¹ 7 C.F.R. § 340(f)(9)

While APHIS gives recommendations on how to meet the performance standards, the instructions are very general in nature and may not appropriately address each new GE plant, including GE alfalfa.¹⁸² They are also not legally binding.¹⁸³ Ultimately, it is the duty of the “applicant” for each regulated planting of genetically engineered plants “to determine the specific procedures that will need to be used to meet the performance standards and to certify that those standards are being met.”¹⁸⁴ Once deregulated, there are no restrictions imposed on the commercial planting of herbicide-tolerant plants, and further testing cannot be requested. USDA does not have the authority to require farmers who plant RR seeds to create refuge or buffer areas to avoid cross-pollination with neighbors’ crops or surrounding weeds.

Oversight of Field Trials

Noncompliance with performance standards or permit conditions can involve a variety of infractions, including incorrect isolation distances or planting without a current permit.¹⁸⁵ According to APHIS, 76 percent of all potential compliance infractions between 1990 and 2001 were actual infractions, and only 12 percent were deemed violations and referred to APHIS’ Investigative and Enforcement Services unit.¹⁸⁶

Although APHIS claims that only two percent of the field tests (in their 1990 – 2001 investigation) resulted in potential compliance infractions,¹⁸⁷ a recent audit report from the USDA Office of Inspector General concluded that APHIS’ current regulations, policies, and procedures do not go far enough to ensure the safe introduction of

¹⁸² U.S. Department of Agriculture, Animal and Plant Health Inspection Service. User's guide for introducing genetically engineered plants and microorganisms, Retrieved on October 9, 2006 from <http://www.aphis.usda.gov/brs/usergd.html>

¹⁸³ Ibid.

¹⁸⁴ Ibid.

¹⁸⁵ U.S. Department of Agriculture, Animal and Plant Health Inspection Service. What is the compliance history with APHIS’ biotechnology regulations? Retrieved on October 1, 2006 from <http://www.aphis.usda.gov/brs/compliance9.html>

¹⁸⁶ Ibid.

¹⁸⁷ Ibid.

agricultural biotechnology.¹⁸⁸ Specifically, the audit found that before APHIS approves field trials, it does not review the containment protocols, which explain how the notification applicant will contain the GE crop to prevent it from persisting in the environment.¹⁸⁹ This is especially disconcerting in light of the fact that the vast majority of field tests are authorized under the notification process (close to 100 percent).

Moreover, as the audit reports:

APHIS does not thoroughly document its reviews of applications in the official files. Specifically, APHIS biotechnologists do not sufficiently document their review process and scientific basis for approving initial field test applications. APHIS also does not effectively track information required during the field tests, including approved applicants' progress reports, which should contain the results of field tests, including any harmful effects on the environment. Although we noted that many permit and notification holders submit these required progress reports late or not at all, APHIS does not always follow up to obtain the information.¹⁹⁰

Not only does APHIS “lack basic information about the field test sites it approves and is responsible for monitoring, including where and how the crops are being grown, and what becomes of them at the end of the field test, the precise locations of all GE field test sites planted in the US are not always known.”¹⁹¹ As far as inspections go, APHIS does not keep track of the total number of inspections completed, and the audit found that the agency “continued to lack an effective, comprehensive management information system to account for all inspections and their outcomes.”¹⁹²

Other reports call for improvement of agency oversight regarding field trials as well. The National Research Council concluded that because no single “bioconfinement”¹⁹³ method is likely to be 100 percent effective, developers should create a redundant system by

¹⁸⁸ U.S. Department of Agriculture, Office of Inspector General. (2005, December). *Audit report: Animal and Plant Health Inspection Service controls over issuance of genetically engineered organism release permits*, Retrieved on April 13, 2006, from www.usda.gov/oig/webdocs/50601-08-TE.pdf

¹⁸⁹ Ibid.

¹⁹⁰ Ibid.

¹⁹¹ Ibid.

¹⁹² Ibid.

¹⁹³ “Bioconfinement” is defined by the committee writing the report as a set of biological techniques used to prevent transgenic animals, plants, and microbes from escaping into natural ecosystems and breeding, thus competing with their wild relatives or passing engineered traits to closely related species.

using more than one method of containment.¹⁹⁴ The report calls for additional research to improve both containment methods and public confidence in regulation.¹⁹⁵ In addition, the committee determined that methods for detecting and culling GE organisms after they escaped “bioconfinement” are limited.¹⁹⁶ An earlier report by the National Research Council recommends that the process for testing and deregulating GE crops “be made significantly more transparent and rigorous” to improve public involvement with policy development and decision making, as well as enhance scientific peer review.¹⁹⁷

Consumers’ Perceptions of Genetic Engineering

Similar to the regulation and marketing of organic products, consumers’ perceptions play an important role in the regulation of genetically engineered food. Next to ensuring the safety of products, the Coordinated Framework was developed to instill public confidence in the regulation of GE crops and food.¹⁹⁸ As shown, the system is problematic, and, as a result, consumers’ perceptions of GE food are influencing the direction of research and development in biotechnology.¹⁹⁹ Significantly, they have been a primary factor in halting the marketing of several new GE foods.²⁰⁰

¹⁹⁴ National Research Council. (2004). *Biological confinement of genetically engineered organisms*, Washington, DC: National Academy Press.

¹⁹⁵ Ibid.

¹⁹⁶ Ibid.

¹⁹⁷ National Research Council. (2002). *Environmental effects of transgenic plants: The scope and adequacy of regulation*, Washington, DC: National Academy Press.

¹⁹⁸ The Pew Initiative on Food and Biotechnology. (2004). *Issues in the regulation of genetically engineered plants and animals* [Electronic version]. Washington, DC: Author, Retrieved on August 24, 2006, from <http://pewagbiotech.org/research/regulation/Regulation.pdf>

¹⁹⁹ The next (second) generation of GE crops—those that focus on consumer-oriented traits, such as nutritional quality, rather than producer-oriented traits, such as herbicide-tolerance—are now the focus of much agricultural biotechnology research. The first of these products, low linolenic soybeans, are already grown on hundreds of thousands of acres in the U.S., and are intended to reduce or eliminate trans fatty acid in a variety of food products. (USA: Kellogg moves to low linoleic oil to cut trans fats, (2005, December 9) Just-food, Retrieved on August 12, 2006, from <http://www.organicconsumers.org/ge/soyoil121205.cfm>

²⁰⁰ According to a report by the National Center for Food & Agriculture Policy, herbicide-tolerant tomato research has “been shelved at this time because of the controversy surrounding genetic engineering.” (National Center for Food and Agriculture Policy. (2002, June). *Plant biotechnology: Current and potential impact for improving pest management in U.S. Agriculture: An analysis of 40 case studies, herbicide tolerant tomato* [Electronic version], Retrieved on July 12, 2006, from www.ncfap.org/40CaseStudies.htm) Herbicide-tolerant lettuce has apparently been abandoned as well. According to a 2004 *New York Times* article, “lettuce growers in California balked at the introduction of Roundup Ready lettuce.” (Pollack, A. (2004, May 20). Narrow path for new biotech food crops [Electronic version], *The New York Times*,

In general, some consumers do not favor the introduction of GE foods,²⁰¹ and believe that laws regulating biotechnology are needed.²⁰² Results from a 2004 Pew Initiative on Food and Agriculture poll show that 40 percent of participants said there is “too little” regulation of GE food; 47 percent are opposed to introducing GE foods into the U.S. food supply; 27 percent believe GE foods are “basically unsafe;” and over 90 percent think GE foods should be labeled.²⁰³ Polls also indicate that consumers are willing to pay more for food that is not genetically engineered. A USDA study showed that in general consumers discount GE food “by an average of 14 percent.”²⁰⁴ U.S. consumers are willing to pay an extra two to three dollars per pound for beef that is from cattle not fed GE feed.²⁰⁵ And other polls show that consumers are willing to pay 5 percent more for non-GE potatoes.²⁰⁶

Retrieved on July 12, 2006, from

<http://query.nytimes.com/gst/fullpage.html?res=9D00E5DB103FF933A15756C0A9629C8B63&sec=health&pagewanted=print>

²⁰¹ The Pew Initiative on Food and Biotechnology. (2004, September). Overview of 2004 findings focus groups & poll, Retrieved on October 3, 2006, from <http://pewagbiotech.org/research/2005update/>

²⁰² Guru, M. (1999). Attitudes concerning biotechnology, Kerr Center for Sustainable Agriculture, Retrieved on August 1, 2006, from www.biotech-info.net/kerr_attitudes.pdf (60% of respondents agreed with this statement.)

²⁰³ Hallman, W. K., Hebden, W. C., Aquino, H.L., Cuite, C.L. & Lang, J.T. (2003). Public perceptions of genetically modified foods: A national study of american knowledge and opinion [Electronic version], Retrieved on September 29, 2006, from www.foodpolicyinstitute.org/docs/reports/NationalStudy2003.pdf (finding that 94% of respondents favor labeling of foods containing GE ingredients); Langer, G. (2001, June 19). Behind the label: Many skeptical of bio-engineered food, ABCNews, Retrieved on September 23, 2006, from <http://abcnews.go.com/sections/scitech/DailyNews/poll010619.html> (finding that 93% of respondents favor labeling of foods containing GE ingredients).

²⁰⁴ Tegene, A., Huffman, W., Rousu, M. & Shogren, J. (2003, March). The effects of information on consumer demand for biotech foods: Evidence from experimental auctions [Electronic version], U.S. Department of Agriculture, Economic Research Service, Retrieved on September 24, 2006, from www.ers.usda.gov/Publications/tb1903

²⁰⁵ Lusk, J.L., Roosen, J., & Fox, J. (2003, February). Demand for beef with growth hormones and fed genetic corn [Electronic version], *American Journal of Agricultural Economics*, 85(1), cited In U.S. Department of Agriculture, Economic Research Service. (2006, April). *The first decade of genetically engineered crops in the United States* [Electronic version], Retrieved on August 23, 2006, from <http://www.ers.usda.gov/publications/EIB11/>.

²⁰⁶ Loureiro, M.L., & Hine, S. (2002, December). Discovering niche markets: A comparison of consumer willingness to pay for local (Colorado grown), organic, and GMO-free products. *Journal of Agricultural and Applied Economics*, 34(3), cited In U.S. Department of Agriculture, Economic Research Service. (2006, April). *The first decade of genetically engineered crops in the United States* [Electronic version], Retrieved on August 23, 2006, from <http://www.ers.usda.gov/publications/EIB11/>.

Since the introduction of genetically engineered food, several labeling initiatives have failed, both at the state and federal level.²⁰⁷ In 2005, however, Alaska became the first state to pass legislation specific to labeling genetically engineered food, requiring the labeling of genetically engineered fish sold in the state.²⁰⁸ (The FDA is currently reviewing a petition for genetically engineered salmon.)²⁰⁹ The most recent push for mandatory labeling is the “Genetically Engineered Food Right to Know Act of 2006” (H.R. 5269), introduced by Ohio Representative Dennis Kucinich, a long-time proponent of mandatory labeling and more rigorous regulation of GE crops and food.²¹⁰

Summary

Unlike organic production, the introduction of GE crops and food in the U.S. came without any new statute to regulate these products in the environment and marketplace, and address potential environmental and human health risks associated with the new technology. Instead, the government continues to rely on a patchwork of existing and often outdated statutes, including those governing plant pests, pesticides, and food. Experts agree that the mix of rules and laws has proved confusing, and, in particular, do not afford proper oversight for environmental risks associated with GE organisms.²¹¹ Specifically, U.S. regulation of agricultural biotechnology research continues to rely more on “voluntary reporting and professional norms than on stringent government

²⁰⁷ In 1999, Rep. Dennis Kucinich introduced the Genetically Engineered Food Right to Know Act of 1999 (H.R. 3377) to require mandatory labeling of GE food; In 2000, Senator Barbara Boxer introduced similar labeling legislation in the U.S. Senate (S. 2080); Measure 27 was an initiative to require labeling of GE foods in Oregon—it failed in Oregon’s fall 2002 ballot, Vote Yes on Measure 27!, Retrieved on September 27, 2006, from <http://www.voteyeson27.com/>

²⁰⁸ The Pew Initiative on Food and Biotechnology, (2006). Legislation tracker 2005, Retrieved on September 16, 2006, from <http://pewagbiotech.org/resources/factsheets/legislation/index.php?Year=2005>

²⁰⁹ Yoon, C.K. (2000, May 1). Altered salmon leading way to dinner plates [Electronic version], but rules lag, *The New York Times*, Retrieved on October 4, 2006, from <http://query.nytimes.com/gst/fullpage.html?sec=health&res=9D03E7DF1239F932A35756C0A9669C8B63&n=Top%2fReference%2fTimes%20Topics%2fPeople%2fY%2fYoon%2c%20Carol%20Kaesuk>

²¹⁰ Genetically Engineered Food Right to Know Act of 2006, H.R. 5269, Retrieved on September 25, 2006, from <http://www.govtrack.us/congress/bill.xpd?bill=h109-5269>

²¹¹ Rissler, J. & Mellon, M. (1996). *The ecological risks of engineered crops*, Cambridge, MA: MIT Press.

regulation.”²¹² Regarding consumers, polls consistently show that choice regarding GE foods is wanted in the marketplace, and that non-GE foods are growing in demand.

Neither the NOP nor the Coordinated Framework directly address the consequences of genetic drift. Specifically, no planting restrictions are placed on growers of deregulated GE crops to mitigate gene flow, leaving the burden to protect organic products from unwanted transgenic material on the shoulders of organic farmers. Even if containment measures are taken, they are not 100 percent effective. As documented by various reports, APHIS’ oversight of regulated plants in field trials is not adequate for protecting the environment and non-GE crops from the introduction of genetically engineered plants.

In the next chapter, I will apply these frameworks to the case of Roundup Ready alfalfa, including a description of the regulatory process that Monsanto and Forage Genetics International followed to get the genetically engineered variety deregulated. I will also explain some potential implications of introducing this variety into the environment and marketplace, paying close attention to important issues identified in this first chapter.

²¹² Uchtmann, D.L. (2002). Starlink TM—A case study of agricultural biotechnology regulation, 7 Drake J. Agric. L. 159.

2.

ROUNDUP READY ALFALFA: THE FIRST GENETICALLY ENGINEERED PERENNIAL FIELD CROP HITS THE MARKET

*Once [Roundup Ready alfalfa] is in the environment, it's there—it will get in everything. Alfalfa as we know it will be gone forever.*²¹³

- Phillip Geertson, Oregon alfalfa seed producer and lead plaintiff in RR alfalfa lawsuit

To fully understand how the Coordinated Framework works it is useful to examine it in the context of one particular genetically engineered (GE) crop. Thus, this chapter analyzes the case of Roundup Ready (RR) alfalfa by first describing the regulatory process that Monsanto and Forage Genetics went through to introduce it. Then, I explain the potential implications of introducing RR alfalfa, focusing on effects to the organic industry. Although some of these implications have been mentioned in public comments submitted in response to Monsanto's petition and a lawsuit against the USDA for deregulating RR alfalfa, to the best of my knowledge, there has not been an effort to comprehensively examine the implications of introducing RR alfalfa for the organic industry.

History of Roundup Ready Alfalfa

RR soybeans entered the market in 1996, followed by RR canola, corn, potatoes, and cotton. Although farmers have used glyphosate since the 1970s, RR crops allow farmers to apply Roundup (or other glyphosate herbicides) in an unprecedented manner: directly over their crops to control certain weeds and unwanted grasses without damaging harvests—hence the name, the crops are “ready” for Roundup.²¹⁴ As mentioned earlier,

²¹³ P. Geertson, personal communication, April 14, 2006.

²¹⁴ Pesticide Action Network. (1996, September). Glyphosate fact sheet [Electronic version], *Pesticides News*, No. 33, Retrieved on November 1, 2006, from <http://www.pan-uk.org/pestnews/actives/glyphosa.htm>

RR crops continue to be readily adopted, and now claim over 100 million acres across the American landscape.²¹⁵

The most recent RR crop to enter fields is alfalfa, produced by the Monsanto Company in partnership with the largest alfalfa seed producer, Forage Genetics International (a subsidiary of Land O'Lakes). The events (J101 and J163) used in RR alfalfa are tolerant to glyphosate, the active ingredient in Monsanto's trademark herbicide, Roundup. RR alfalfa is the first genetically engineered perennial plant to be commercialized for widespread planting in the United States.²¹⁶

Alfalfa (*Medicago sativa* L.) is the most important forage crop in the U.S., and is grown throughout the nation, covering over 22 million acres in 2006.²¹⁷ It is the third most economically valuable crop to U.S. agriculture.²¹⁸ Alfalfa is an important animal feed because of its high protein and low fiber content, and is a staple of most livestock diets, especially dairy cows.²¹⁹ Because of alfalfa's pervasiveness throughout the nation, and because it is typically grown as a perennial crop, it provides important habitat for wildlife, including migratory birds and endangered species.²²⁰ For all these reasons, it is dubbed the "Queen of Forages."²²¹

Monsanto incorporated the gene sequence (CP4 EPSPS) from a native soil microorganism, *Agrobacterium*, into the alfalfa genome to confer resistance to

²¹⁵ International Service for the Acquisition of Agri-Biotech Applications. (2005). Global status of biotech/GM crops in 2005, Retrieved on October 4, 2006, from <http://www.isaaa.org/kc/bin/briefs34/es/index.htm>

²¹⁶ Genetically engineered papaya trees were the first perennial plant to be commercialized, but are primarily grown in Hawaii. Roundup Ready alfalfa is the first perennial in the Roundup Ready line.

²¹⁷ U.S. Department of Agriculture, National Agriculture Statistics Service. (2006). Hay alfalfa (Dry), Retrieved on October 9, 2006 from http://www.nass.usda.gov/Statistics_by_Subject/index.asp

²¹⁸ U.S. Department of Agriculture, National Agriculture Statistics Service. (2006, February). Crop values, 2005, Retrieved on November 11, 2006, from <http://usda.mannlib.cornell.edu/reports/nassr/price/zcv-bb/cpv10206.txt>

²¹⁹ Martin, N.P. & Mertens, D.R. (2005). Reinventing alfalfa for dairy cattle and novel uses, *Proceedings of California Alfalfa and Forage Symposium*, Visalia, CA, Retrieved on August 24, 2006, from <http://alfalfa.ucdavis.edu>.

