Gone to Seed

Transgenic Contaminants in the Traditional Seed Supply

Union of Concerned Scientists

Citizens and Scientists for Environmental Solutions

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The Union of Concerned Scientists is a nonprofit partnership of scientists and citizens combining rigorous scientific analysis, innovative policy development, and effective citizen advocacy to achieve practical environmental solutions.

The goal of the Union of Concerned Scientists Food and Environment Program is to create a food system that encourages innovative and environmentally sustainable ways to produce high-quality, safe, and affordable food, while ensuring that citizens have a voice in how their food is grown.

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The Union of Concerned Scientists is solely responsible for the contents of this report.

Executive Summary

Nothing is more fundamental to agriculture and our food supply than seeds. Whether eaten directly or processed through animals, seeds are the ultimate source of human nutrition. The variety, abundance, and safety of foods are all dependent on the availability and quality of seeds.

The prowess of genetic engineers notwithstanding, seeds cannot be made from scratch. They must be harvested, saved, and shepherded from generation to generation by knowledgeable, engaged individuals. The value to the food supply of the seeds entrusted to our generation cannot be overstated.

In this report, the Union of Concerned Scientists (UCS) examines a new phenomenon that may threaten the quality of the seed supply: the contamination of traditional seeds by DNA sequences derived from genetically engineered crop varieties. These varieties are produced by molecular techniques—variously known as genetic engineering, genetic modification, or transgenic techniques—that allow scientists to move novel traits into plants from distantly related organisms such as animals and bacteria.

The number of transgenes that might potentially contaminate the seed supply is large. Although most commercial transgenic varieties of corn, cotton, soybeans, and canola contain only two traits (herbicide and insect resistance), hundreds of other novel genes have been engineered into crops that have been field tested but have not been, and may never be, commercialized.

Most of the transgenes used by genetic engineers are new to foods and some are not intended for use in foods at all. For these and other reasons, concerns have arisen about the possibility that transgenes introduced into crop varieties through genetic engineering might unintentionally contaminate the seed supply for traditional, or non-genetically engineered, varieties of crops.

The research covered in this report addresses that possibility with a small pilot study of seeds of traditional varieties of three major food crops: corn, soybeans, and canola. The study found that the seeds of traditional varieties bought from the same retailers used by U.S. farmers are pervasively contaminated with low levels of DNA sequences originating in genetically engineered varieties of those crops.

Our conclusion:

Seeds of traditional varieties of corn, soybeans, and canola are pervasively contaminated with low levels of DNA sequences derived from transgenic varieties.

This conclusion is based on tests conducted by two respected commercial laboratories using duplicate samples of seeds of six traditional varieties each of corn, soybeans, and canola. One laboratory detected transgenically derived DNA in 50 percent of the corn, 50 percent of the soybean, and 100 percent of the traditional canola varieties tested. The other laboratory detected transgenically derived DNA in 83 percent of the traditional varieties of each of the three crops. The most

conservative expression of the combined results is that transgenically derived DNA was detected in 50 percent of the corn, 50 percent of the soybean, and 83 percent of the canola varieties tested.

Other than suggesting that the levels are low, the pilot study is too limited to support quantitative estimates of overall contamination levels in seeds of traditional crop varieties. The data available lead us to expect levels of contaminated seed roughly in the range of 0.05 to 1 percent, but larger studies are needed to determine contamination levels with any degree of precision.

In the interim, we are concerned that the significance of low-level contamination might be too quickly dismissed. Contamination levels in the 0.05 to 1 percent range would represent huge absolute amounts of seed. To illustrate, we calculated the tonnage of transgenically contaminated corn seeds that would have been planted in fields of traditional corn varieties if the seed supply were contaminated at a one percent rate. Our calculations, based on U.S. Department of Agriculture (USDA) data on corn acres planted with traditional varieties in 2002, suggest a total of 6,250 tons of transgenically derived seeds—an amount that would fill 240 large tractor-trailer trucks.