²²⁰ California Alfalfa & Forage Association. (2001). *Alfalfa, wildlife and the environment the importance and benefits of alfalfa in the 21st century* [Electronic version], Retrieved on August 1, 2006, from www.alfalfa.ucdavis.edu/subpages/Wildlife/BrochureFINAL.pdf

²²¹ Ibid.

glyphosate.²²² Glyphosate acts on various enzyme systems and inhibits amino acid metabolism in what is known as the shikimic acid pathway.²²³ RR alfalfa plants, on the other hand, actually survive glyphosate applications, because the biosynthesis of aromatic amino acids is maintained by the continued action of the CP4 EPSPS enzyme in the presence of glyphosate.²²⁴

Dairy producers will be the likely adopters of RR alfalfa, because they often depend on pure alfalfa stands free of weeds and grasses, whereas beef cattle producers and horse owners typically feed their animals an alfalfa-grass mixed hay.²²⁵ RR alfalfa is not useful to mixed stands, as applications of Roundup kill the desired grasses. The majority of U.S. alfalfa acreage is planted to pure stands (40 percent), whereas a quarter is planted with grasses or another companion crop.²²⁶

Regulatory Process Leading to the Commercialization of Roundup Ready Alfalfa

The path of RR alfalfa from field trials initiated in 1998 to approval for moving the crop into the marketplace in 2005 involved several key steps, reviewed below and summarized in Table 2. What we see is a governmental process that posed few serious hurdles along the way for Monsanto; yet, one that was also clearly discomfoting to many observers of

²²² Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

²²³ Pesticide Action Network. (1996, September). Glyphosate fact sheet [Electronic version], *Pesticides News*, No. 33, Retrieved on November 1, 2006, from <http://www.pan-uk.org/pestnews/actives/glyphosa.htm>

²²⁴ Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

²²⁵ Putnam, D. (2005). Market sensitivity and methods to ensure tolerance of biotech and non-biotech alfalfa production systems, Proceedings of California Alfalfa & Forage Symposium, Visalia, CA, Retrieved on September 23, 2006, from <http://alfalfa.ucdavis.edu>

²²⁶ Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html; (The remaining 35 percent is planted with a cover crop.)

that process, resulting ultimately in a lawsuit challenging many of the government's assumptions and findings.

Field Trials Under APHIS' notification program, Monsanto applied for over 300 glyphosate-tolerant alfalfa field trial permits throughout the U.S. between 1998 and 2005.²²⁷ According to the Information Systems for Biotechnology database, only seven of these notifications were either withdrawn or denied.²²⁸ The average acreage of these field trials was 435 acres.²²⁹ It is difficult to determine the total acreage and locations of these field trials, because both notifications and permits list the amount of proposed acreage for the entire notification or permit, and not the particular states where the trials take place. Therefore, it is impossible to estimate the amount of acreage proposed for a particular state when multiple states are listed under a single notification. Also, according to Neil Hoffman, Director of the Regulatory Division for APHIS, the amount of acreage proposed usually exceeds the amount planted.²³⁰

It is also difficult to determine if Monsanto and Forage Genetics met the performance standards outlined in the previous chapter (7 C.F.R. 340.3(c)), as there is no record of RR field trial inspections in Monsanto's petition or APHIS' Environmental Assessment (EA), and little record of the containment protocol used for the field trials.²³¹ The only containment measure mentioned in the companies' petition is the use of different equipment for harvesting RR alfalfa from that used for harvesting conventional alfalfa.²³² That said, Forage Genetics did conduct two groups of studies that measured the distance

²²⁷ Information Systems for Biotechnology. (2006). Field test releases in the U.S., Retrieved on October 1, 2006 from <http://www.isb.vt.edu/cfdocs/fieldtests1.cfm>

²²⁸ Ibid.

²²⁹ Gurian-Sherman, Doug. (2006). *Contaminating the wild? gene flow from experimental field trials of genetically engineered crops to related wild plants*, Washington, DC: The Center for Food Safety, Retrieved on July 2, 2006, from www.centerforfoodsafety.org/pubs/Contaminating_the_Wild_Report.pdf

²³⁰ N. Hoffman, personal communication, May 15, 2006.

²³¹ In March 2006, I requested this information from the Biotechnology Regulatory Service, and was told that I would need to file a Freedom of Information Act (FOIA) request for information not provided in the Environmental Assessment and industry petition. Neither of these documents discussed containment protocol in the field trials, only containment for commercial seed planting. There is no evidence for field trial inspections.

²³² Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

leafcutter and honey bees transfer pollen from RR alfalfa plants to surrounding conventional plants.²³³ These trials were conducted to gain a better understanding of alfalfa pollen flow, and to determine suggested isolation standards for minimizing the spread of the RR trait in commercial scale plantings.²³⁴ Yet there is little evidence that isolation distances were implemented for RR alfalfa field trials in general. A sentence in the Federal Register notice advising the public of RR alfalfa's deregulation status mentions that field trials "were conducted under conditions of reproductive and physical confinement or isolation."²³⁵

Petition for Deregulation It took four years for Monsanto and Forage Genetics to complete the regulatory process that eventually brought RR alfalfa to the marketplace. In 2002, the two companies began preparing its petition to APHIS for the deregulation of RR alfalfa, beginning with the EPA. Monsanto first submitted glyphosate residue data and proposed labeling for the use of Roundup herbicide over the top of RR alfalfa, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).²³⁶ Subsequently, Monsanto submitted a petition for "Reduced Risk" status for review of the data, which EPA granted on July 23, 2002.²³⁷ The "Reduced Risk" status allows for a fast-track review of the use of glyphosate in conjunction with RR alfalfa.²³⁸

²³³ Fitzpatrick, S., Reisen, P. & McCaslin, M. (2002). Alfalfa pollen-mediated gene flow studies, 2000-2001, In *Report of the 38th North American Alfalfa Improvement Conference*, Sacramento, California, Retrieved on September 12, 2006, from www.foragegenetics.com/pdf/102000-01NAAICAbstract.pdf

²³⁴ Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

²³⁵ 70 Fed. Reg. 36918 (June 27, 2005)

²³⁶ Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

²³⁷ The "Guidelines for Expedited Review of Conventional Pesticides under the Reduced-Risk Initiative and for Biological Pesticides" was a response to the Food Quality Protection Act of 1996, which requires that EPA expedite the review of applications for registration of pesticides, 62 Fed. Reg. 47808 (September 11, 1997); Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

²³⁸ Ibid.

On April 17, 2002, EPA issued a notice in the Federal Register that, pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA), Monsanto had petitioned the agency to establish tolerances for glyphosate residues on alfalfa.²³⁹ Pursuant to section 408(d) of the FFDCA, EPA established a tolerance for residues of glyphosate “in or on animal feed, nongrass, group” at 400 parts per million (ppm), and “in or on grass forage, fodder and hay, group” at 300 ppm.²⁴⁰ Because these tolerances did not extend to alfalfa seed, Monsanto petitioned EPA again to fill this regulatory gap.²⁴¹ Monsanto further proposed to delete the tolerances for alfalfa forage and hay, as the company believed these tolerances were no longer needed.²⁴² These tolerances were to apply to both conventional and genetically engineered alfalfa.²⁴³ Three months later, EPA denied Monsanto’s request to eliminate the tolerances for alfalfa forage and alfalfa hay.²⁴⁴ Because EPA previously established an exemption for the CP4 EPSPS protein and the genetic material necessary for the production of this protein in all raw agricultural commodities, it was unnecessary for Monsanto and Forage Genetics to acquire an exemption or tolerance for this protein.²⁴⁵

In accordance with FDA’s policy statement concerning the regulation of genetically engineered food and feed products,²⁴⁶ Monsanto voluntarily submitted a food and feed safety and nutritional assessment summary for events J101 and J163 in October 2003.²⁴⁷ Although FDA published an overview of the data submitted by Monsanto (discussed below), the actual data submitted to FDA is only available to the public through a

²³⁹ 67 Fed. Reg. 18894 (April 17, 2002)

²⁴⁰ 67 Fed. Reg. 60934 (Sept. 27, 2002)

²⁴¹ 69 Fed. Reg. 51303 (August 18, 2004)

²⁴² *Ibid.*

²⁴³ *Ibid.*

²⁴⁴ 69 Fed. Reg. 65081 (November 10, 2004)

²⁴⁵ 40 CFR §180.1174; This rule extends to Roundup Ready alfalfa, as it established an “exemption from the requirement of a tolerance for residues of the plant pesticide inert ingredient [CP4 EPSPS] and the genetic material necessary for its production in *all plants*.” [emphasis added], 61 Fed. Reg. 40338 (August 2, 1996)

²⁴⁶ 57 Fed. Reg. 22984 (May 29, 1992)

²⁴⁷ Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

Freedom of Information Act (FOIA) request.²⁴⁸ At this time, Monsanto also made submissions for regulatory import and production approvals to several countries, including Canada, Mexico, Japan, Taiwan, and Korea.²⁴⁹

On November 24, 2004, USDA published a notice in the Federal Register announcing that Monsanto and Forage Genetics had submitted their petition to deregulate RR alfalfa and that APHIS' preliminary EA was available for public comment.²⁵⁰ The public comment period was set to end on January 24, 2005, but was later extended to February 17, 2005.²⁵¹

The next month, FDA issued its Biotechnology Consultation Note regarding RR alfalfa.²⁵² The Note summarizes Monsanto's food and feed safety and nutritional assessment documents. Because FDA neither conducted independent tests, nor required mandatory food safety testing, its opinion on RR alfalfa is based on Monsanto's own determination that Roundup Ready alfalfa is not materially different from conventional alfalfa:

Monsanto and Forage Genetics have concluded that their glyphosate-tolerant alfalfa event J101 and event J163, and the feeds and foods derived from them, are not materially different in safety, composition, or any other relevant parameter from alfalfa now grown, marketed, and consumed. At this time, based on Monsanto's and Forage Genetics' description of its data and information, the Agency considers this consultation on alfalfa event J101 and event J163 to be complete.²⁵³

²⁴⁸ C. Hendrickson, Food and Drug Administration, personal communication, October 10, 2006.

²⁴⁹ Doll, J. (2005, July 21) Roundup Ready alfalfa approved for use [Electronic version], *Wisconsin Crop Manager*, 12(20), Retrieved on October 6, 2006, from <http://ipcm.wisc.edu/wcm/pdfs/2005/05-20Weeds2.html>; (When the petition was filed, imports of Roundup Ready alfalfa products had not been approved in any of these countries. Since achieving nonregulated status, Roundup Ready alfalfa has been approved in all major export countries.)

²⁵⁰ 69 Fed. Reg. 68300-68301 (November 24, 2004)

²⁵¹ 70 Fed. Reg. 5601-5602 (February 3, 2005)

²⁵² Center for Food Safety and Applied Nutrition/Office of Food Additive Safety. (2004, December 8). Biotechnology Consultation Note to the File BNF 000084, Retrieved June 2, 2006, from <http://www.cfsan.fda.gov/~rdb/bnfm084.html>

²⁵³ U.S. Food and Drug Administration. (2004, December 8). Biotechnology Consultation Note to the File: BNF No. 000084, Retrieved June 2, 2006, from <http://www.cfsan.fda.gov/~rdb/bnfm084.html>

By 2005, it seemed that Monsanto and Forage Genetics had few hurdles left in its path to achieving nonregulated status for RR alfalfa. EPA set a tolerance level of 0.5 ppm for glyphosate residue on alfalfa seed in February, the final decision the agency would make in the approval process.²⁵⁴ Though not mandatory, FDA had reviewed a summary of the companies' data on RR alfalfa's food and feed characteristics. The petition was still pending through APHIS, but evidence pointed toward an approval that year, including several articles in agricultural media.²⁵⁵

Thus, people following RR alfalfa's development were not surprised when USDA announced its decision to deregulate RR alfalfa in May 2005, paving the way for the crop to move into the marketplace. The requirements pertaining to regulated articles under 7 C.F.R. 340 no longer applied to the genetically engineered alfalfa variety or its progeny.²⁵⁶ APHIS published its Finding of No Significant Impact (FONSI), which concluded that alfalfa events J101 and J163 "would not present a risk of plant pest introduction or dissemination," and that the events "will not harm threatened or endangered species or organisms that are beneficial to agriculture; and. . .should not reduce the ability to control pests and weeds in alfalfa or other crops."²⁵⁷ A FONSI indicates that the agency does not need to prepare an Environmental Impact Statement (EIS).²⁵⁸ Perhaps this is not surprising: there has never been an EIS performed for any of

²⁵⁴ 70 Fed. Reg. 7861-7864 (February 16, 2005)

²⁵⁵ Cline, H. (2004, September 29). Benefits, challenges of Roundup Ready alfalfa examined [Electronic version], *Western Farm Press*, Retrieved on September 12, 2006 from http://westernfarmpress.com/mag/farming_benefits_challenges_rr/; Wilkins, D. (2005, February 11). Roundup Ready Alfalfa On The Way [Electronic version], *Capital Press Agriculture Weekly*, Retrieved on September 11, 2006, from <http://www.capitalpress.info/main.asp?FromHome=1&TypeID=1&SectionID=67&ArticleID=15277&SubSectionID=792>; Cline, H. (2006, January 11). Growing, marketing herbicide-resistant alfalfa will be challenging, worthwhile [Electronic version], *Western Farm Press*, Retrieved on September 12, 2006, from <http://westernfarmpress.com/news/1-11-05-herbicide-resistant-alfalfa/>

²⁵⁶ 70 Fed. Reg. 36918 (June 27, 2005)

²⁵⁷ Ibid.

²⁵⁸ 7 C.F.R. 372.5(d); The agency is currently performing an EIS for Roundup Ready creeping bentgrass, a popular turfgrass used in golf courses and lawns, produced by Monsanto and the Scotts Company. The EIS was prompted by a study that discovered the Roundup Ready bentgrass trait in wild grass species over thirteen miles from field trials (Watrud, L. S., et al. (2004). Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker [Electronic version], *Proceedings of the National Academy of Sciences*, 101(40) 14533-14538, Retrieved on August 2, 2006, from www.pnas.org/cgi/reprint/101/40/14533.pdf.

the GE crops on the market (although one is currently underway for RR creeping bentgrass).

Table 2	
Regulatory Process Leading Up to the Commercialization of Roundup Ready Alfalfa	
May 2, 1998	RR field trials alfalfa begin
April 17, 2002	EPA issues a notice in the Federal Register that Monsanto had petitioned EPA pursuant to the FDCA to establish tolerances for glyphosate residues related to alfalfa.
September 27, 2002	EPA establishes “tolerances for residues of glyphosate in or on animal feed, nongrass group; grass, forage, fodder and hay, group and adds potassium salt of glyphosate to the tolerance expression.”
October 2003	Monsanto submits a food and feed safety and nutritional assessment summary for events J101 and J163 in October 2003
August 18, 2004	EPA issues a notice in the Federal Register that Monsanto had petitioned EPA pursuant to the FDCA to establish tolerances for residues of glyphosate for alfalfa seed. Monsanto also petitions to eliminate the tolerances set for alfalfa, forage, and alfalfa hay because they were allegedly no longer needed.
November 10, 2004	EPA denies Monsanto’s request to eliminate the tolerances for alfalfa forage and alfalfa hay.
November 24, 2004	USDA publishes a notice in the Federal Register announcing the Monsanto/Forage Genetic International’s petition to deregulate genetically engineered alfalfa and that the Environmental Assessment (EA) is available for public comment due by January 24, 2005
February 3, 2005	Comment period is extended through February 17, 2005
December 8, 2004	FDA issues a Biotechnology Consultation Note to the File BNF No. 000084 regarding Glyphosate-tolerant Alfalfa Event J101 and Event J163
February 16, 2005	EPA sets a tolerance level of 0.5 ppm for alfalfa seed codified at 40 CFR § 180.364(a)
May 2005	USDA issues an Environmental Assessment and Finding of No Significant Impact (FONSI)
June 27, 2005	USDA publishes notice in Federal Register advising the public of its determination that glyphosate-tolerant alfalfa events J101 and J163 are no longer considered regulated articles.

Public Response By the close of the RR alfalfa comment period, APHIS had received a strong response: 663 comments.²⁵⁹ According to the Federal Register, comments came from alfalfa growers and seed producers, organic growers, animal producers, growers associations, consumer groups, agriculture industries, university professionals, and private citizens.²⁶⁰ The vast majority of respondents (520) did not support deregulating RR alfalfa, while 137 supported the petition.²⁶¹ The main concerns raised by the opposition included market acceptance and cross-pollination between RR and organic alfalfa varieties.²⁶² The concerns, however, went unheeded by APHIS.

After USDA gave Monsanto and Forage Genetics a green light to commercialize RR alfalfa, a coalition of alfalfa producers and non-governmental organizations filed a lawsuit against the agency on five claims, including violations of the National Environmental Policy Act (NEPA), the Administrative Procedure Act (APA), and the Endangered Species Act (ESA). It is the first lawsuit to be filed against USDA in response to the deregulation of a particular GE crop. The plaintiffs argue that RR alfalfa will affect the integrity of organic products, creating marketing and liability problems; it will introduce more herbicides into the environment and create Roundup-resistant weeds; and it will damage export markets. The suit was filed in federal court in the Northern District of California, and asks USDA to rescind its decision to deregulate RR alfalfa and perform a full EIS. It also asks for an EPA consultation with U.S. Fish and Wildlife about the potential for RR alfalfa to affect endangered or threatened species and their habitats.²⁶³ The case is still pending.

²⁵⁹70 Fed. Reg. 36918 (June 27, 2005); I use the word “strong” here, because compared to other public comment periods for the regulation of GE crops and food, 663 comments appears to be a high number of respondents. When FDA published its policy statement for regulating biotechnology products in 1984, only 34 people commented (51 Fed. Reg. 23302, June 26, 1986). In 2006, APHIS received 96 comments in response to a petition from the Agricultural Research Service to deregulate a genetically engineered plum variety (Though a final decision on the plum has not been published, I tallied the public comments on www.regulations.gov)

²⁶⁰ 70 Fed. Reg. 36918 (June 27, 2005)

²⁶¹ Ibid.

²⁶² Ibid.

²⁶³ Geertson Seed Farms, *et al.* v. Mike Johanns, *et al.* 2006 Cal C06-1075 CRB; Plaintiffs include Geertson Farms Inc., Trask Family Seeds, Center for Food Safety, Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, and Western Organization of Resource Councils.

Potential Implications of Introducing Roundup Ready Alfalfa into the Marketplace and Environment

The lawsuit highlights various problems with the regulatory process involving RR alfalfa, but also implications to the organic industry. Since the introduction of RR crops, scientists, public interest groups, and farm organizations have raised concerns regarding their impact on the environment, human health, and the marketplace. Experience with RR soybeans, corn, canola, and cotton show that herbicide-tolerant crops are considerably different than their conventional counterparts (despite the regulatory assumption that they are not). Indeed, RR crops have posed new agronomic, economic, and environmental challenges to U.S. farmers. The introduction of RR alfalfa raises similar concerns as past crops, but also new risks emerge because of its perennial nature and ability to cross-pollinate with crop and weed relatives. These concerns are explored below, including herbicide use trends and glyphosate-resistant weeds, contamination and market acceptance.

Environmental and Agronomic Concerns

Increased Herbicide Use and Weed Resistance RR crops have been rapidly adopted; for example, in 2006, 89 percent of soybeans planted in the U.S. were an herbicide-tolerant variety. Indeed, Roundup use alone has grown by an estimated 700 percent with the introduction of herbicide-tolerant crops.²⁶⁴ Suggested application rates of glyphosate have increased by 50 to 200 percent, largely attributed to the growing resistance in weeds.²⁶⁵

²⁶⁴ Cline, H. (2005, March 5). Glyphosate resistance new concern [Electronic version], *Western Farm Press*, Retrieved on August 14, 2006, from http://westernfarmpress.com/mag/farming_glyphosate_resistance_new/

²⁶⁵ Benbrook, C. (2004). *Genetically engineered crops and pesticide use in the United States: The first nine years* [Electronic version], Biotech InfoNet, Retrieved on July 1, 2006, from www.biotech-info.net

Glyphosate-resistant weeds are now the bane of many farmers' operations, as farmers must resort to more toxic and costly chemicals to control resistant weeds.²⁶⁶ Farmers must now contend with so-called "superweeds," a weed that survives a normal dose of a chemical application that previously would have killed it.²⁶⁷ Weeds develop resistance for several reasons, including: frequent exposure to a particular chemical, the spread of naturally resistant weed seeds, and the outcrossing of herbicide-tolerant genes from GE plants to weedy relatives.

This issue of increased pesticide use and resistance is obviously of concern for conventional farmers, but for organic farmers these issues raise additional concerns, such as pesticide drift. An increase in herbicide use is likely to cause more herbicides to enter the environment, and spraying causes chemicals to drift, at times fairly far from the targeted organism, as mentioned in the last chapter. Additionally, the development of weed resistance to particular herbicides, especially glyphosate, has encouraged the use of more toxic chemicals to control resistant weeds.

RR alfalfa enters the marketplace at a time when several cases of weed resistance to glyphosate have been reported. For example, glyphosate-resistant horseweed (*Conyza canadensis*), or marestalk, has infested a half-million acres since it first showed up in 2003, and may have cost Arkansas farmers as much as \$500 million in inputs in 2005.²⁶⁸ Glyphosate-resistant horseweed has been documented in California, Delaware, Kentucky, Indiana and Ohio. Similarly, glyphosate-resistant Palmer amaranth (*Amaranthus*

²⁶⁶ Gurian-Sherman, D. (2003, December). *Roundup Ready wheat: An overview based on advancements in the risk assessment of genetically engineered crops* [Electronic version], Washington, DC: Center for Science in the Public Interest, Retrieved on November 1, 2006, from www.cspinet.org/biotech/RRwheat_paper.pdf

²⁶⁷ Canon, S. (2001, August 29). Roundup Ready soybeans giving rise to superweeds [Electronic version], *The Kansas City Star*, Retrieved on August 12, 2006, from <http://www.organicconsumers.org/Monsanto/Roundupsuperweeds.cfm>

²⁶⁸ James, L. (2005, July 21). Resistant weeds could be costly [Electronic version], *Delta Farm Press*, Retrieved on September 1, 2006, from <http://deltafarmpress.com/news/050721-resistant-weed/index.html>; The \$500 million figure is based on a 50% loss of yields in a 900,000-acre cotton crop and a 25% yield loss in three million-plus acres of soybeans;

palmeri), or pigweed, was discovered in Georgia in 2005.²⁶⁹ The weeds survived a dosage of glyphosate almost ten times the recommended rate.²⁷⁰ In Missouri, scientists have since found glyphosate-resistant pigweed that survives eight times the suggested dose of glyphosate.²⁷¹ Even the most intensive control mechanisms for these weeds seem to fail.²⁷²

These weeds develop in fields where farmers consistently grow RR crops.²⁷³ Therefore, introducing another crop into the RR line is likely to further compound these problems of weeds' resistance to glyphosate, and lead to higher input costs for farmers and higher chemical concentrations in our environment and food. Furthermore, many farmers who produce alfalfa have traditionally used few if any herbicides. Although more recent figures are not available, in 1998 a University of Wisconsin weed control specialist reported that herbicides are applied to less than 17 percent of U.S. alfalfa hay acreage.²⁷⁴ Providing the option of spraying herbicides directly over alfalfa is likely to increase the amount of chemicals used in alfalfa production. In fact, the National Center for Food and

²⁶⁹ Haire, B. (2005, October 27). Resistant pigweed plagues central Georgia cotton [Electronic version], *Southeast Farm Press*, Retrieved on October 1, 2006, from <http://southeastfarmpress.com/news/102705-Georgia-pigweed/>

²⁷⁰ Wan-Ho, M. & Cummins, J. (2005, March 10). Roundup Ready sudden death, superweeds, allergens [Electronic version], Retrieved on November 1, 2006, from <http://www.i-sis.org.uk/RRSDSA.php>

²⁷¹ Won, R. (2005, October 17). Study lauds modified crops [Electronic version], *Courier-Medill News Service*, Retrieved on October 12, 2006, from <http://www.wcfcourier.com/articles/2005/10/17/business/local/d7009b5a666402bd8625709d004cc408.txt>

²⁷² Kendig, A. (2003, December 19). Missouri's pigweed problem increases [Electronic version], *Delta Farm Press*, Retrieved on October 3, 2006, from http://deltafarmpress.com/mag/farming_missouris_pigweed_problem/index.html

²⁷³ Glyphosate-resistant waterhemp moves into the corn belt [Electronic version]. (2002, December 12). *Plant Health Progress*, Retrieved on November 1, 2006, from <http://www.plantmanagementnetwork.org/pub/php/news/waterhemp/>; ("Researchers say the culprit in glyphosate resistance and weed shifts is continuous use of glyphosate in Roundup Ready cropping systems.")

²⁷⁴ Wilke, C.W. (1998, January 1). Roundup Ready alfalfa might benefit corn, too [Electronic version], *Hay & Forage Grower*, Retrieved on August 12, 2006, from http://hayandforage.com/mag/farming_roundup_ready_alfalfa_2/index.html; This figure is a result of a study entitled *Alfalfa: The importance of pesticides and other pest management practices in U.S. alfalfa production*, a project of the U.S. Department of Agriculture National Agricultural Pesticide Impact Assessment Program, and authored by Arthur A. Hower, Jayson K. Harper, and Gordon R. Harvey.

Agriculture Policy estimates that RR alfalfa could result in the application of 200,000 pounds more herbicides per year in California alone.²⁷⁵

Weed specialists identified weed resistance in RR alfalfa field trials years before the variety was approved for commercial sale. A University of California-Davis weed specialist observed a shift in the prevalence of a weed in experimental plots where RR alfalfa had been grown and sprayed for three years: “When we started this study, there were four or five stinging nettle plants on [one] end of the field. . . Now you can see nettle all along the field. We’re seeing more and more nettle each year.”²⁷⁶ There is also evidence that glyphosate may not kill bermudagrass at the proposed labeled rates for weed control in RR alfalfa.²⁷⁷ Additional weeds found in alfalfa stands appear to be developing resistance too, including lambsquarter and barnyardgrass.²⁷⁸ Farmers who adopt RR alfalfa will rely on additional herbicides whether Roundup-resistant weeds surface or not, because Roundup is weak on some of the most important alfalfa weeds, including malva, nettle, henbit, cheeseweed, marestail, hairy fleabane and filaree.²⁷⁹

At the end of an alfalfa stand’s life (anywhere from three to twelve years), many farmers use Roundup to kill remaining plants in order to proceed with crop rotations.²⁸⁰

Alternatives for taking out RR alfalfa stands are often more toxic than glyphosate herbicides, such as 2,4-D and Dicamba.²⁸¹ According to Cornell University’s Environmental Impact Quotient (EIQ), a system that rates pesticides’ effect on the

²⁷⁵ National Center for Food and Agriculture Policy. (2002, June). *Plant biotechnology: Current and potential impact for improving pest management in U.S. agriculture: An analysis of 40 case studies, herbicide tolerant alfalfa* [Electronic version], Retrieved on July 12, 2006, from www.ncfap.org/40CaseStudies.htm

²⁷⁶ University of California studies genetically engineered alfalfa to produce objective information about the new agricultural technology [Electronic version], (2004, April 1). *Ascribe Higher Education News Service*, Retrieved on August 1, 2006, from <http://ucanr.org/externalstories/alfalfa.shtml>

²⁷⁷ Scientists studying roundup resistant strains of alfalfa [Electronic version]. (2004, April 15). *Livestock Weekly*

²⁷⁸ University of California studies genetically engineered alfalfa to produce objective information about the new agricultural technology [Electronic version], (2004, April 1). *Ascribe Higher Education News Service*, Retrieved on August 1, 2006, from <http://ucanr.org/externalstories/alfalfa.shtml>

²⁷⁹ Cline, H. (2004, September 19). Benefits, challenges of Roundup Ready alfalfa examined [Electronic version], *Western Farm Press*, Retrieved on July 14, 2006, from <http://westernfarmpress.com/news/9-29-04-roundup-ready-alfalfa/>

²⁸⁰ Ibid.

²⁸¹ Ibid.

environment, Dicamba has an EIQ of approximately 28, almost twice that of glyphosate.²⁸²

Evidence for increased herbicide use and a reliance on more toxic chemicals to control resistant weeds points to more chemicals entering the environment and food system. Organic farmers have dealt with pesticide drift for decades, and chemical residues continue to show up in certified organic products. An increase in herbicide use poses another challenge to protecting the integrity of organic products. Coupled with genetic drift, it seems that the integrity of organic agriculture is at the whim of the wind. Of course, then there are pollinators.

Gene Flow

Alfalfa seed producers rely on pollinators, especially leafcutter and honey bees, to pollinate their alfalfa plants in order to yield a large amount of seed. Cross-pollination occurs when bees collect pollen for food, “and in doing they transfer some pollen from the flowers of one plant to the flowers of another,” a process “necessary” for setting seed in alfalfa.²⁸³ When bees transfer pollen from one crop to the next, genetic material is sometimes transported as well. Thus, gene flow is a concern for organic farmers who need to avoid the presence of transgenes in their crops and products. Both commercial and wild pollinators contribute to gene flow in agricultural fields, including to wild relatives, such as volunteer alfalfa (seeds that germinate late, often a year or more after they are sown) that becomes established on the edges of fields and along roads. Feral RR alfalfa plants that are not harvested will go to seed, becoming vehicles for gene flow.

Gene Flow: Crop-to-Wild Volunteer alfalfa may present serious problems in managing unwanted alfalfa plants, including limiting yields of crops succeeding an

²⁸² Kovach, J., Petzoldt, C., Degni, J. & Tette, J. IPM Program. A method to measure the environmental impact of pesticides, Cornell University, New York State Agricultural Experiment Station Geneva, New York, Retrieved on August 5, 2006, from <http://nysipm.cornell.edu/publications/eiq/default.asp>; (See Table 2: EIQ values)

²⁸³ Montana Pest Management Center. (2002, August). Crop profile for alfalfa grown for seed in Montana, Retrieved November 3, 2006, from <http://www.ipmcenters.org/cropprofiles/docs/mtalfalfaseed.html>

alfalfa stand.²⁸⁴ All alfalfa has a certain percentage of “hard seed” content. “Hard seeds” are viable, but have an impervious seed coat that keeps water from entering the seed to start germination.²⁸⁵ Therefore, they germinate late in the season or even years later, sometimes leading to volunteer alfalfa plants. These volunteer and feral crop populations “can act as potential sources for the reintroduction of transgenes,”²⁸⁶ complicating control measures for pollen flow to surrounding alfalfa fields and feral alfalfa. Some RR alfalfa field trials averaged 43 to 71 percent hard seed content.²⁸⁷

According to Norman Ellstrand, a leading expert on plant genetics at the University of California, Riverside, “some cultivated plants volunteer after cultivation. . . founding feral populations that create problems. . . In some cases, the tendency to found feral populations could increase as the result of acquiring new traits.”²⁸⁸ That is, transgenic crops might evolve into a more aggressive plant.²⁸⁹ Volunteer RR alfalfa will be especially problematic when RR alfalfa is rotated with other RR crops, such as RR corn.²⁹⁰ County crews also use Roundup to control feral alfalfa along roadsides and in ditches.²⁹¹ If RR alfalfa outcrosses with feral alfalfa, Roundup will be ineffective on feral

²⁸⁴ Altieri, M. A. (2001, March). The ecological impacts of transgenic crops on agroecosystem health, *Ecosystem Health*, 6(1), Retrieved on August 26, 2006, from http://www.cnr.berkeley.edu/~agroeco3/the_ecological_impacts.html

²⁸⁵ Montana State University. (2005, May). Establishing a successful alfalfa crop, Retrieved on October 30, 2006 from <http://www.montana.edu/wwwpb/pubs/mt200504.html>

²⁸⁶ Gulden, R.H., Shirliffe, S.J., & Thomas, A.G. (2003). Harvest losses canola (brassica napus) cause large seedbank inputs. *Weed Science*, 51: 83-86, cited In Marvier, M. & Van Acker, R.C. (2005). Can crop transgenes be kept on a leash? [Electronic version], *Frontiers in Ecology and the Environment*, 3(2): 99–106, Retrieved on November 13, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1540-9295&volume=003&issue=02&page=0093>

²⁸⁷ Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

²⁸⁸ Ellstrand, Norman. (2006). When crop transgenes wander in California, should we worry? [Electronic version], *California Agriculture*, 60(3), Retrieved on November 1, 2006, from <http://repositories.cdlib.org/anrcs/californiaagriculture/v60/n3/p116/>

²⁸⁹ Ibid.

²⁹⁰ Vargas, R. (2004, December). Stewardship issues for Roundup Ready alfalfa, A California perspective on Roundup Ready alfalfa, *Proceedings on California Alfalfa & Forage Symposium*, San Diego, CA, Retrieved on September 2, 2006, from http://ucanr.org/alf_symp/year.asp

²⁹¹ Cline, H. (2004, September 29). Benefits, challenges of Roundup Ready alfalfa examined [Electronic version], *Western Farm Press*, Retrieved on September 12, 2006 from http://westernfarmpress.com/mag/farming_benefits_challenges_rr/

alfalfa plants that have received the tolerance trait from surrounding RR alfalfa plants.²⁹² Even if the probability of problems due to gene flow in RR alfalfa is low, managing the problems can be costly.²⁹³ Ellstrand believes that the majority of herbicide-tolerant plants are “apt to give a weed a fitness boost in certain environments,” and his studies confirm that cultivated plants will hybridize with their wild relatives when grown in close proximity.²⁹⁴ A report by the Ecological Society of America concludes, “Currently, it is not possible to prevent gene flow between sexually compatible species that inhabit the same region because pollen and seeds disperse too easily and too far to make complete reproductive confinement practical.”²⁹⁵

The case of RR creeping bentgrass may be instructive. A recent study shows that RR creeping bentgrass pollen (a popular golf course and lawn turf grass) escaped from field trials and hybridized with wild relatives over two miles from the test plot.²⁹⁶ These findings follow an earlier EPA study that confirmed RR bentgrass pollen had traveled to plants of the same species in different test plots thirteen miles away. As a result of this first study, USDA decided to perform the first EIS ever to be conducted on a genetically engineered plant. Both the U.S. Forest Service and Bureau of Land Management fear that RR creeping bentgrass will outcross the herbicide tolerant trait to its wild relatives (of which there are 23 in the U.S.), precluding the agencies from controlling unwanted bentgrass with their current herbicide of choice: glyphosate.²⁹⁷ Additionally, RR creeping

²⁹² Cline, H. (2005, January 15). Resistant alfalfas face challenges [Electronic version], *Western Farm Press*, Retrieved on August 25, 2006, from

http://westernfarmpress.com/mag/farming_resistant_alfalfas_face/

²⁹³ Ellstrand, Norman. (2006). When crop transgenes wander in California, should we worry? [Electronic version], *California Agriculture*, 60(3), Retrieved on November 1, 2006, from

<http://repositories.cdlib.org/anrcs/californiaagriculture/v60/n3/p116/>

²⁹⁴ Ibid.

²⁹⁵ Snow, A. A., Andow, D.A., Gepts, P., Hallerman, E.M., Power, A., Tiedje, J.M. & Wolfenbarger, L.L. (2004). Genetically engineered organisms and the environment: Current status and recommendations

[Electronic version], *Ecological Applications*, 15(2) pp. 377-404, Retrieved on July 7, 2006, from

<http://www.esajournals.org/esaonline/?request=get-abstract&issn=1051-0761&volume=015&issue=02&page=0377>

²⁹⁶ Reichman, J., Watrud, L.E., Lee, H., Burdick, C., Bollman, M., Storm, M., King, G., & Mallory-Smith, C. (2006). Establishment of transgenic creeping bentgrass (*Agrostis stolonifera* L.) in non-agronomic habitats [Electronic version], *Molecular Ecology*, 15, 4243–4255, Retrieved on November 14, 2006, from www.epa.gov/scienceforum/2006/poster_abstracts/global_challenges/GC_Reichman.pdf

²⁹⁷ Smith, Z. (2004, October 11). Biotech companies engineer a ‘superweed’ [Electronic version], *High Country News*, Retrieved on November 1, 2006, from

http://www.hcn.org/servlets/hcn.PrintableArticle?article_id=15045

bentgrass is planted in field trials covering thousands of acres, making the findings mentioned above especially alarming.²⁹⁸

Gene Flow: Crop-to-crop Evidence shows that crop-to-crop movement of transgenic traits is likely, even more likely than crop-to-wild movement.²⁹⁹ Still, “the ecological and evolutionary consequences of crop-to-crop gene flow are just beginning to be investigated.”³⁰⁰ What we do know is that “it is easy to lose track of transgenic genes,” and as Ellstrand explains:

Different varieties of the same crop are usually fully sexually compatible. It is not unusual for adjacent and simultaneously flowering fields of the same crop to cross-pollinate. Also, gene flow by seed becomes an issue in this context. Unless very carefully segregated, seed from different varieties often becomes mixed during seed production. If a seed bank persists in the soil, individuals from last year’s planting can appear within this year’s crop.³⁰¹

“Genetic pollution” occurs when transgenic traits make it into crops intended for markets that aim to meet a particular level of purity, such as organic crops.³⁰² Unlike the presence of a pesticide, a single crop has the opportunity to multiply itself, whereas a chemical molecule remains a single molecule or breaks down into metabolites.³⁰³ Unwanted genes in plants increase their numbers through reproduction, complicating attempts to recall or contain the genes.³⁰⁴ If transgene flow is maintained “from a large source population,”

²⁹⁸ Gurian-Sherman, D. (2006). *Contaminating the wild? gene flow from experimental field trials of genetically engineered crops to related wild plants* [Electronic version], The Center for Food Safety, Retrieved on October 5, 2006, from www.centerforfoodsafety.org/pubs/Contaminating_the_Wild_Report.pdf

²⁹⁹ Ellstrand, Norman. (2006). When crop transgenes wander in California, should we worry? [Electronic version], *California Agriculture*, 60(3), Retrieved on November 1, 2006, from <http://repositories.cdlib.org/anrcs/californiaagriculture/v60/n3/p116/>

³⁰⁰ Snow, A. A., Andow, D.A., Gepts, P., Hallerman, E.M., Power, A., Tiedje, J.M. & Wolfenbarger, L.L. (2004). Genetically engineered organisms and the environment: Current status and recommendations [Electronic version], *Ecological Applications*, 15(2) pp. 377-404, Retrieved on July 7, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1051-0761&volume=015&issue=02&page=0377>

³⁰¹ Ellstrand, Norman. (2006). When crop transgenes wander in California, should we worry? [Electronic version], *California Agriculture*, 60(3), Retrieved on November 1, 2006, from <http://repositories.cdlib.org/anrcs/californiaagriculture/v60/n3/p116/>

³⁰² Ibid.

³⁰³ Ibid.

³⁰⁴ Ibid.

the extent these traits spread could be great, including the “potential to persist indefinitely in cultivated or free-living populations .”³⁰⁵

Canada’s experience with transgenic canola is an example of how extensive hybridization between crops can be. After planting three different varieties of herbicide-tolerant canola, Canadian growers now find that canola plants volunteering in subsequent seasons are resistant to three herbicides owned by different companies (each of the three herbicides for which the different varieties were individually engineered to tolerate, including glyphosate). This rampant spread of transgenic canola traits makes controlling volunteer canola extremely difficult. It has also negatively impacted markets that shun genetic engineering, as nearly 75 percent of Canadian canola is exported each year.³⁰⁶ For example, the European Union (EU) export market for Canadian canola was \$425 million in 1994, but is now “virtually zero” because of the EU’s opposition to GE products, according to a report by the Standing Committee on Agriculture and Forestry in Canada.³⁰⁷ Many also argue that GE canola has destroyed the Canadian organic market. As will be shown, the contamination of organic and other non-GE products continues to be a problem in an age where two agricultural industries are growing, quite literally, side-by-side.