Most of the specific DNA sequences for which the laboratories tested are found in popular transgenic crop varieties currently allowed on the U.S. market. Although the study sheds little light on how the seed contamination occurred, there is no reason to believe that the transgenes detected in this study are the only ones moving into the traditional seed supply.

Instead, it seems likely that the contamination is a symptom of generally porous seed production and distribution systems. Until we know otherwise, it seems minimally prudent to assume that novel genes originating in less popular transgenic varieties, as well as the hundreds of engineered varieties that have been field tested in the United States, could potentially contaminate the seed supply of food and feed crops.

IMPLICATIONS

The recognition that the seed supply is open to contamination by low levels of a wide variety of genetically engineered sequences has broad implications. In general terms, seed contamination is important for two reasons. First, seeds reproduce and carry genes into future generations. Every season of seed production offers new opportunities for the introduction of new genes. In the case of genetic engineering, transgenic sequences that enter the seed supply for traditional crop varieties will be perpetuated and will accumulate over time in plants where they are not expected and could be difficult to control.

Second, seeds are the wellspring of our food system, the base on which we improve crops and the source to which we return when crops fail. Seeds will be our only recourse if the prevailing belief in the safety of genetic engineering proves wrong. Heedlessly allowing the contamination of traditional plant varieties with genetically engineered sequences amounts to a huge wager on our ability to understand a complicated technology that manipulates life at the most elemental level. Unless some part of our seed supply is preserved free of genetically engineered sequences, our ability to change course if genetic engineering goes awry will be severely hampered.

Seed contamination by transgenically derived sequences also has implications in a number of other regulatory and policy contexts. Pharm crops, trade, and organic food production are discussed briefly in this summary, but our report also addresses implications for food safety, the environment, intellectual property, the food system, and the agriculture of developing countries.

Pharmaceutical and industrial crops receive special attention in this report because the trans-

genic products they make—drugs, vaccines and industrial chemicals—would raise immediate alarms if they contaminated the food supply, and seed contamination is the back door to the food supply. The realization that seeds for food crops are vulnerable to contamination with pharm and industrial transgenes and that, in fact, some seeds may already have been contaminated is alarming. The report urges prompt action to protect seed production from these sources of contamination.

On the trade front, U.S. grain and oilseed exporters face enormous challenges in a global marketplace bristling with regulatory regimes that apply to genetically engineered crops. U.S. companies need to assure export customers that grain and oilseed shipments do not contain unapproved transgenes and transgenic crop varieties. While gene flow and physical commingling during production and transport probably account for most of the unapproved transgenes and transgenic seed varieties present in exported grain and oilseed, traditional crop varieties carrying transgenically derived sequences may also contribute to the problem. Contamination of the seeds of traditional plant varieties also makes it difficult to supply commodity products free of genetically engineered sequences to those customers who want them.

Transgenic contamination of traditional seed varieties poses a special threat to the future of organic agriculture, an increasingly important sector of U.S. agriculture. To meet both consumer demand and federal standards that forbid the use of genetically engineered crops and inputs, organic growers strive to produce crops that are free of transgenically derived DNA. If, through no fault of their own, they are unable to supply such products, they potentially face eroding markets. The ease with which the traditional seed supply can be contaminated with transgenically derived DNA unfairly frustrates organics farmers seeking to deliver high-quality products.

RECOMMENDATIONS

UCS hopes that, as a result of this report, the seed and food industries, the scientific community, and the federal government will begin to acknowledge and confront the issues raised by the contamination of the traditional seed supply with sequences originating in genetically engineered crops. While not entirely reversible, this contamination can be substantially reduced. With sufficient attention and will, it is possible to look forward to sources of seeds that are free of genetically engineered sequences. The first step, however, is acknowledging and understanding the problem.

More specifically, UCS recommends the following actions:

1. The USDA should sponsor a full-scale investigation of the extent, causes, and impacts of contamination of the traditional seed supply by transgenically derived DNA sequences.

2. The USDA, the Food and Drug Administration, the Environmental Protection Agency, and appropriate coordinating elements of the federal government should amend the regulations for transgenic pharm and industrial crops to ensure that the seed supply for food and feed crops is not contaminated at any level with drugs, vaccines, plastics, or related substances.

3. The USDA should establish a reservoir of seeds for non-engineered varieties of major food and feed crops free of transgenically derived sequences.

4. The USDA and land-grant (agricultural) universities should reinvigorate the public plant breeding establishment to help ensure a supply of pure seed of traditional crop varieties.

5. The Association of Official Seed Certifying Agencies should establish a national standard

for breeder and foundation seed of traditional crop varieties: no detectable level of contamination by transgenes and associated sequences originating in genetically engineered crops.

6. The USDA, the organic agriculture community, land-grant universities, and plant breeders should develop new policies and programs to provide organic agriculture with pure seeds of traditional crop varieties.
7. The USDA, the organic and biotechnology industries, and national growers' associations, among others, should sponsor a series of meetings to begin addressing how those sectors of U.S. agriculture that have adopted transgenic crops and those threatened by contamination with transgenically derived DNA sequences from those crops can coexist.
8. Private seed companies in the United States should periodically test their seed stocks, especially breeder and foundation seed and parental inbred lines, for the presence of transgenically derived DNA sequences. They should then make public the extent to which the seeds of the traditional varieties they market are free of transgenically derived contaminants.

Chapter 1

Introduction

This report describes the results of a pilot study designed to address the extent to which genetic elements introduced into the crop gene pool via genetic engineering are now present in crop varieties with no history of genetic engineering. The results suggest that seeds representing a wide array of corn, soybean, and canola varieties currently on the market commonly contain identifiable genetic material originating from transgenic crop varieties.

The varieties collected for analysis in this study were produced by traditional, field-based plant breeding techniques. These techniques rely on identifying and mating parent plants that possess promising traits and repeatedly selecting for superior performance among their offspring. Seeds for offspring that do well in performance trials are then increased prior to sale as a commercial crop variety. Traditional plant breeding, a potent technology often taken for granted, is largely responsible for the tremendous gains in productivity of global agriculture during the twentieth century. (See Figure 1-1, p. 8, and Appendix A for more information on variety development and seed production.)

The sources of the novel genetic elements that now appear to contaminate the seed supply of traditionally bred crop varieties are varieties created by newer molecular-level laboratory techniques. These techniques, collectively known as genetic engineering, allow scientists to insert and express genetic material originating in organisms unrelated to the crops in question.

Unlike traditional breeding methods that rely on mating between male and female parents to generate new or improved traits, laboratory-based techniques can move genetic material directly into plants from organisms as distantly related as bacteria or animals. These techniques are also referred to as genetically modified or transgenic. The organisms produced by these techniques are referred to as genetically engineered organisms, genetically modified organisms (GMOs), and transgenics.

In this report, we will refer to crop varieties with no history of genetic engineering as traditional varieties and the seeds for those varieties as traditional seeds or the traditional seed supply. Crop varieties produced via genetic engineering techniques are described as transgenic, although we recognize that field-based techniques used to develop traditional varieties are also used in the production of commercial transgenic varieties. Transgenic seeds or the transgenic seed supply refers to seeds used to grow transgenic crop varieties.

The DNA sequences introduced into plants during the genetic engineering process are referred to as transgenically derived or transgenic sequences, and novel genes transferred to crops using genetic engineering techniques are referred to as transgenes. Biochemical techniques that make it possible to identify specific DNA sequences, even at very low levels, were critical to conducting this study.

GENETIC ENGINEERING IN AGRICULTURE

Genetic engineering has been a controversial technology from the beginning, especially in Europe and other countries outside the United

States. Concerns about the use of the technology in agriculture have focused on a tangle of issues ranging from concerns about food and feed safety to environmental risk and corporate control of the food system.