Market Concerns & Contamination

Biological factors and human error both contribute to the unwanted spread of transgenic pollen and seed. Such contamination is problematic not only ecologically, but also in terms of differentiation in the marketplace. Although biotechnology corporations believe

³⁰⁵ Snow, A. A., Andow, D.A., Gepts, P., Hallerman, E.M., Power, A., Tiedje, J.M. & Wolfenbarger, L.L. (2004). Genetically engineered organisms and the environment: Current status and recommendations [Electronic version], *Ecological Applications*, 15(2) pp. 377-404, Retrieved on July 7, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1051-0761&volume=015&issue=02&page=0377>

³⁰⁶ Hammond, D. (2005). Canola pesticides and trade, Canola Council of Canada, *Proceedings of 2005 Manitoba Agronomists Conference*, Retrieved on November 8, 2006 from www.umanitoba.ca/afs/agronomists_conf/proceedings/2005/hammond_canola_pesticides.pdf

³⁰⁷ The Standing Committee on Agriculture and Forestry. (2002, June 13). *Canadian Farmers at Risk* [Electronic version], Retrieved on November 2, 2006, from www.parl.gc.ca/371/parlbus/commbus/senate/com-e/agri-e/rep-e/rep10jun02-e.htm

“co-existence” is a reality, keeping transgenic and conventional products separate throughout the food supply chain has proven more than difficult—some argue it is impossible. Many ecologists believe that “strict confinement of [genetically engineered organisms] is often impossible after large-scale field releases have occurred.”³⁰⁸ Others assert that genetic drift is inevitable. Scientists from Santa Clara University and the University of Manitoba recently concluded that the movement of transgenes beyond their intended destination is a “virtual certainty.”³⁰⁹

As GE crops continue to be readily adopted, contamination events involving organic and other non-GE crops ensue. A recent report published by two public interest groups documented 88 cases of GE contamination in 39 countries on five continents.³¹⁰ Although most of these contamination cases are not fully investigated, cross-pollination appears to be a cause in the majority of cases.³¹¹ Not only can GE seeds get mixed with non-GE seeds at any stage of production, farmers often unknowingly plant seeds that, while not a GE variety, contain GE material—ensuring a contaminated harvest from the beginning. The Union of Concerned Scientists tested samples of conventional varieties of corn, soybeans, and canola, and concluded that the varieties are pervasively contaminated with low levels of DNA sequences derived from GE varieties.³¹² The report notes that foundation seed of traditional crop varieties used for breeding—seeds with no detectable level of GE contamination—need protection for future research and market demands.³¹³

³⁰⁸ Snow, A. A., Andow, D.A., Gepts, P., Hallerman, E.M., Power, A., Tiedje, J.M. & Wolfenbarger, L.L. (2004). Genetically engineered organisms and the environment: Current status and recommendations [Electronic version], *Ecological Applications*, 15(2) pp. 377-404, Retrieved on July 7, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1051-0761&volume=015&issue=02&page=0377>

³⁰⁹ Marvier, M. & Van Acker, R.C. (2005). Can crop transgenes be kept on a leash? [Electronic version], *Frontiers in Ecology and the Environment*, 3(2): 99–106, Retrieved on November 13, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1540-9295&volume=003&issue=02&page=0093>

³¹⁰ GeneWatch UK and Greenpeace International. (2005). *GM contamination report, A review of cases of contamination, illegal planting, and negative side effects of genetically modified organisms*, Retrieved on July 12, 2006, from www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/gm_contamination_report.pdf

³¹¹ Ibid.

³¹² Union of Concerned Scientists. (2004). *Gone to seed: Transgenic contaminants in the traditional seed supply* [Electronic version], Retrieved on June 1, 2006, from http://www.ucsusa.org/food_and_environment/genetic_engineering/gone-to-seed.html

³¹³ Ibid.

Even seed industries question whether current foundation seed varieties can meet a one percent purity level.³¹⁴

But seed industries have done little to slow contamination or educate their farming customers. For instance, Genetic ID, a GE organism testing facility based in Fairfield, IA, tested five different conventional seed varieties from four major seed companies, and found that all the varieties of supposedly non-GE seeds from each company tested positive for a small percentage of GE material.³¹⁵ As a result, GE crops continue to turn up in fields that farmers believe are completely free of GE crops, and, consequently, in markets that do not want GE food, such as organic markets and some export markets.³¹⁶

Cross-pollination, impure seeds, and the convoluted path seeds travel through—from farm fields to grain elevators and transport trucks, to ocean barges and food companies—are not the only routes to contamination. At times, it is the companies' own mismanagement of genetic resources. In 2004, Syngenta, one of the largest agricultural biotechnology companies, reported an error in GE corn breeding to U.S. authorities.³¹⁷ For three years, Syngenta inadvertently produced and distributed a GE corn variety that did not have regulatory approval.³¹⁸ As a result, several hundred tons were grown and distributed in the U.S., most likely exported to other countries, and used in field trials in Spain.³¹⁹ Syngenta believes that the unapproved corn variety was mistakenly used in breeding.³²⁰ Similarly, in 2003, University of California-Davis scientists mistakenly sent

³¹⁴ Olson, J. (2000, November 1). Tracking seed to shelf [Electronic version], *Farm Industry News*, Retrieved on November 6, 2006, from

http://farministrynews.com/mag/farming_tracking_seed_shelf_2/index.html

³¹⁵ Bett, K. S. (1999, December 1). Mounting evidence of genetic pollution from GE crops: Growing evidence of widespread GMO contamination [Electronic version], *Environmental Science and Technology*, Retrieved on October 1, 2006, from <http://www.organicconsumers.org/ge/gepollution.cfm>

³¹⁶ Barboza, D. (2001, June 10). As biotech crops multiply, consumers get little choice, [Electronic version], *The New York Times*, Retrieved July 27, 2006, from <http://www.commondreams.org/headlines01/0610-02.htm>

³¹⁷ Macilwain, C. (2005, March 23). U.S. launches probe into sales of unapproved transgenic corn [Electronic version], *Nature*, Retrieved on August 2, 2006, from <http://www.nature.com/news/2005/050321/full/nature03570.html>

³¹⁸ Ibid.

³¹⁹ Ibid.

³²⁰ Macilwain, C. (2005, March 23). U.S. launches probe into sales of unapproved transgenic corn [Electronic version], *Nature*, Retrieved on August 2, 2006, from <http://www.nature.com/news/2005/050321/full/nature03570.html>

GE tomato seeds to researchers at twelve institutions in the U.S. and to researchers in fourteen countries.³²¹ Apparently, the UC-Davis scientists were unaware the seeds contained genes derived from genetic engineering. Seminis Seed, the company UC-Davis scientists originally obtained the seeds from, was fined for sending the seeds without correct documentation.³²²

While numerous contamination events have been documented around the world, no event has received more public attention than the discovery of Aventis' StarLink corn in the human food supply—a variety not approved for human consumption. In 1999, Iowa farmers planted less than 0.4 percent of their corn to StarLink.³²³ By harvest time, half the harvests registered positive for the GE variety.³²⁴

After this discovery, seed companies, farmers, processors and food makers spent more than one billion dollars trying to eradicate Starlink.³²⁵ Three years after StarLink was found in the food supply and pulled from the market, contaminated grain still pervaded the nation's corn supply.³²⁶ In 2003, Aventis agreed to pay \$110 million to settle claims from corn growers who did not grow StarLink but were hurt by the declining market for U.S. corn because of the contamination.³²⁷ Neil E. Harl, a professor of economics at Iowa State University, estimates that Aventis has paid out more than \$500 million to farmers,

³²¹ UC Davis News and Information. (2003, December 18). Tomato seed from seed bank found to be genetically modified [Electronic version], Retrieved on August 24, 2006, from www.news.ucdavis.edu/search/news_detail.lasso?id=6833

³²² Ibid.

³²³ Zitner, A. (2001, June 4). Fields of gene factories [Electronic version], *Los Angeles Times*, Retrieved on October 2, 2006, from http://www.biotech-info.net/fields_of_genes.html

³²⁴ North Dakota organic farmers worry about biotech contamination. (2001, February 6). *Cropchoice* Retrieved on August 2, 2006, from <http://www.cropchoice.com/leadstry8b5a.html?recid=232>

³²⁵ Barboza, D. (2001, June 10). As biotech crops multiply, consumers get little choice [Electronic version], *The New York Times*, Retrieved on November 1, 2006, from <http://www.commondreams.org/headlines01/0610-02.htm>

³²⁶ Jacobs, P. (2003, December 1). Banned GE StarLink corn still contaminating 1% of U.S. corn crop [Electronic version], *Knight Ridder Newspapers*, Retrieved on October 4, 2006, from <http://www.centredaily.com/mld/centredaily/news/7386628.htm>

³²⁷ Ibid.

food processors and grain handlers.³²⁸ Experts agree that it will take years to remove StarLink from the human food supply.³²⁹

Tests Reveal Widespread Contamination in Organic Food Products As explained in chapter one, the National Organic Program (NOP) provides production standards for organic crops (and processed products) only, and testing for unwanted genetic material is not required for organic crops. Because the government has never required testing, many farmers and consumer and environmental groups have investigated the extent of GE contamination in conventional seeds.³³⁰ For example, StarLink was discovered in the food supply after a coalition of non-governmental organizations tested corn taco shells for GE material.³³¹ (StarLink corn was the last transgenic crop variety to receive “split approval”—approval for animal feed but not human consumption.) Since this finding, several contamination events have been revealed across the country.³³² Because organic farmers depend on organic seed varieties (or conventional varieties if particular organic varieties are not available) to meet organic standards and consumer demand, seed contamination places an unfair burden on organic producers by hindering their ability to

³²⁸ Jacobs, P. (2003, December 1). Banned GE StarLink corn still contaminating 1% of U.S. corn crop [Electronic version], *Knight Ridder Newspapers*, Retrieved on October 4, 2006, from <http://www.centredaily.com/mld/centredaily/news/7386628.htm>

³²⁹ Barboza, D. (2001, June 10). As biotech crops multiply, consumers get little choice [Electronic version], *The New York Times*, Retrieved on November 1, 2006, from <http://www.commondreams.org/headlines01/0610-02.htm>

³³⁰ Vermont Public Interest Research Group. (2003, December). *Blowing in the wind, The road to extinction for Vermont's organic farms: Testing confirms genetic pollution of organically grown corn* [Electronic version], Montpelier, VT: Author, Retrieved on April 17, 2006, from www.gefreevt.org/images/downloads/blowing%20in%20the%20wind%20report.pdf; GeneWatch UK and Greenpeace International. (2005). *GM contamination report, A review of cases of contamination, illegal planting, and negative side effects of genetically modified organisms*, Retrieved on April 1, 2006 from www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/gm_contamination_report.pdf; Hawaii SEED. (2006). *Hawaiian papaya: GMO contaminated*, Retrieved on August 3, 2006, from http://www.gmofreemaui.com/press_releases/Contamination_Report.pdf

³³¹ Kraft to Recall Taco Shells [Electronic version]. (2000, September 22). CBS News, Retrieved on October 4, 2006, from <http://www.cbsnews.com/stories/2002/01/31/health/main326681.shtml>

³³² GeneWatch UK and Greenpeace International. (2005). *GM contamination report, A review of cases of contamination, illegal planting, and negative side effects of genetically modified organisms*, Retrieved on April 1, 2006 from www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/gm_contamination_report.pdf.

find GE-free seed.³³³ Some U.S. organic farmers now import seeds from as far as China to ensure seed purity.³³⁴

Organic grower David Vetter in Nebraska has tested his seeds regularly since 1997, and discovered contamination of his corn harvest in 2000.³³⁵ Because he confirmed the purity of his seeds before planting, Vetter attributes the contamination to cross-pollination with GE corn in neighbors' fields.³³⁶ Vetter tests his seeds because seed dealers will not guarantee the purity—some refuse to test their seeds.³³⁷ Consequently, farmers shoulder the cost of testing if they want to guarantee their crops as GE-free. These tests add about 25 percent to Vetter's corn seed bill.³³⁸ He spent \$450 on the tests that revealed the contamination of his corn crop and \$1,500 to evaluate a load of corn worth \$4,000.³³⁹ While he bears the costs, he has little recourse, save going to the court for damages—something that has not been done by an organic farmer in the U.S.

Illinois-based Clarkson Grain Company takes strict identity preservation measures to ensure its crops are non-GE, and uses an optical scanner to sort through conventional and organic blue and white corn varieties.³⁴⁰ Despite these precautions, GE material still contaminates about six percent of Clarkson's grain. Clarkson describes GE crops as a “leaky technology” and says contamination limits his market, especially abroad, where some countries have zero tolerance for GE material in organic products.³⁴¹

³³³ Union of Concerned Scientists. (2004). *Gone to seed: Transgenic contaminants in the traditional seed supply* [Electronic version], Retrieved on June 1, 2006, from http://www.ucsusa.org/food_and_environment/genetic_engineering/gone-to-seed.html

³³⁴ GMO impacts on organic spreading worldwide [Electronic version], (2005, December). *The Non-GMO Report*, Retrieved on November 6, 2006, from www.non-gmoreport.com

³³⁵ Schubert, R. (2001, April 11). Nebraska organic farmer bears costs of GM testing, *Cropchoice*, Retrieved on August 12, 2006, from <http://www.cropchoice.com/leadstry0898.html?recid=289>

³³⁶ Ibid.

³³⁷ North Dakota organic farmers worry about biotech contamination. (2001, February 6). *Cropchoice*, Retrieved on August 18, 2006, from http://www.biotech-info.net/ND_contamination.html

³³⁸ Schubert, R. (2001, April 11). Nebraska organic farmer bears costs of GM testing, *Cropchoice*, Retrieved on August 12, 2006, from <http://www.cropchoice.com/leadstry0898.html?recid=289>

³³⁹ Ibid.

³⁴⁰ GMO impacts on organic spreading worldwide [Electronic version], (2005, December). *The Non-GMO Report*, Retrieved on November 6, 2006, from www.non-gmoreport.com

³⁴¹ Ibid.

Most recently, a GE rice variety not approved for commercial use (only approved for field trials) showed up in the U.S. rice supply, half of which is exported.³⁴² Fearing the same thing could happen to them, India's lead exporters and farmers unions are asking their government to terminate all GE rice field trials in order to protect their markets. Rice receives a good price on the export market, and growers fear that countries that doubt India's non-GE status will begin testing or rejecting shipments.³⁴³ Research on the unapproved herbicide-tolerant rice variety, produced by Bayer CropScience of Germany, was abandoned in 2001. Margaret Mellon of the Union of Concerned Scientists says the situation offers "more evidence. . .that all of these things that have been getting tested ultimately have a route to the food supply."³⁴⁴

Is Organic Alfalfa at Risk?

If RR alfalfa makes its way into the organic alfalfa market, organic alfalfa farmers risk serious consequences: costly eradication efforts and potential loss of market; loss of consumer confidence and higher prices for consumers; and loss of genetic resources used in organic and conventional alfalfa seed breeding. Alfalfa is insect-pollinated, primarily by bees; therefore, markets for alfalfa seed and hay that shun or outright reject GE material in seeds and feed risk contamination by RR alfalfa.³⁴⁵ Considering alfalfa's importance to the organic livestock industry, contamination concerns cannot be overlooked.

³⁴² Weiss, R. (2006, August 19). U.S. rice supply contaminated: Genetically altered variety is found in long-grain rice [Electronic version], *Washington Post*, Retrieved on November 7, 2006, from <http://www.washingtonpost.com/wp-dyn/content/article/2006/08/18/AR2006081801043.html>

³⁴³ India's rice industry warns against GE trials. (2006, October 31). *Reuters*, Retrieved on November 7, 2006, from <http://today.reuters.com/News/CrisesArticle.aspx?storyId=DEL318564>

³⁴⁴ Weiss, R. (2006, August 19). U.S. rice supply contaminated: Genetically altered variety is found in long-grain rice [Electronic version], *Washington Post*, Retrieved on November 7, 2006, from <http://www.washingtonpost.com/wp-dyn/content/article/2006/08/18/AR2006081801043.html>

³⁴⁵ St. Amand, P. C., Skinner, D. Z., & Peaden, R. N. (2000). Risk of alfalfa transgene dissemination and scale-dependent effects [Electronic version], *Theoretical and Applied Genetics*, 101, 107-114, Retrieved on July 2, 2006, from <http://www.isb.vt.edu/brarg/brasym95/amand95.htm>

Under the NOP, organic livestock must be fed certified organic feed. Milk cows accounted for over half of the total number of certified animals in 2003.³⁴⁶ The total number of certified organic livestock, including beef cattle, pigs, sheep and lambs, increased by 572 percent between 1997 and 2003.³⁴⁷ And the demand for alfalfa-derived organic products appears to be growing. For example, in 2005, California experienced a shortage in organic feed, and is looking to North Dakota to increase production of organic grain and forage, including alfalfa.³⁴⁸ California currently has to import organic feed from China and South America to meet its rapidly growing demand for organic livestock and poultry markets.³⁴⁹ The U.S. also recently experienced a shortage in organic milk, one of the fastest growing segments of the organic market.³⁵⁰ In fact, organic milk is one of the first organic products a consumer is likely to purchase, and has been called a “gateway to organic food.”³⁵¹ While the shortage was mostly attributed to a lack of certified organic cows, this demand is implicitly coupled with a need for more organic alfalfa hay.³⁵²

Pollen drift between RR alfalfa and conventional alfalfa was recorded in field trials years before the new forage hit the market. Researchers at Kansas State University studied alfalfa pollen drift and found that complete containment of transgenes within alfalfa seed

³⁴⁶ USDA, Economic Research Service. Data sets: Organic production, Retrieved on October 5, 2006 (<http://www.ers.usda.gov/Data/organic/>)

³⁴⁷ Ibid.; Total certified organic livestock equaled 18,513 in 1997, 74,435 in 2003.

³⁴⁸ California organic farmers looking to North Dakota for feed. (2005, May 10). *Valley City Times-Record*

³⁴⁹ Ibid.

³⁵⁰ Weinraub, J. & Nicholls, W. (2005, June 1). Organic milk supply falls short [Electronic version], *Washington Post*, Retrieved on August 3, 2006, from <http://www.washingtonpost.com/wp-dyn/content/article/2005/05/31/AR2005053100363.html>; Klonsky, K. (2000). Forces impacting the production of organic foods, *Agriculture and Human Values* 17: 239.

³⁵¹ Severson, K. (2005, November 9). An organic cash cow [Electronic version], *The New York Times*, Retrieved on August 3, 2006, from <http://www.nytimes.com/2005/11/09/dining/09milk.html?ex=1289192400&en=54f6d84cb3f51bcf&ei=5088&partner=rssnyt&emc=rss>

³⁵² An organic cash cow [Electronic version], *The New York Times*, Retrieved on August 3, 2006, from <http://www.nytimes.com/2005/11/09/dining/09milk.html?ex=1289192400&en=54f6d84cb3f51bcf&ei=5088&partner=rssnyt&emc=rss>; Klonsky, K. (2000). Forces impacting the production of organic foods, *Agriculture and Human Values* 17: 239. (“Obviously, the demand for organic feed will increase along with the increase in the supply of organic milk.”)

or hay production fields would be unlikely using current production practices.³⁵³ And a market researcher and promoter of RR alfalfa at Washington State University believes that it is difficult to certify that non-GE alfalfa will not be contaminated if grown in an area where GE alfalfa cultivars are produced.³⁵⁴

Even manufacturers and proponents of RR technology acknowledge the unintended spread of engineered traits. Monsanto's 2007 Technology Use Guide outlines factors that contribute to cross-pollination but does not require preventative measures for mitigating the transfer of the GE trait:

Roundup Ready Alfalfa should be managed for high quality hay/forage production including timely cutting to promote high forage quality and to prevent seed development. In geographies where conventional common alfalfa seed production is intermingled with forage production and the agronomic conditions (climate and water/irrigation availability) are such that forage alfalfa is allowed to stand and flower late in the season, Roundup Ready Alfalfa must be harvested at or before 10 percent bloom to minimize potential pollen flow from hay to common alfalfa seed production.³⁵⁵

Because the NOP does not allow GE material in certified organic farming systems, cross-pollination of RR alfalfa with organic crops could increase production costs, reduce profits, or even eliminate markets for organic alfalfa producers. These markets afford organic alfalfa producers a ten to fifty percent premium for their hay compared to non-organic producers, and are a viable means to making farming profitable.³⁵⁶ USDA does not have rules in place that require farmers who plant RR seeds to create refuge or buffer areas to avoid cross-pollination with neighbors' crops or surrounding weeds. As explained in chapter one, the burden of keeping "excluded" material out of certified

³⁵³ St. Amand, P. C., Skinner, D. Z., & Peadar, R. N. (2000). Risk of alfalfa transgene dissemination and scale-dependent effects [Electronic version], *Theoretical and Applied Genetics*, 101, 107-114, Retrieved on July 2, 2006, from <http://www.isb.vt.edu/brarg/brasym95/amand95.htm>

³⁵⁴ Woodward, W. T.W. (2004, December 13-15). Issues with GMO alfalfa in the marketplace [Electronic version], *Proceedings of California Alfalfa & Forage Symposium*, San Diego, CA, Retrieved on August 3, 2006, from <http://alfalfa.ucdavis.edu>

³⁵⁵ The Monsanto Company. (2006). 2007 Technology Use Guide [Electronic version], Retrieved on November 13, 2006, from www.monsanto.com/monsanto/us_ag/content/stewardship/tug/2007TUGPDF.pdf

³⁵⁶ Lehnert, D. (1998, February 1). Tap the market for organic hay [Electronic version], *Hay & Forage Grower*, Retrieved on July 2, 2006, from http://hayandforage.com/mag/farming_tap_market_organic/

organic fields is on the organic producer, not the neighbor planting GE crops, and not the patent owner of the escaped GE trait (in this case, Monsanto).

Still, Monsanto argues that alfalfa hay fields will not significantly contribute to gene flow.³⁵⁷ Monsanto spokesperson Mica DeLong said that:

Farmers' concerns about cross-contamination are unfounded because the only way alfalfa can go to seed is if farmers let it, and farmers using Monsanto's Roundup Ready products sign a licensing agreement precluding them from saving and replanting the seeds. . .since the majority of growers produce Roundup Ready alfalfa only for hay, animal feed or exports, growers would not allow their crops to go to seed because that would reduce the quality of the forage.³⁵⁸

DeLong's statement is misleading and over-simplified, as alfalfa farmers cannot control weather or other factors contributing to their harvest schedule. Just because a farmer signs a contract acknowledging recommended growing practices, there is no legal requirement for farmers to harvest hay at a certain time, or to ensure that their fields are isolated from alfalfa fields grown for seed production (where fields go to full bloom in order to set seed). If RR alfalfa becomes well established in the environment and marketplace, organic and conventional alfalfa seed may start testing positive for transgenic material, as the Union of Concerned Scientists discovered in the conventional corn, soybean and canola supply. According to one expert on RR alfalfa, the "most likely contamination could be in purchased seed because of seed production practices that may not allow adequate isolation distances."³⁵⁹ Hay producers typically harvest before alfalfa blooms or at a very small percentage bloom (extension literature often recommends 10 percent bloom).³⁶⁰ Opponents of RR alfalfa insist that most alfalfa hay is cut after flowers

³⁵⁷Komp, C. (2006, March 3). Farmers sue USDA over modified alfalfa crop [Electronic version], *The New Standard*, Retrieved on September 3, 2006, from <http://newstandardnews.net/content/index.cfm/items/2883>

³⁵⁸ Ibid.

³⁵⁹ Woodward, W.T.W. (2006, January 18-19). Roundup Ready alfalfa test kits and influence on the market [Electronic version], *Proceedings of 2006 Washington State Hay Growers Association's Annual Conference & Trade Show*, Kennewick, WA, Retrieved on November 3, 2006, from www.wa-hay.org/.../Roundup%20Ready%20Alfalfa%20Test%20Kits%20and%20Influence%20-%20Woodward.pdf

³⁶⁰ Monsanto and Forage Genetics International. (2004, April 16). Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Medicago sativa* L.) Events J101 and J163 [Electronic version], Petition # 04-AL-116U, Retrieved on August 2, 2006, from http://www.aphis.usda.gov/brs/not_reg.html

have already produced viable pollen.³⁶¹ Therefore, while cross-pollination between hay fields is less of a concern than between alfalfa seed production fields, it is nevertheless a valid concern for alfalfa producers who want to avoid RR alfalfa.

Of course, pollen does not stop at national borders either. Although RR alfalfa is currently approved for import in Canada (not for planting), the company acknowledges that cross-pollination can happen across the border. As one Monsanto spokesperson explains:

The company had to take into account the possibility that circumstances beyond its control could lead to the GM alfalfa crossing into Canada once it was released to growers in the U.S. That could happen through illegal shipments of seed into Canada or through insects such as bees carrying pollen from Roundup Ready alfalfa fields near the border. Cross-pollination with non-GM alfalfa crops could result. It's a plant, so we're going to have some possibility for movement.³⁶²

Should RR alfalfa in the U.S. contaminate Canadian alfalfa, or if RR alfalfa is approved for planting in Canada, sources of non-GE alfalfa seed for U.S. organic alfalfa producers may further be limited. Experts agree that more needs to be written about the effects of crop-to-crop gene flow, especially in light of recent contamination events.³⁶³

Export Markets

Even though RR alfalfa is only approved for commercial use in the U.S., it may cause controversy in countries that do not share a North American border. Both organic farmers and conventional farmers who export (especially to sensitive markets) rely on seeds and harvests that are free of transgenic material. Farmers who export to countries that shun GE crops and food are just as concerned as organic farmers about their ability to provide

³⁶¹ Komp, C. (2006, March 3). Farmers sue USDA over modified alfalfa crop [Electronic version], *The New Standard*, Retrieved on September 3, 2006, from <http://newstandardnews.net/content/index.cfm/items/2883>

³⁶² Bell, I. (2004, November 5). Monsanto seeks approval of GM alfalfa [Electronic version], *Western Producer*, Retrieved on October 23, 2006 from <http://www.agbios.com/main.php?action=ShowNewsItem&id=5999>

³⁶³ Ellstrand, Norman. (2006). When crop transgenes wander in California, should we worry? [Electronic version], *California Agriculture*, 60(3), Retrieved on November 1, 2006, from <http://repositories.cdlib.org/anrcs/californiaagriculture/v60/n3/p116/>

a GE-free product. There was much contention around the introduction of RR alfalfa in areas where alfalfa is largely produced for export, because both alfalfa farmers and export businesses knew the nature of alfalfa—its ability to cross-pollinate with other varieties—did not bode well for an industry that depends on foreign customers who are wary of accepting GE products.

Nearly all alfalfa exported from the U.S. is grown in the western U.S. Ninety-five percent of U.S. alfalfa is kept for use as animal feed; the balance is exported. Japan accounts for 75 percent of the export market (around \$500 million a year), and the rest goes to South Korea, Taiwan, Mexico, and Canada.³⁶⁴ Even though Monsanto and Forage Genetics have received approval from most of these governments, many U.S. export companies and producers insist their customers do not want it.³⁶⁵ As one market researcher put it, “the issues are more of a concern with the customer than with government approval. Most of the alfalfa hay customers have indicated a low tolerance for GMOs in hay products.”³⁶⁶ Several alfalfa export companies submitted comments to APHIS in opposition to RR alfalfa for this reason.³⁶⁷ The contention around RR alfalfa in the context of exports was also documented in the media. Mark Anderson of Anderson Hay and Grain Inc., one of the largest hay exporting companies in the U.S., stated that he did not want RR alfalfa because of the politics and problems that go with it.³⁶⁸ Jeff Plourd of El Toro Export in El Centro, CA is quoted: “Some of our Japanese hay customers are asking us to sign documents saying no genetically modified products will be coming

³⁶⁴ Cline, H. (2006, January 11). Growing, marketing herbicide-resistant alfalfa will be challenging, worthwhile [Electronic version], *Western Farm Press*, Retrieved on September 12, 2006, from <http://westernfarmpress.com/news/1-11-05-herbicide-resistant-alfalfa/>

³⁶⁵ Moore, T. (2005, August 12). Washington hay growers balk at Roundup Ready alfalfa [Electronic version], *Capital Press Agriculture Weekly*, Retrieved on September 5, 2006, from <http://www.seedquest.com/News/releases/2005/august/13194.htm>; Korea currently doesn't regulate animal feed, but is developing an approval process. Taiwan has a voluntary regulatory system for GE crops, and it is legal for RR alfalfa to be shipped there.

³⁶⁶ Woodward, W.T.W. (2006, January 18-19). Roundup Ready alfalfa test kits and influence on the market [Electronic version], *Proceedings of 2006 Washington State Hay Growers Association's Annual Conference & Trade Show*, Kennewick, WA, Retrieved on November 3, 2006, from www.wa-hay.org/.../Roundup%20Ready%20Alfalfa%20Test%20Kits%20and%20Influence%20-%20Woodward.pdf

³⁶⁷ Comments can be found in Docket No. 04-085-1 at <https://web01.aphis.usda.gov/regpublic.nsf/04-085-1?OpenView>, Retrieved in June 2005. Three large export companies submitted comments in opposition of RR alfalfa, including Mark Anderson Hay and Grain, Inc., El Toro Export, and Haykingdom.

³⁶⁸ King, A. (2005, January 20). Growers Avoid Altered Alfalfa [Electronic version], *Tri-City Herald*, Retrieved on July 19, 2006, from <http://www.saynotogmos.org/ud2005/ujan05a.html>

over.”³⁶⁹ Many alfalfa processors and exporters have indicated that their Japanese customers do not want GE material in their forage products.³⁷⁰ So, regardless of any tolerance level set by the government (Japan has a 5 percent tolerance for GE material in non-GE products), customers may continue to demand zero tolerance for GE alfalfa.

Significantly, the Washington State Hay Growers Association took a strong stance against the immediate release of RR alfalfa.³⁷¹ The Association asked that Monsanto and Forage Genetics hold off on selling RR alfalfa in Washington until its foreign customers were willing to accept the technology.³⁷² Still, Monsanto and Forage Genetics insisted on moving forward with sales in some parts of the state, causing tension between the two stakeholders, and increasing fears among exporters that their markets in the Pacific Rim would be lost.³⁷³ Hay is the largest export commodity by volume in the Pacific Northwest, and Columbia Basin growers export about \$140 million in alfalfa to Japan each year.³⁷⁴ Growers fear that Japanese customers will stop purchasing all U.S. alfalfa out of contamination fears, a case similar to the beef embargos imposed by Japan in 2003 and 2006 in response to Bovine Spongiform Encephalopathy (BSE), or mad cow disease, as well as Japan’s response to the prospect of GE wheat, a response that ultimately gave

³⁶⁹ Bernick, J. (2005, March 17). Biotech alfalfa this year, AgWeb.com, Retrieved on July 12, 2006, from http://www.agweb.com/get_article.asp?pageid=116276

³⁷⁰ Woodward, W.T.W. (2006, January 18-19). Roundup Ready alfalfa test kits and influence on the market [Electronic version], *Proceedings of 2006 Washington State Hay Growers Association’s Annual Conference & Trade Show*, Kennewick, WA, Retrieved on November 3, 2006, from www.wa-hay.org/.../Roundup%20Ready%20Alfalfa%20Test%20Kits%20and%20Influence%20-%20Woodward.pdf

³⁷¹ Moore, T. (2005, August 12). Washington hay growers balk at Roundup Ready alfalfa [Electronic version], *Capital Press Agriculture Weekly*, Retrieved on September 5, 2006, from <http://www.seedquest.com/News/releases/2005/august/13194.htm>;

³⁷² To view correspondences between the Washington State Hay Growers Association and Monsanto and Forage Genetics, see <http://www.wa-hay.org/resources/>, Retrieved on October 12, 2006

³⁷³ King, A. (2005, August 5). Roundup ready alfalfa worries growers [Electronic version], *Tri-City Herald*, Retrieved on July 17, 2006, from <http://www.newfarm.org/news/2005/0805/081205/alfalfa.shtml>;
Another article mentions that “a limited launch began last fall, but no Roundup Ready seed was sold in states where significant amounts of hay are grown for export.” (Japan approves Roundup Ready alfalfa [Electronic version], (2006, February 17). *Hay & Forage Grower*, Retrieved on July 17, 2006, from <http://hayandforage.com/ar/Japan-Approves-RR-Alfalfa/>)

³⁷⁴ Ibid.

Monsanto little choice but to pull its petition for the deregulation of RR wheat from APHIS.³⁷⁵

Clearly, the issue of acceptance of GE crops by export markets looms large. When RR alfalfa was first deregulated—approved for commercial sales and planting—some of the most important export countries had not yet approved the transgenic forage for import. Therefore, Monsanto implemented a “Limited Domestic Launch,” which was an additional contract that RR alfalfa growers had to sign (in addition to the Technology Agreement). Simply put, it stated that RR alfalfa was to be grown for domestic use only, pending international market approval. In February 2006, Monsanto and Forage Genetics removed the domestic use requirements after receiving final import approval from some important export markets.³⁷⁶

Notably, certified organic producers and hay exporters may not be the only ones avoiding RR alfalfa. Some “natural” beef producers who prefer non-GE feed are currently unable to purchase grain with any guarantee that it does not contain GE traits.³⁷⁷ If RR alfalfa is widely adopted, and follows the precedent of RR soybeans, corn, and canola, non-GE options will be limited if not impossible to find for farmers and ranchers committed to non-GE seed and feed sources.³⁷⁸ Furthermore, in the event of organic alfalfa hay shortages, consumers can expect prices of organic meat and dairy products to increase.

Sprout Industry

Consumers may also be concerned about the potential for RR alfalfa to enter another market that it is not intended for: sprouts. Alfalfa sprouts are a popular item in health

³⁷⁵ Ibid.; Wisner, R. (2003). *Market risks of genetically modified wheat: The potential short-term impacts of GMO spring wheat introduction on U.S. wheat export markets and prices* [Electronic version], Retrieved on June 1, 2006, from http://www.worc.org/issues/art_issues/gmwheat.html#

³⁷⁶ Roundup ready alfalfa moving forward with full product launch [Electronic version]. (2006.) *The Haymaker: Progress in Alfalfa Research and Management*, Winter, Retrieved on November 4, 2006 www.wlresearch.com/WLHaymakerWinter06FP.pdf

³⁷⁷ W. Tusick, Montana Natural Beef, personal communication, July 19, 2005.

³⁷⁸ Union of Concerned Scientists. (2004). *Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply* [Electronic version], Retrieved on June 1, 2006, from http://www.ucsusa.org/food_and_environment/genetic_engineering/gone-to-seed.html

food stores because of their many nutritional benefits.³⁷⁹ Monsanto states in its 2007 Technology Use Guide that RR alfalfa seed may not be planted for the production of sprouts,³⁸⁰ despite that it has been approved for human food use.³⁸¹ RR alfalfa seed may impact the sprouting industry despite not being marketed directly to sprout growers. This is because the introduction of RR alfalfa into the environment and marketplace may eventually limit seed sources. Sprout producers who wish to maintain GE-free will find it extremely difficult, if not impossible, to locate pure seed sources in the future should RR alfalfa be widely adopted. This is especially alarming for producers who market or are considering marketing their sprouts as organic or GE-free. Many large food retail chains, including Trader Joe's, Wild Oats, and Whole Foods, are committed to keeping GE ingredients off their shelves. As these markets continue to grow, sprout growers should be aware of the difficulty and added costs (testing for transgenic material in their products) of providing sprouts that are GE-free. Woodward points out that sprout producers, as well as producers who provide alfalfa for natural supplement companies, are not likely to know that RR alfalfa is on the market, and may impact their production and processing operations. In his words: "It is questionable if the health or sprout market knows that an alfalfa GMO will be on the market and that they might have to test for its presence."³⁸²

Honey Industry

The honey industry is another stakeholder in the alfalfa industry, as honey bees are an important pollinator of alfalfa, and most U.S. honey is produced from an alfalfa or clover

³⁷⁹ Meyerowitz, S. Health benefits of sprouts, International Specialty Supply, Retrieved on November 4, 2006 from http://www.sproutnet.com/Press/health_benefits_of_sprouts.htm

³⁸⁰ The Monsanto Company. (2006). 2007 Technology Use Guide [Electronic version], Retrieved on November 13, 2006, from www.monsanto.com/monsanto/us_ag/content/stewardship/tug/2007TUGPDF.pdf

³⁸¹ Although split approvals, as explained in the StarLink case, are no longer allowed under Coordinated Framework policy, Monsanto creates a de facto split approval for RR alfalfa by stating in its licensing agreement that it is forbidden to use RR alfalfa seeds for sprout production—to produce it for direct consumption by humans.

³⁸² Woodward, W.T.W. (2006, January 18-19). Roundup Ready alfalfa test kits and influence on the market [Electronic version], *Proceedings of 2006 Washington State Hay Growers Association's Annual Conference & Trade Show*, Kennewick, WA, Retrieved on November 3, 2006, from www.wa-hay.org/.../Roundup%20Ready%20Alfalfa%20Test%20Kits%20and%20Influence%20-%20Woodward.pdf

floral source. Honey producers risk losing markets that demand honey free of transgenic traits. Honey bees can transfer pollen several miles, and could cross-pollinate RR alfalfa with conventional varieties. Between 1998 and 2000, honey exported to the EU from Canada dropped by five million dollars (55 percent) because of traces of RR canola. At the time, transgenic canola was not approved in the EU. It is important to note that Monsanto and Forage Genetics are not seeking EU approval for RR alfalfa, meaning that any trace of the transgenic forage in food products will be deemed illegal and refused.

Importantly, the NOP does not specifically address certification of honey. In 2004, the Policy Development Committee recommended to the NOSB that apiculture operations be certified organic and that the NOP “should proceed with rulemaking, using recommendations submitted by NOSB to construct proposed rule amendments.”³⁸³ These rules were recommended because of the unique practices involved in apiculture. Such rules are not yet in place, though honey is technically covered by the NOP. There is a growing market for certified organic honey, according to a report by the Saskatchewan Agriculture, Food, and Rural Revitalization Department. The report also notes that issues involving GE organisms “continue to be a concern for many honey producers who export to certain markets.”³⁸⁴ Although testing for transgenic material is not mandatory under the NOP, countries that import U.S. honey may test products, especially in light of RR alfalfa’s introduction, as the EU did years ago with Canadian honey imports.

Summary

Evidence for pollen drift confirms certified organic alfalfa hay and seed producers’ concern that containing the RR alfalfa trait may be extremely difficult.³⁸⁵ Of course, this

³⁸³ Policy Development Committee. (2004, September 28). National Organic Program scope [Electronic version], Retrieved on November 12, 2006, from

www.ams.usda.gov/nosb/meetingbooks/Oct2004/NOPScope9_04.pdf

³⁸⁴ Saskatchewan Agriculture, Food and Rural Revitalization. (2004, February). Honey Industry Profile, Retrieved on November 4, 2006 from www.agr.gov.sk.ca/docs/crops/apiculture/HoneyIndustry.pdf

³⁸⁵ Vermont Public Interest Research Group. (2003, December). *Blowing in the wind, The road to extinction for Vermont’s organic farms: Testing confirms genetic pollution of organically grown corn* [Electronic version], Montpelier, VT: Author, Retrieved on April 17, 2006, from www.gefreevt.org/images/downloads/blowing%20in%20the%20wind%20report.pdf

perspective neglects the issue of alfalfa sprouts. Even with demonstrated gene flow between alfalfa varieties, proponents do not expect much resistance from consumers, because alfalfa is “one step removed” from the food product.³⁸⁶ Still, opponents view RR alfalfa’s release as a silent introduction of a new GE ingredient into the food system, and, in addition to market risks for farmers, fear negative environmental consequences, such as an increase in herbicide use.³⁸⁷ Because GE food, and food derived from GE feed, is not labeled in the United States, consumers are left to make the connection from field to plate—from those hay bales that dot the rural landscape to their glass of milk, slab of butter and cheese, beef steak, honey, and many other livestock products.

It is clear that the introduction of RR alfalfa into the marketplace has caused controversy among farmers and consumers alike, and may create similar problems as its RR predecessors: an increase in herbicide use and glyphosate-resistant weeds, market rejection and cross-contamination. Keeping organic products free of GE material has proven difficult, and appears to be a hefty burden for organic producers who struggle to ensure the genetic purity of their seeds and harvests.

Organic alfalfa is an important component to the organic livestock industry, an industry that continues to grow each year. Evidence for the likely transfer of transgenic alfalfa traits into surrounding fields indicates that organic alfalfa producers will face new challenges in ensuring organic alfalfa products free of GE material. Export producers are also likely to face market challenges, as Japanese customers have already expressed a desire for U.S. forage to remain GE-free. The introduction of RR alfalfa may also impact the alfalfa sprout market and honey producers seeking non-GE status.

So, are the existing regulatory frameworks with respect to agricultural biotechnology and the National Organic Program sufficient for protecting the integrity of organic food in the face of genetically engineered crops? Given the potential impacts of introducing RR

³⁸⁶ UC studies genetically engineered alfalfa to produce objective information. (2004, April). University of California Agriculture and Natural Resources, Retrieved on July 7, 2006, from <http://ucanr.org/spotlight/gmoalfalfa.shtml>

³⁸⁷ Geertson Seed Farms, *et al.* v. Mike Johanns, *et al.* 2006 Cal C06-1075 CRB

alfalfa, I will analyze and assess whether existing regulations are sufficient for protecting the integrity of organic alfalfa in the next chapter.

3.

LIVING TECHNOLOGIES IN AGRICULTURE

They've introduced technology that they can't manage and now I have to pay the bills.

-David Vetter, Organic Farmer in Nebraska³⁸⁸

As examined in the last chapter, there are several potential implications of introducing RR alfalfa that make it a good case study for evaluating the effectiveness of current regulatory frameworks. Specifically, are they adequate to protect the integrity of organic alfalfa in the face of RR alfalfa? Alfalfa is an important component of the organic industry, and the demand for organic alfalfa continues to increase each year. The extent of the contamination of non-GE feed sources, primarily corn, canola, and soybeans, is deeply problematic, and the introduction of RR alfalfa may further limit non-GE seed and feed options should conventional varieties become contaminated. Focusing on the issue of genetic drift, this chapter points out weaknesses in the National Organic Program (NOP) and Coordinated Framework that may allow RR alfalfa to enter the organic marketplace, and further evaluates additional issues pertinent to the integrity of organic alfalfa products.

The National Organic Program: The Burden of Avoiding a Living Technology

Genetic engineering has been a core issue in organic agriculture discussions for decades; yet, as mentioned in chapter one, few solutions to the challenges genetic engineering poses to organic production and regulation have surfaced. An obvious weakness of the NOP in regards to genetic engineering—to “excluded methods” in general—is the lack of mandatory testing of both seeds and harvests. Because USDA’s intentions were to create process-based standards, the agency argues that mandatory testing for transgenic material in certified organic products would signify a product-based standard.³⁸⁹ Moreover, in the event transgenic material is identified USDA goes further to allow the excluded substance in organic products as long as the production standards were followed, and the

³⁸⁸ Schubert, R. (2001, April 11). Nebraska organic farmer bears costs of GM testing, *Cropchoice*, Retrieved on August 12, 2006, from <http://www.cropchoice.com/leadstry0898.html?recid=289>

³⁸⁹ 65 Fed. Reg. 80548, (December 21, 2000)

excluded material was not intentionally used: the “presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards.”³⁹⁰ In response to public comments concerning transgenic pollen drift, USDA stated that:

The emphasis and basis of these standards is on process, not product. We have specifically structured the provisions relating to excluded methods to refer to the use of methods. [Prohibiting] the products of excluded methods. . . would not be consistent with this approach to organic standards as a process-based system.³⁹¹

It may not be surprising that USDA discourages testing, as the agency initially rejected residue standards in general, even for pesticides on organic foods.³⁹² Although consumers tend to demand zero tolerance of transgenic material in organic products, the standards do not establish or address a limit for the unintended presence of this material. Interestingly, the Organic Foods Production Act (OFPA) was intended to “require periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations,”³⁹³ and is not exclusively process-based.³⁹⁴ A Senate Report on the Act indicates that Congress may have intended for the NOP to monitor the effectiveness of the standards. The report explains that farmers “may produce products with minimum residues due to inadvertent environmental contamination such as drift from a neighboring farm” even if the organic standards are strictly followed.³⁹⁵ The report also notes that organic food is not necessarily residue-free, but that “residue testing plays an important role in organic certification.”³⁹⁶

³⁹⁰ 65 Fed. Reg. 80548, (December 21, 2000)

³⁹¹ 65 Fed. Reg. 80547, 80549 (December, 21 2000)

³⁹² Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. *Envtl. L.J.* 379.

³⁹³ 7 U.S.C. 6506(a)(6)

³⁹⁴ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. *Envtl. L.J.* 379.

³⁹⁵ S. REP. NO. 101-357, at 300 (1990), reprinted in 1990 U.S.C.C.A.N. 4656, 4954, cited In Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. *Envtl. L.J.* 379.

³⁹⁶ *Ibid.*

The Senate Report indicates that testing serves as a check on “the honesty of the system,” and a way to ensure that consumers are getting what they pay for: “This legislation provides that if prohibited materials are present at levels that are greater than the unavoidable residual environmental contamination. . .then such food shall not be labeled organically produced.”³⁹⁷ While Congress may have thought the residue testing requirement in OFPA would enforce both process standards and product standards, the “current NOP regulations serve neither, as the regulations do not require any form of random or periodic residue testing.”³⁹⁸

The nature of pollen drift makes regulating transgenic material extremely difficult. Farmers and certifying agents cannot identify transgenic material that has become integrated within a plant without testing. But there are several reasons why testing is unlikely to happen. First, certifiers and farmers are unlikely to know if transgenic pollen has entered a field and product, unless they are aware of farming neighbors who grow transgenic crops that easily cross-pollinate. Second, the regulations read that testing “may” occur only if “there is reason to believe” that a farmer has violated his/her plan. Third, because certifying agents are hired by farmers, there is competition with other certifiers and therefore pressure to keep costs down; meaning, “agents risk losing clients to less strict certifiers if they impose burdens on farmers not required by law.”³⁹⁹ Fourth, the cost of testing falls on the shoulders of certifying agents (if they request testing) or farmers (if they want to investigate the genetic content of seeds or harvests). And people in the organic industry may, rightly, feel that it is not their responsibility to test when the risks are posed by others. Lastly, there is no real incentive for farmers to test their organic products, because these products can still be sold as organic even if they include transgenic material, as long as the farmer did not intentionally use transgenic seeds.

³⁹⁷ Ibid.

³⁹⁸ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. *Envtl. L.J.* 379.

³⁹⁹ Ibid.

Contaminated Products are Entering the Market

Because USDA does not require planting restrictions on herbicide-tolerant crops—such as isolation distances to mitigate gene flow to non-GE crops—the onus of protecting organic plants is on the organic producer. Even with biological barriers in place, organic farmers simply cannot control the movement of transgenic material by pollinators and wind, and certainly cannot control the genetic content of organic and conventional seed that may contain traces of transgenic material without their knowledge. The nature of alfalfa lends itself to the argument that RR alfalfa will end up in markets where it is not allowed. To review, alfalfa is pollinated by insects, commercially by bees that can carry pollen for miles, especially honey bees. Alfalfa is also a perennial crop with a certain percentage of “hard seed,” seeds that germinate in succeeding seasons, sometimes a year or more later. Controlling 100 percent of volunteer alfalfa resulting from hard seeds, especially on a large acreage, is unrealistic, just as unrealistic as the argument that every farmer growing RR alfalfa will harvest each plant before viable pollen is formed. For the reasons identified in the last chapter, and reviewed above, it is likely that RR alfalfa will make its way into the organic market.

A clear pattern of contamination has been documented for many RR crops during the last decade. Consumers’ knowledge of this problem is largely unknown, though sources point to a limited awareness (or awareness that it is a problem of the future).⁴⁰⁰ Still, few solutions to ensure the integrity of organic products have been identified, perhaps for the following reasons. For one, biotechnology companies claim there is a successful “co-existence” between transgenic and conventional crops (including organic), so efforts to continue containment should be minimal. Secondly, both industries arguably depend on consumers’ lack of knowledge about transgenic content in organic products. As attorney Michelle Friedland points out:

Although it may seem as if the interests of the organic industry and the biotech food industry would be entirely in opposition to each other,

⁴⁰⁰ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. Evtl. L.J. 379.

because the availability of organic food likely reduces political opposition to biotech foods, the existence of the organic food industry and the public belief that organic foods are free of biotech products actually benefits the biotech industry. . . The biotech industry certainly does not want to tell consumers that organic food does not actually offer a complete alternative to biotech products.⁴⁰¹

The organic industry also has an incentive to fuel—or at least ignore—consumer misperceptions about organic food, to support the belief that organic is a true (perhaps “pure”) alternative to food derived from biotechnology. Thus, the NOP regulations place organic farmers in an “awkward position.”⁴⁰² Because regulations essentially allow contaminated products to be sold as organic:

Organic farmers who refuse to knowingly sell contaminated crops, or who paid for expensive testing of their crops to ensure that they did not do so, would be at a competitive disadvantage to organic farmers who merely complied with the NOP regulations’ requirements. Moreover, because consumers do not understand that the regulations allow contaminated crops to be sold as organic, and because this lack of understanding increases demand for organic food, organic farmers also have incentive to maintain consumers’ misperceptions about organic food.

Nevertheless, many organic farmers are genuinely concerned about the product their consumers are receiving, the integrity of organic seeds, and the rampant spread of transgenic material. Some producers frequently test their own products to identify contamination, not because it is required by their certifying agent or food processor, but because of their efforts to “save organics.”⁴⁰³

⁴⁰¹ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. Evtl. L.J. 379.

⁴⁰² Ibid.

⁴⁰³ Lilliston, B. (2001, September). Farmers fight to save organic crops [Electronic version], *The Progressive*, Retrieved on August 13, 2006, from <http://www.commondreams.org/views01/0822-01.htm>; Schubert, R. (2001, April 11). Nebraska organic farmer bears costs of GM testing, *Cropchoice*, Retrieved on August 1, 2006, from <http://www.cropchoice.com/leadstry0898.html?recid=289>; North Dakota organic farmers worry about biotech contamination. (2001, February 6). *Cropchoice* Retrieved on August 2, 2006, from <http://www.cropchoice.com/leadstry8b5a.html?recid=232>; Vermont Public Interest Research Group. (2003, December). *Blowing in the wind, The road to extinction for Vermont’s organic farms: Testing confirms genetic pollution of organically grown corn* [Electronic version], Montpelier, VT: Author, Retrieved on April 17, 2006, from www.gefreevt.org/images/downloads/blowing%20in%20the%20wind%20report.pdf Hawaii SEED. (2006). *Hawaiian papaya: GMO contaminated*, Retrieved on August 3, 2006, from http://www.gmofreemaui.com/press_releases/Contamination_Report.pdf

When contamination is detected, organic producers are left with the burden of eradicating the excluded material from their field. In the instance of contamination by RR alfalfa, removing all the material will prove to be a difficult task, if not impossible, as seeds can lay dormant in the ground until the following growing season (or even later), and volunteer alfalfa cannot be readily identified as transgenic. Implementing more stringent biological barriers, as well as fronting the cost of testing harvests, will be costly.⁴⁰⁴

The Tolerance Debate

A position paper on co-existence, authored by the International Federation of Organic Agriculture Movements (IFOAM) European Union Group, states that organic certification currently has zero tolerance for contamination by genetically engineered material.⁴⁰⁵ Even though consumers of organic products expect this zero tolerance, there continues to be a debate around whether a tolerance for transgenic material should be established in the U.S. USDA says the NOP does not establish zero tolerance for transgenic material, though the rules imply a zero tolerance by including genetic engineering as an excluded method. Some seed industries do not favor setting a tolerance either. The American Seed Trade Association says that a tolerance of “zero is not possible” and is against setting a tolerance for transgenic material in organic products.⁴⁰⁶ In countries where tolerance levels are established, such as the EU (0.9 percent), IFOAM takes a strong stance on the definition of a tolerance level, asserting that these levels “indicate the maximum tolerance for exceptional and unforeseeable contamination events, not for permanent levels of contamination.”⁴⁰⁷

⁴⁰⁴ Schubert, R. (2001, April 11). Nebraska organic farmer bears costs of GM testing, *Cropchoice*, Retrieved on August 12, 2006, from <http://www.cropchoice.com/leadstry0898.html?recid=289>

⁴⁰⁵ International Federation of Organic Agriculture Movements (IFOAM) EU Group. (2003, October). Co-existence between GM and non-GM crops: Necessary anti-contamination and liability measures [Electronic version], Retrieved on November 10, 2006, from www.ifoam.org/about_ifoam/around_world/eu_group/pdfs/IFOAM_EU_position_GM_coexistence.pdf

⁴⁰⁶ American Seed Trade Association. (2003, July 15). The View of the American Seed Trade Association on Organic Agriculture, Retrieved on November 12, 2006 from <http://www.amseed.com/newsDetail.asp?id=74>

⁴⁰⁷ International Federation of Organic Agriculture Movements (IFOAM) EU Group. (2003, October). Co-existence between GM and non-GM crops: Necessary anti-contamination and liability measures [Electronic

The tolerance debate is complex. On one hand, a tolerance level for contamination by transgenic material might be a good idea. Curiously, while there is a limit to how much pesticide contamination can be in an organic product, there is no allowable limit as to the amount of transgenic material that can be present in the event of contamination.⁴⁰⁸ Before the government can set tolerances, however, “it needs to know what kinds of genes are present in grain or food.”⁴⁰⁹ The Union of Concerned Scientists’ *Gone to Seed* report indicates that the government does not have this information; therefore, transgenic material from a variety of DNA sequences are possibly making their way into the conventional seed supply, but there is no scientific basis on which to determine and enforce tolerances.⁴¹⁰

On the other hand, consumers depend on certified organic products as an alternative to conventionally raised food, many of which now contain transgenic ingredients. Supporters of strong organic standards have worked hard to ensure that the organic label represents the principles held by the organic movement, including the rejection of genetically engineered products. Although “no sector of the food system is trying harder to meet consumer demand for choice” than the organic industry, it is clear that contamination events continue to threaten the integrity of the organic label.⁴¹¹

Protecting Seed Purity

Seeds are the most fundamental component to agriculture and our food supply.⁴¹² Seed laws at both the federal and state level do not address the unintended presence of

version], Retrieved on November 10, 2006, from

www.ifoam.org/about_ifoam/around_world/eu_group/pdfs/IFOAM_EU_position_GM_coexistence.pdf

⁴⁰⁸ Friedland, M. T. (2005). You call that organic? The USDA’s misleading food regulations, 13 N.Y.U. Evtl. L.J. 379.

⁴⁰⁹ Union of Concerned Scientists. (2004). *Gone to seed: Transgenic contaminants in the traditional seed supply* [Electronic version], Retrieved on June 1, 2006, from

http://www.ucsusa.org/food_and_environment/genetic_engineering/gone-to-seed.html

⁴¹⁰ Ibid.

⁴¹¹ Ibid.

⁴¹² Kloppenburg, J. (1988). *First the seed: The political economy of plant biotechnology*, Madison: The University of Wisconsin Press.

transgenic material in seed labeled as conventional or organic.⁴¹³ The NOP only requires organic producers to use organically produced seeds (or conventionally produced seed if organic is unavailable), and does not require testing of seeds to ensure the absence of transgenes. If testing is conducted on seeds, and results show “significant quantities of genetically modified DNA. . . even the most comprehensive post-planting controls for admixture may fail to preserve the expected premiums for the farmer.”⁴¹⁴

Experience with other crops is instructive. For example, in 2002, North Dakota State University’s Foundation Seedstocks Program identified transgenic contamination of a special variety of soybean marketed to Japan and the EU.⁴¹⁵ The following year, researchers at the University of Manitoba found that certified seed stocks of canola were significantly contaminated by transgenic material, finding that 95 percent of 27 certified seed lots were contaminated with transgenic DNA, some with traits that resist two different herbicides.⁴¹⁶ Fourteen seed lots (52 percent) exceeded the .25 percent maximum contamination standard for certified seed.⁴¹⁷

Compounding the problem of foundation and certified seed contamination is that seed banks used to house collections of seeds essential for broadening the genetic diversity of crops are deteriorating due to lack of resources. According to Paul Raeburn, author of *The Last Harvest: The Genetic Gamble That Threatens to Destroy American Agriculture*, seeds are the raw materials necessary for securing agricultural security, for improving crops in the face of global warming, pollution and other new threats.⁴¹⁸ Therefore, it becomes imperative to prevent genetic uniformity and protect the genetic diversity and integrity of a variety of seeds, in the field as well as in the seed bank, including the

⁴¹³ Endres, B. (2005). Revising Seed purity laws to account for the adventitious presence of genetically modified varieties: a first step towards coexistence, 1 J. Food L. & Pol’y 131.

⁴¹⁴ Ibid.

⁴¹⁵ Pates, M. (2002, November 18). Seed contamination raises control issues: Sustainable ag group says gene-altered soybeans spilled onto non-GMO stocks [Electronic version], *Grand Forks Herald*, Retrieved on November 2, 2006, from http://www.biotech-info.net/control_issues.html

⁴¹⁶ Friesen L.F., Nelson A.G. and Van Acker R.C. (2003). Evidence of contamination of pedigreed canola (*Brassica napus*) seedlots in western Canada with genetically engineered herbicide resistance traits. *Agron. J.* 2003, 95.

⁴¹⁷ Ibid.

⁴¹⁸ Raeburn, P. (1995). *The last harvest: The genetic gamble that threatens to destroy American agriculture*, New York, NY: Simon & Schuster.

containment of transgenic DNA. According to Farm Verified Organic, an organic certification service in North Dakota: “The GM pollution of American commodities is now so pervasive, we believe it is not possible for farmers in North America to source seed free from it.”⁴¹⁹

The Coordinated Framework: Regulatory Shortcomings and Insufficient Oversight

Promises were made about containment and segregation, and they weren't kept, and you might say they could never be kept.

- Philip Regal, University of Minnesota biologist⁴²⁰

Twenty years have passed since the implementation of the Coordinated Framework. As mentioned earlier, the laws that make up the framework were created before novel genes derived from recombinant DNA technology entered the marketplace, and continue to be the focus of controversy as new genetically engineered crops enter the marketplace. Not surprisingly, the patchwork approach to regulation has created much confusion among the public and regulated industries.⁴²¹ Some scientists argue that USDA oversight of field trials is inadequate, a concern echoed by the Inspector General of Agriculture, and point to weak risk assessments as well. Agency jurisdiction over regulating crops is generally lacking and weak, lending to activists' and scientists' arguments that government agencies are biased toward biotechnology firms.

Field Trials & Risk Assessments

Alfalfa is currently among the top ten crops for the most approved field trials, planted in at least 35 states.⁴²² (Remember, when a manufacturer submits a notification for a field

⁴¹⁹ Organic crop certifiers decry transgenic contamination [Electronic version]. (2001, May 1), *Cropchoice*, Retrieved on October 3, 2006, from <http://www.cropchoice.com/leadstryal6a.html?recid=310>

⁴²⁰ Zitner, A. (2001, June 4). Fields of gene factories [Electronic version], *Los Angeles Times*, Retrieved on October 2, 2006, from http://www.biotech-info.net/fields_of_genes.html

⁴²¹ Mandel, G. N. Gaps. (2004). Inexperiences, inconsistencies, and overlaps: Crisis in the regulation of genetically modified plants and animals, 45 *Wm and Mary L. Re.*

⁴²² U.S. Public Interest Group. (2005). *Raising risk: Field testing of genetically engineered crops in the United States* [Electronic version], Retrieved on June 3, 2006, from <http://uspirg.org/home/reports/report->

trial, there is no limit as to the amount of acreage that can be planted, and no limit as to how many states one notification may cover.) Pollen drift may have occurred during RR alfalfa field trials, and certainly could have entered organic fields during this time, depending on where the field trials were conducted. For example, the state of Idaho boasts the largest number of certified organic alfalfa hay acres, as well as the second greatest number of RR alfalfa field trials (over 40), potentially covering thousands of acres.⁴²³ Because farmers are not given information regarding experimental field trials happening in their communities, RR alfalfa may have entered organic or other conventional alfalfa fields unbeknownst to the farmers nearby.⁴²⁴ The recent audit report that found APHIS' current field trial oversight to be inadequate on several fronts, including containment of transgenes, lends to the likelihood that RR traits have already entered conventional alfalfa fields.⁴²⁵

For notifications (which include RR alfalfa field trials), APHIS simply has to “acknowledge” an applicant’s notification for field trials within 30 days, and does not perform an Environmental Assessment before the environmental release. Even if performance standards are followed, requirements specific to preventing the gene flow are not adequate to completely stop the movement of pollen—and APHIS’ recommendations for containment are not legally enforceable. Furthermore, APHIS can request additional information from applicants, but cannot *require* the requested information be submitted.⁴²⁶

[archives/more-reports/more-reports/raising-risk--field-testing-of-genetically-engineered-crops-in-the-united-states](#)

⁴²³ Data derived from the Information Systems for Biotechnology, Field test releases in the U.S., Retrieved on November 12, 2006 from <http://www.isb.vt.edu/cfdocs/fieldtests1.cfm>

⁴²⁴ U.S. Public Interest Group. (2005). *Raising risk: Field testing of genetically engineered crops in the United States* [Electronic version], Retrieved on June 3, 2006, from <http://uspirg.org/home/reports/report-archives/more-reports/more-reports/raising-risk--field-testing-of-genetically-engineered-crops-in-the-united-states>

⁴²⁵ U.S. Department of Agriculture, Office of Inspector General. (2005, December). *Audit report: Animal and Plant Health Inspection Service controls over issuance of genetically engineered organism release permits*, Retrieved on April 13, 2006, from www.usda.gov/oig/webdocs/50601-08-TE.pdf

⁴²⁶ Mandel, G. N. (2004). Gaps, inexperience, inconsistencies, and overlaps: Crisis in the regulation of genetically modified plants and animals, 45 *Wm and Mary L. Re.*

Furthermore, scientists criticize risk assessments conducted before commercial releases as having “several inherent weaknesses.”⁴²⁷ For example, the smaller scale of field studies might not represent large-scale commercial production. As noted in an Ecological Society of America study, “pre-commercial field studies are not likely to include the large amount of replication needed to identify small but important effects.”⁴²⁸ Scientists claim that monitoring a GE crop after it is commercialized is crucial for identifying any unintended effects, yet once deregulated, a commercialized GE crop is completely removed from USDA’s oversight, including follow-up tests.⁴²⁹ A 2002 National Academy of Sciences report found that: “There has been no environmental monitoring of these transgenic crops, so any effects that might have occurred could not have been detected. The absence of evidence of an effect is not evidence of absence of an effect.”⁴³⁰

Even if more stringent containment measures are implemented, there are no rules in place requiring growers of RR alfalfa to adhere to them. As noted by University of California Extension Farm Advisor, Shannon Mueller, “Although standards can be revised to modify isolation and control pollination, movement of pollen beyond the borders of an individual field cannot be prevented entirely.”⁴³¹

⁴²⁷ Snow, A. A., Andow, D.A., Gepts, P., Hallerman, E.M., Power, A., Tiedje, J.M. & Wolfenbarger, L.L. (2004). Genetically engineered organisms and the environment: Current status and recommendations [Electronic version], *Ecological Applications*, 15(2) pp. 377-404, Retrieved on July 7, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1051-0761&volume=015&issue=02&page=0377>

⁴²⁸ Ibid.

⁴²⁹ Kareiva, P., Parker, I.M. & Pascual, M. (1996). Can we use experiments and models in predicting the invasiveness of genetically engineered organisms? *Ecology* 77:1670-1675 cited In Snow, A. A., Andow, D.A., Gepts, P., Hallerman, E.M., Power, A., Tiedje, J.M. & Wolfenbarger, L.L. (2004). Genetically engineered organisms and the environment: Current status and recommendations [Electronic version], *Ecological Applications*, 15(2) pp. 377-404, Retrieved on July 7, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1051-0761&volume=015&issue=02&page=0377>; Tokar, B. (2006, June). *Deficiencies in federal regulatory oversight of genetically engineered crops*, Retrieved on June 1, 2006 from <http://environmentalcommons.org/RegulatoryDeficiencies.html>

⁴³⁰ National Research Council. (2002). *Environmental effects of transgenic plants: The scope and adequacy of regulation*, Washington, DC: National Academy Press.

⁴³¹ Mueller, S. (2004, December 14-15). Seed production issues for genetically enhanced alfalfa [Electronic version], Proceedings of California Alfalfa & Forage Symposium, San Diego, CA, Retrieved on November 2, 2006, from www.alfalfa.ucdavis.edu/symposium/2004/proceedings/Mueller_Seed%20Production%20Issues%20for%20OGMO%20Alfalfa.pdf

Agency & Industry Oversight

Compounding the fact that RR alfalfa cross-pollinates with other varieties is the reality that farmers who plant RR alfalfa for hay are not bound to any planting restrictions, including containment measures. Instead, growers who plant RR alfalfa enter into Monsanto's "Technology/Stewardship Agreements" that acknowledge RR alfalfa is capable of moving across field borders, but does not require growers to implement containment strategies in their operations. Even if farmers are careful to harvest their RR alfalfa hay before pollen is produced, ensuring this is impossible, and there is likely to be some gene flow, especially in absence of biological barriers. All of these measures are dependent on farmers' oversight, and therefore allows for human error.⁴³² Even if a buffer area or isolation distance for mitigating the spread of RR alfalfa pollen is established, 100 percent containment is not possible, especially using one method of containment.⁴³³

Another inherent weakness of the Coordinated Framework is that it is not proactive. As shown in the Starlink case, regulatory action is usually taken in response to events of contamination.⁴³⁴ The Coordinated Framework is based on the assumption that transgenic crops behave the same way as conventional crops.⁴³⁵ Yet, not only do several sources point to a need for improvement in how genetically engineered crops are regulated in the U.S., historical contamination events prove that 1) containment is extremely difficult, and 2) contamination events, if uncovered, are costly.⁴³⁶ Moreover, contamination events are

⁴³² Marvier, M. & Van Acker, R.C. (2005). Can crop transgenes be kept on a leash? [Electronic version], *Frontiers in Ecology and the Environment*, 3(2): 99–106, Retrieved on November 13, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1540-9295&volume=003&issue=02&page=0093>

⁴³³ National Research Council. (2004). *Biological confinement of genetically engineered organisms*, Washington, DC: The National Academy Press.

⁴³⁴ Endres, B. (2005). Revising seed purity laws to account for the adventitious presence of genetically modified varieties: A first step towards coexistence, 1 *J. Food L. & Pol'y* 131.

⁴³⁵ National Research Council. (2002). *Environmental effects of transgenic plants: The scope and adequacy of regulation*, Washington, DC: National Academy Press.

⁴³⁶ Ibid.; Snow, A. A., Andow, D.A., Gepts, P., Hallerman, E.M., Power, A., Tiedje, J.M. & Wolfenbarger, L.L. (2004). Genetically engineered organisms and the environment: Current status and recommendations [Electronic version], *Ecological Applications*, 15(2) pp. 377-404, Retrieved on July 7, 2006, from <http://www.esajournals.org/esaonline/?request=get-abstract&issn=1051-0761&volume=015&issue=02&page=0377>

extremely difficult to fix, and may compromise organic and other conventional field operations for years. This creates a dangerous scenario in light of potential human health and ecological impacts. For example, should evidence surface that RR alfalfa is making its way into alfalfa seed operations marketed to edible sprout producers, or that cows are developing health problems from eating RR alfalfa hay, recalling a living technology from the environment and removing products from a convoluted food system will likely be a difficult, expensive, and lengthy process, as was seen with the StarLink case.⁴³⁷

Agency Priorities

USDA may have a stronger interest in protecting the interests of large biotechnology companies than they do in organic producers. The National Research Council concluded that APHIS' risk assessments may be biased toward a finding of no significant impact, which means an Environmental Impact Statement (EIS) will not be triggered.⁴³⁸ In the case of RR alfalfa, APHIS has been criticized by plaintiffs in the lawsuit challenging the agency's decision on RR alfalfa for not addressing the issue of organic contamination in its Environmental Assessment, including the potential socio-economic impacts.⁴³⁹ Similarly, the National Research Council speaks to this lack of attention to other farming systems: "Currently, APHIS environmental assessments focus on the simplest ecological scale. . . APHIS should include any impact on regional farming practice or systems in its deregulation assessments."⁴⁴⁰

USDA also has a history of a "revolving door," a label given to situations where employees who work for the government sometimes regulate industries that they once worked for or managed.⁴⁴¹ For example, Neil Hoffman, the Director of Biotechnology

⁴³⁷ Jacobs, P. (2003, December 1). Banned GE StarLink corn still contaminating 1% of U.S. corn crop [Electronic version], *Knight Ridder Newspapers*, Retrieved on October 4, 2006, from <http://www.centredaily.com/mld/centredaily/news/7386628.htm>

⁴³⁸ National Research Council. (2002). *Environmental effects of transgenic plants: The scope and adequacy of regulation*, Washington, DC: National Academy Press

⁴³⁹ Geertson Seed Farms, *et al.* v. Mike Johanns, *et al.* 2006 Cal C06-1075 CRB

⁴⁴⁰ National Research Council. (2002). *Environmental effects of transgenic plants: The scope and adequacy of regulation*, Washington, DC: National Academy Press

⁴⁴¹ Mattera, P. (2004). *USDA, inc.: How agribusiness has hijacked regulatory policy at the U.S. Department of Agriculture* [Electronic version], Agribusiness Accountability Initiative and Corporate

Regulatory Services in USDA once worked for a biotechnology company called Paradigm Genetics, Inc. (now Icoria, Inc.), a firm that collaborated with Monsanto on biotechnology projects. In 2005, the firm sold its Agricultural Genomics Assets to Monsanto for over six million dollars.⁴⁴² The press release for this sale highlights the conflict-of-interest for Mr. Hoffman, whose responsibility is to oversee APHIS' biotechnology deregulation process for transgenic traits: "The acquired assets are related to the field of transgenic traits for agriculture, which has been the focus of research conducted under an existing six-year, \$55-million agreement signed in 1999 between Monsanto and Icoria, formerly Paradigm Genetics."⁴⁴³ Hoffman joined Paradigm Genetics, Inc. in 1999, the same year the \$55 million agreement was signed with Monsanto.⁴⁴⁴

Furthermore, of all the funds USDA allocates to biotechnology research, only one percent goes toward risk assessment—about \$1-2 million per year.⁴⁴⁵ Given the current amount of transgenic crop acreage—both field trials and commercial cultivation—these resources are insufficient to even discover the "tip of the iceberg."⁴⁴⁶ Such funding seems necessary if agencies continue to heavily rely on manufacturers' own studies when determining deregulation status of transgenic crops.

Research Project, Good Jobs First, Retrieved on August 1, 2006, from

http://www.agribusinessaccountability.org/bin/view.fpl/1198/cms_category/1836.html

⁴⁴² Monsanto Company to acquire selected agricultural genomics assets from Icoria. (2004, March 24).

Icoria News Release, Retrieved on November 1, 2006, from <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/03-24-2005/0003246617&EDATE=>; Genes analyzed by paradigm genetics enter crop testing pipeline at Monsanto. (2003, May 27). Icoria News Release, Retrieved on November 1, 2006, from <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/05-27-2003/0001953788&EDATE=>

⁴⁴³ Monsanto Company to acquire selected agricultural genomics assets from Icoria. (2004, March 24).

Icoria News Release, Retrieved on November 1, 2006, from <http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=104&STORY=/www/story/03-24-2005/0003246617&EDATE=>

⁴⁴⁴ Biotechnology Symposium 2006 at University of Maryland University College. (2006). Speakers biographies, Retrieved on November 18, 2006 from

http://polaris.umuc.edu/mts/biot_symposium/2006/speakers.html (Neil Hoffman's biography)

⁴⁴⁵ Altieri, M. A. (2001, March). The ecological impacts of transgenic crops on agroecosystem health, *Ecosystem Health*, 6(1), Retrieved on August 26, 2006, from

http://www.cnr.berkeley.edu/~agroeco3/the_ecological_impacts.html

⁴⁴⁶ Ibid.

Summary

Both the NOP and Coordinated Framework fail to address issues concerning the nature of introducing RR alfalfa. Alfalfa is a perennial forage crop, meaning it remains in the ground for more than one year (anywhere from three to twelve years). Because alfalfa is insect-pollinated, transgenic traits will travel from field-to-field even with isolation distances or biological barriers in place. Evidence for pollen flow shows that bees can carry transgenic pollen for miles, making containment measures largely ineffective for keeping RR alfalfa pollen within planting borders. No containment strategy is 100 percent effective, due to environmental factors and human error. Moreover, without frequent testing of organic products, we will never learn the extent of the problem, including whether organic alfalfa becomes contaminated by RR alfalfa. Regardless of any measure taken to protect organic products from transgenic contamination, the burden of protecting organic plants from transgenic pollen drift continues to be on the shoulders of organic farmers.

We know that the organic market is growing, especially the market for organic alfalfa hay, due to the expansion of organic livestock production. Neither the NOP and Coordinated Framework go far enough to ensure that organic alfalfa will be protected in the face of genetically engineered alfalfa. Though contamination of organic alfalfa could have occurred in field trials, it is even more likely to occur now that RR alfalfa is available for commercial production and is not bound to further oversight by APHIS, including restrictions on planting.

And what about consumer confidence? After all, this is what drives market demand, especially organic (since these foods are labeled). The outpouring of public comment in response to the proposed NOP rules, and the way the organic industry united to preserve the integrity of their products, show support for strong organic standards, including the omission of products derived from genetic engineering. As these two industries grow, the inability to keep GE material out of conventional seed varieties will continue to reduce the integrity of organic food products, and makes it unrealistic for consumers to expect a

guarantee that all organic foods are free of GE material. If consumers purchasing organic products to avoid genetically engineered ingredients learn that it is not uncommon for transgenic material to make its way into organic products, it may be hard for them to trust the label.

Can the two industries co-exist? That is, can transgenic crops and conventional (including organic) be grown with little or no impact to the other? The advantages of concealing contamination to both the organic and biotechnology industry is curious. Strictly speaking from an economic perspective, fueling consumers' belief that organic products do not contain any transgenic material ensures two things. First, that organic products deserve a premium price for being "pure"—that consumers are paying for a product that meets their expectations. Second, that biotechnology companies can point to a complete alternative to their own products, asserting that consumers do have a choice whether to eat transgenic ingredients or not.

If the purpose of the NOP is to give consumers confidence in the legitimacy of products sold as organic and to increase the supply and variety of available organic products, as well as facilitate international trade in organic products,⁴⁴⁷ then contamination of organic products weakens all of these purposes: it lessens consumer confidence in the legitimacy of products, and decreases the supply and variety of available organic products both for domestic use and international trade. It appears that a large sector of the organic industry will continue to push for more stringent containment of genetically engineered products. It is what the consumers of organic products want, and it is what organic producers need to—perhaps not meet the standards as they currently are written—but to fulfill the values they see as inherent within organic agriculture. The principle of rejecting transgenic material in organic agriculture systems will become moot if avoiding this technology becomes impossible.

⁴⁴⁷ Rawson, J. M. (2005). Organic agriculture in the U.S.: Program and policy issues [Electronic version], Congressional Research Service Report for Congress, Washington, DC: Congressional Research Service, Retrieved on August 16, 2006, www.fpc.state.gov/documents/organization/57848.pdf

CONCLUSION

INTEGRITY IN THE ORGANIC MARKETPLACE

Our challenge is to develop practical strategies for promoting and preserving organic integrity. We will be evaluated and judged on what organics becomes as well as what we choose to leave out. It is up to all of us. We must not become what we set out to be the sane alternative to.

- Michael Sligh, founding chair, National Organic Standards Board⁴⁴⁸

The organic and biotechnology industries have enjoyed enormous growth in the last decade. They also have had their share of controversies; yet, continue to expand their presence in the field and the marketplace. As they do, it becomes clear that their products cannot remain separate, that “co-existence” is not possible, because genetically engineered crops are essentially living technologies. They do not belong and are not allowed in organic fields and products, but continue to show up there, becoming a burden that some organic producers pay to avoid and sometimes eradicate.

This paper looked at two regulatory frameworks important to U.S. agriculture: The National Organic Program (NOP) and Coordinated Framework for the Regulation of Biotechnology. Using Roundup Ready (RR) alfalfa as a case study was useful in understanding the role of these laws and regulations, but also helped to illustrate a larger problem with the existing frameworks. Although both industries acknowledge that transgenic material is moving into fields and markets where it is not allowed or wanted, little has been done to address the problem through the regulatory processes outlined in this paper.

The biotechnology industry does not believe contamination is serious enough to claim that “co-existence” between its products and those certified organic is not possible. However, disbelief in “co-existence” has motivated some producers and processors to test

⁴⁴⁸ Sligh, Michael. 2002. Organics at the crossroads: The past and the future of the organic movement, In Kimbrell, A. (Ed.), *Fatal harvest: The tragedy of industrial agriculture* (p. 345). San Francisco, CA: Island Press.

their organic products, uncovering a disturbing pattern of contamination events. As these two industries continue to grow side-by-side, experience with GE crops coupled with insufficient regulatory frameworks point to a future where contaminated organic products is commonplace.

This is unfortunate in light of the organic industry's efforts to ensure that strong organic standards were established to protect the integrity of organic products. Clearly, many consumers purchase organic products to avoid genetically engineered ingredients in their food. While consumer confidence in organic products affords the biotechnology industry an opportunity to point to a complete alternative to its genetically engineered products, it also places organic farmers in an awkward position. In the event contamination is detected, organic farmers must choose between maintaining the integrity of the products they provide to the organic market and knowingly sending contaminated products to the organic market. As this paper shows, the organic standards allow for an unlimited amount of contamination by transgenic material, as long as the excluded material was not intentionally used. Furthermore, the NOP does not require testing, so the extent of contamination in organic products is largely unknown, and will likely continue to be unknown, as there is no real incentive for a certifier or producer to test organic seeds and harvests.

The NOP also places organic farmers in a vulnerable position. Consumers have established an implied zero tolerance for transgenic material in organic products, and polls show confidence in organic products as clear alternatives to GE ingredients. The biotechnology industry has also been influenced by consumers' perceptions of its technologies, including a burgeoning interest in "consumer-oriented" traits and an abandonment of research projects involving herbicide-tolerant traits in popular foods, including wheat, lettuce, and strawberries, to name a few. The organic industry risks losing credibility altogether should a large part of its consumer base become aware that transgenic material is contaminating some organic products. And this risk is closer than the organic industry may like to admit, because the reality is that transgenic material has been entering the organic marketplace for years. The NOP and Coordinated Framework

do not go far enough to ensure that genetically engineered material stays contained and out of fields and marketplaces where it is not wanted and allowed. The two regulatory frameworks are not protecting the integrity of organic products, and certainly will not protect the integrity of organic alfalfa if Roundup Ready (RR) alfalfa is widely adopted.

Thus, it seems that organic farmers should have recourses in the event genetically engineered material enters their crops. As part of their “organic plan,” farmers are supposed to implement measures to protect their crops from excluded material, including pesticide and transgenic drift, such as planting buffer areas and purchasing organically produced seed. Yet farmers who grow herbicide-tolerant crops are not bound to any planting restrictions to mitigate the movement of transgenes to their neighbors’ fields. Therefore, organic farmers are left with the economic and agronomic costs of detecting and eradicating GE material, taking measures to avoid future contamination, and receiving a lower price for their products (unless they send the contaminated product to the organic market).

USDA does not view GE and organic crops as different from conventionally raised crops. Still, the NOP establishes labeling for certified organic crops, while the Coordinated Framework does not, which is curious: GE crops are patented, meaning the U.S. Patent and Trademark Office has determined them to be “novel.” The history of plant patents involves intense debates and litigation. According to Daniel Charles, author of *Lords of the Harvest: Biotech, Big Money, and the Future of Food*, patents are the “bedrock on which the biotechnology industry is built.”⁴⁴⁹ He writes that the industry learned early on that discoveries are only useful if they lead to a “proprietary position,” in his words: “something approaching monopoly.”⁴⁵⁰

Biotechnology companies capitalize off current patent law to maintain not just profit, but control over markets, and ultimately, farmers. Only, the effects reach further than patent numbers on seed bags and royalty fees to the company. Seeds tie farmers to the land, to

⁴⁴⁹ Charles, D. (2001). *Lords of the harvest: Biotech, big money, and the future of food*, Cambridge, MA: Perseus Publishing.

⁴⁵⁰ Ibid.

their livelihood, and this relationship is altered when seeds are owned by the companies producing them even after money is exchanged, even after the seed is sown. Of course, seeds are unique pieces of property: they self-propagate. Patents follow transgenes wherever they turn up, including a neighbor's field. The legal issues around patented seeds are numerous. There are liability risks around contamination of conventional crops, and contract law issues concerning license agreements (Monsanto's Technology Agreements), including the misuse of the technology.⁴⁵¹ Additionally, liability concerns associated with non-GE seed and marketing contracts include contamination of crops destined for non-GE markets, the consequence of which forces the farmer to find and pay for a replacement crop or compensate the buyer.⁴⁵² Again, the onus of dealing with unwanted GE material falls squarely on the shoulders of non-GE producers; yet, in many cases, the contamination is not the farmer's fault. It begs the question: Is this a case for the U.S. courts?

One legal scholar has written extensively about the potential role of the U.S. judicial system in conventional and organic contamination events involving agricultural biotechnology. Drew L. Kershen's law review articles explore recourses farmers can take in the event they are contaminated by GE material by placing the contamination event into the context of the following claims: civil and strict liability; damage to property, person, and economic interests (markets); trespass; negligence; and private nuisance.⁴⁵³ Four of these claims—trespass, nuisance, strict liability, and negligence—are part of a lawsuit filed on behalf of all certified organic farmers in Saskatchewan. The lawsuit seeks compensation from Monsanto and Aventis Cropscience for damage to organic canola

⁴⁵¹ McEowen, R.A. (2004). Legal issues related to the use and ownership of genetically modified organisms, 43 Washburn L.J. 611.

⁴⁵² Moeller, D. (2001). GMO liability threats for farmers: Legal issues surrounding the planting of genetically modified crops [Electronic version], Farmers' Legal Action Group, Retrieved on May 8, 2006, from <http://www.mindfully.org/GE/GE3/GMO-Liability-For-FarmersNov01.htm>

⁴⁵³ For thorough examinations of these recourses and liability issues in general, see the following articles: Kershen, D. L. (2002). Legal liability issues in agricultural biotechnology, The National Agricultural Law Center, Retrieved on May 2, 2006 from www.nationalaglawcenter.org/assets/articles/kershen_biotech.pdf; Kershen, D. L. (2004). Of straying crops and patent rights, Washburn Law Journal, Vol. 43, No. 3, pp. 575-610; McEowen, R.A. (2004). Legal issues related to the use and ownership of genetically modified organisms, 43 Washburn L.J. 611.

farmers by the companies' GE varieties.⁴⁵⁴ According to the 2002 Saskatchewan Organic Directorate press release, "The claim alleges that GE canola has spread across the prairies and contaminated conventional crops so extensively that most certified organic grain farmers no longer attempt to grow canola."⁴⁵⁵ In May 2005, the judge rejected the case as a class-action lawsuit; the two farmers filed an appeal the same month.⁴⁵⁶ The appeal was granted and the class action lawsuit status is still to be determined.

Perhaps the most notable and publicized case involving contamination by transgenic crops is another Canadian case, *Monsanto Company vs. Percy Schmeiser*. Percy Schmeiser, a canola breeder and farmer, was found guilty of patent infringement for having Monsanto's patented canola genes on his property. In an appeal to the Supreme Court, he argued that his canola was contaminated by Monsanto's traits and that he should not be liable for possessing unwanted patented traits in his plants—traits that ruined years of careful canola breeding. In a close decision, the Supreme Court of Canada ruled in favor of Monsanto, deciding that it did not matter how the GE material made its way onto his property and into his plants, that he was guilty for possessing Monsanto's patented genes without a license.

Legal scholars expect litigation to play a role in future U.S. contamination lawsuits, similar to the two cases described above. Although U.S. courts have not seen an organic contamination case, the U.S. Court for the Northern District of California will soon play an important role in the future of RR alfalfa, which, as revealed in this paper, has the potential to significantly affect the organic industry. The potential implications of introducing RR alfalfa into the environment and marketplace point to many economic, agronomic, and environmental risks, including: chemical drift from an increase in herbicide use, gene flow from RR alfalfa to organic, conventional, and feral alfalfa, market rejection due to organic and export product contamination, economic risks to

⁴⁵⁴ Kershen, D. L. (2002). Legal liability issues in agricultural biotechnology, The National Agricultural Law Center, Retrieved on May 2, 2006 from www.nationalaglawcenter.org/assets/articles/kershen_biotech.pdf

⁴⁵⁵ Saskatchewan Organic Directorate. (2002, January 10). Organic farmers sue Monsanto and Aventis, Retrieved on November 18, 2006 from <http://www.saskorganic.com/oapf/news.html#pr-rel-8nov04>

⁴⁵⁶ Organic farmers dig in for another court challenge. (2005, May 27). *Regina Leader-Post*, Retrieved on November 12, 2006, from www.saskorganic.com/oapf/pdf/Organic_farmers_dig_in_SP.pdf

honey and sprout industries, and impacts to foundation and certified alfalfa seed—an important component to U.S. food and agriculture security. APHIS did not heed many of these concerns in approving RR alfalfa for commercial production, concerns voiced by over 500 citizens during the RR alfalfa comment period. Thus, the agency’s decision spurred the first lawsuit to be filed in response to the approval of a single GE crop. In February 2006, alfalfa seed producers (including an organic producer) and several public interest organizations filed a lawsuit against the USDA for its approval of RR alfalfa. The case is still pending, and if the plaintiffs succeed, the court may require APHIS to conduct a full Environmental Impact Statement (EIS) and an injunction on further sales of RR alfalfa.

Practicing Democracy: Local Initiatives Go Further Than Federal Rules

More progress on protecting organic farming from GE crops has been made through local initiatives than in the U.S. courtroom. These local initiatives seek to address the shortcomings of federal regulations governing GE crops, and to ultimately avoid scenarios similar to the cases explained above. The community actions have garnered much attention, and are laudable forces effecting change at the local level. Although no state has ever enacted regulations governing GE crops, five counties in California have passed initiatives that place limitations on agricultural biotechnology, most of which ban growing genetically engineered crops.⁴⁵⁷ And nearly 100 New England towns have passed resolutions regarding GE crops, almost a quarter of which call for local moratoria on planting GE seeds.⁴⁵⁸

Though these local initiatives typically cover a relatively small area and population, biotechnology companies have responded vigorously by proposing a series of preemption bills aimed to dissolve local and state control over seeds and plants. According to the Pew Initiative on Food and Biotechnology, “Preemption bills represented the single largest

⁴⁵⁷ Pew Initiative on Food and Biotechnology. (2005). State legislative activity related to agricultural biotechnology in 2005, Retrieved on November 15, 2006 from <http://pewagbiotech.org/resources/factsheets/legislation/factsheet.php>

⁴⁵⁸ Background: Industry aims to strip local control of food supply. (2006). Environmental Commons, Retrieved on November 17, 2006 from <http://environmentalcommons.org/seedlawbackgrounder.html>

share of adopted state legislation on agricultural biotechnology in 2005 (40 percent of all bills adopted).”⁴⁵⁹ As of August 2006, these preemption bills have been successful in 15 states.⁴⁶⁰ Opponents of the preemption bills believe they undermine democracy and local control over public health issues, and take away communities’ right “to address important gaps in federal and state policy.”⁴⁶¹ Specifically, to address problems pertaining to GE crops that are not adequately addressed by federal regulations.⁴⁶²

While these local efforts help mitigate potential risks of GE seeds and crops, can the federal regulations be changed to properly address the problems that local initiatives try to remedy? What will it take to keep biotechnology out of organic products? I conclude that the only way the integrity of organic agriculture can be protected is to ban genetically engineered crops from agricultural fields. Numerous scientists argue that complete containment is not possible, that the continued movement of transgenes into markets that reject genetically engineered products is a certainty. Additionally, a precautionary approach to GE crops is warranted for several reasons: regulatory frameworks are not adequate to address the uncontrollable nature of these living technologies, and reversing contamination events is extremely difficult, if not impossible, which compromises the safety of the food system and environment should evidence surface that the technology is harmful.

Still, the companies producing seed technologies have convinced government agencies that the technology does not pose any new risks and that “co-existence” is a reality. Barring the removal of genetically engineered seeds and plants from the environment and marketplace, there are several steps that can be taken to lessen the impact of genetically engineered crops on the organic industry. Below are five policy recommendations that

⁴⁵⁹ Pew Initiative on Food and Biotechnology. (2005). State legislative activity related to agricultural biotechnology in 2005, Retrieved on November 15, 2006 from <http://pewagbiotech.org/resources/factsheets/legislation/factsheet.php>

⁴⁶⁰ Seed & plant preemption law by state. (2006). Environmental Commons, Retrieved on November 18, 2006 from <http://environmentalcommons.org/image/seed-preemption-map.jpg>

⁴⁶¹ Background: Industry aims to strip local control of food supply. (2006). Environmental Commons, Retrieved on November 17, 2006 from <http://environmentalcommons.org/seedlawbackgrounder.html>

⁴⁶² Tokar, B. (2006, June). *Deficiencies in federal regulatory oversight of genetically engineered crops*, Retrieved on June 1, 2006 from <http://environmentalcommons.org/RegulatoryDeficiencies.html>

address issues associated with the unwanted contamination of organic products by GE material.

1) The Process for Regulating GE Crops Needs a Major Overhaul

APHIS' oversight of GE crops needs to be improved, starting with field trials. First, recommendations given by the Inspector General of Agriculture in its 2004 audit report on APHIS' oversight of field trials should be adopted. Clearly, both organic and conventional crops risk contamination by GE crops not approved for commercial use. Strengthening field trial oversight could involve more involvement of state agriculture departments. For deregulated crops, a monitoring program should be implemented as a way to identify risks not identified in risk assessments during field trials. Most significantly, USDA should require growers of GE crops to establish buffer areas and other containment measures to mitigate pollen flow from RR crops to neighboring fields. USDA should also require patent holders to fund a bond that is available to organic and conventional farmers who are harmed by contamination of their technologies.⁴⁶³

2) The Government Needs to Protect the Public Interest

USDA should conduct a comprehensive evaluation of contamination in organic and conventional seeds, including foundation and certified seed, as well as food products, to determine the extent and content of genetic contamination in non-GE products. Such an evaluation would allow the government to begin owning up to its responsibility to protect the public interest. Both the FDA and USDA claim that organic products are alternatives to GE food, and must ensure that consumers continue to have a choice between the two.

⁴⁶³ A similar bond was introduced through legislation in Montana, but died in the Senate Committee on Agriculture, Livestock, and Irrigation in 2003. Senate Bill 266 said that "Any company holding a patent for genetically engineered wheat varieties that wishes to begin commercial production in Montana must post a \$10M bond with the newly formed Wheat Bond Board. Legislation also outlines the membership and duties of the board and stipulates that a company's liability is not limited to the bond value." (Pew Initiative on Food and Biotechnology. (2005). State legislative activity related to agricultural biotechnology in 2005, Retrieved on November 15, 2006 from <http://pewagbiotech.org/resources/factsheets/legislation/factsheet.php>)

3) The Organic Industry Must Confront Contamination

The organic industry cannot ignore the contamination issue. Even if the standards allow for the unintended presence of transgenic material in organic products, consumers deserve to know the reality of contamination, and should be mobilized to protect the integrity of organic products. The NOP was built on transparency, and not addressing the contamination issue now will lead to future problems that may prove irreversible, including losing consumers' confidence in the organic label. The organic industry fought hard for standards that reflect several principles inherent within organic agriculture during the beginning phases of the NOP, and excluding GE products was an important component of this value system.

4) The Organic Industry Should Discuss the Issues of Testing and Tolerance Levels

The testing and tolerance issues need to be discussed by the organic industry to weigh the benefits and risks of establishing a tolerance level for transgenic material in organic products, as well as possibly imposing a testing system (perhaps for seeds). Currently, the standards do not set a limit for an allowable amount of unwanted transgenic material in organic products. Without testing, the amount and extent of contamination remains largely unknown. So, there is no scientific basis to determine and enforce tolerance levels. Because the onus of protecting organic products from transgenic contamination is on the organic producers, testing costs should not fall on their shoulders, but need to come from the owners of the patents and perhaps growers of the technology. The organic industry should discuss these two issues, and demand that the biotechnology industry front costs for the unwanted presence of its technology.

5) RR alfalfa should be removed from the market until a full EIS is performed

USDA is currently performing its first Environmental Impact Statement (EIS) on a GE crop: RR creeping bentgrass, another perennial plant that, like alfalfa, cross-pollinates with relatives. USDA should do the same for RR alfalfa, paying close attention to

potential economic risks to regional farming practices and markets, especially organic. In light of precedents set by other RR crops, a precautionary approach should be taken to the introduction of RR alfalfa in order to protect sensitive markets and the integrity of organic and conventional alfalfa seed. If nothing else, RR alfalfa producers should be required to implement isolation distances and buffer zones to mitigate gene flow, as well as communicate with neighboring alfalfa farmers about the potential for transgene flow to surrounding plants. Neighboring farms would then be able to better protect any sensitive markets through cautious management and testing.

Alfalfa is the starting point of countless foods. It is feed for dairy cows and beef cattle, for lambs, pigs, and honeybees. So, even if we do not see alfalfa on our dinner plates, it plays a crucial role in the food we do eat—it is a staple of the American farming diet. For consumers who value organic livestock products—milk and ice cream derived from cows not fed RR hay—this choice may disappear if RR alfalfa is widely adopted. As the demand for organic alfalfa grows, organic farmers may find it challenging to locate alfalfa seeds free of transgenic traits, as they have found it challenging in the face of GE corn, soybeans, and canola. And alfalfa is pervasive, covering over 22 million acres across the United States. Therefore, transgenic traits serve as a reminder of the interconnectedness of things, of the persistence of life, of plants—of pollinators. GE crops are already woven into the North American landscape, threads of DNA that are reproduced time and time again, effectively spreading a living technology for years to come.

These policy recommendations are just a few of many that could be implemented. Several more steps can be taken to keep transgenic crops contained, to shift some of the burden to protect the organic industry onto the shoulders of the patent owner and grower of GE crops. However, from the perspective of the organic industry, taking a precautionary approach to this technology seems ideal. The organic industry has always been concerned with the integrity of its products, and currently GE crops, including RR alfalfa, may be the biggest threat to maintaining crops and products that meet the collective vision of what constitutes a truly organic agriculture. The organic movement

enjoyed success the last time it mobilized in response to threats to the organic standards. It may be time to step up again, to a threat that was only partially dealt with at the time the rules were written. Although genetic engineering is an “excluded method,” its presence in organic products shows it is far from being totally excluded.

Indeed, RR alfalfa is on the market and has been sown in several states, but its introduction has been relatively limited. The federal government and both the organic and biotechnology industries need to acknowledge the precedent that RR alfalfa follows—the uncontrollable nature of living technologies, the inability to keep these technologies fully contained and out of organic food. Protecting the integrity of organic seed and feed sources can begin, as so many of our food products, with alfalfa.

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