In theory, genetic engineering can modify plants to produce a wide range of new traits. Yet most engineered varieties commercially planted in the United States and around the world have been modified to express only two narrow categories of traits: resistance to a particular herbicide (thus permitting the use of that herbicide) or the expression of a pesticidal toxin derived from the soil bacterium *Bacillus thuringiensis* (Bt). These are referred to as herbicide-resistant and insect-resistant (or Bt) varieties, respectively.[1]

Bt and herbicide-resistant versions of major crops were first planted on a large scale in 1996 and have been widely adopted in the United States during the last few years.[2] In 2002, for example, about three-fourths of U.S. soybean acres, one-third of U.S. corn acres,[3] and nearly 70 percent of North Dakota's canola acres[4] were planted with engineered varieties. (North Dakota accounts for 89 percent of U.S. canola production.[5]) Traditional, or non-engineered, crop varieties nevertheless remain popular as well, and U.S. farmers continue to plant them in large quantities.[6]

This study is the first systematic attempt to examine a part of the contamination issue that so far has received little attention: the extent to which the traditional seed supply for commodity crops has become contaminated with genetic sequences originating from transgenic varieties.

In addition to the handful of transgenes present in commercial varieties of herbicide-resistant and Bt crops, hundreds of other transgenes have been engineered into crops. These varieties, though not yet commercialized, have been field tested in the open environment. Appendix B of this report contains a list of transgenes and transgenic traits taken from a database of U.S. Department of Agriculture (USDA) records of field tests of corn, soybeans, and canola over the past 16 years.[7]

Because transgenic and traditional varieties of major crops are both planted widely and moved

1 Union of Concerned Scientists (UCS). 2002. Genetically Engineered Foods Allowed on the Market. Cambridge, MA: UCS. On the UCS website at *http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageid=337*, accessed on August 13, 2003. Several herbicide-resistant and Bt varieties are on the market in the United States, including canola, corn, and soybeans resistant to glufosinate and glyphosate herbicides; cotton resistant to glyphosate and bromoxynil herbicides; and Bt corn and Bt cotton.

2 For information on the growth in acreage of genetically engineered crops in the United States and elsewhere, see International Service for the Acquisition of Agri-biotech Applications (ISAAA) Briefs on the ISAAA website at *http://www.isaaa.org*.

3 U.S. Department of Agriculture, National Agricultural Statistics Service (USDA NASS). 2003. Prospective Plantings. March 23, pp. 20, 21on the USDA NASS website at *http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bbp/pspl0303.pdf*, accessed on August 15, 2003.

4 Berglund, D.R. 2003. Personal communication, August 15. D.R. Berglund is a professor and extension agronomist at North Dakota State University. According to Dr. Berglund, approximately 900,000 of North Dakota's 1,300,000 acres of canola were planted with engineered varieties in 2002.

5 USDA NASS. 2003. Crop Production: 2002 Summary. Publication CrPr2-1(03). p. 31. On the USDA NASS website at *http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bban/cropan03.pdf*, accessed on November 25, 2003.

6 Traditional crop varieties remain popular for a number of reasons, including the large international markets for such varieties, the relatively high price of seeds for engineered varieties, and personal preferences.

7 Information Systems for Biotechnology (ISB). 2003. Field Test Releases in the U.S. Blacksburg, VA: Virginia Polytechnic Institute and State University. On the ISB website at *http://www.isb.vt.edu/cfdocs/fieldtests1.cfm*, accessed on December 15, 2003.

together through the U.S. grain distribution system, there are many activities that can mix the two kinds of crops. Most of the commercial bulk oilseeds and grains in the United States, for instance, are now a mixture of engineered and non-engineered seeds. As discussed below, this high degree of commingling has made it difficult for the United States to segregate and deliver a non-genetically engineered product for customers who demand it.

THE CURRENT SITUATION

This study is the first systematic attempt to examine a part of the contamination issue that so far has received little attention: the extent to which the *traditional seed supply* for commodity crops has become contaminated with genetic sequences originating from transgenic varieties.

We use the term "contamination" here to refer to seeds or genetic sequences that are unwanted in a particular place for one reason or another. Corn, for example, is unwanted in shipments of soybeans and in such shipments is properly called a contaminant. The term has no negative connotation other than the sense that a particular entity is for some reason unwanted or inappropriate where it is found.

"Adventitious presence," another term sometimes heard in this context, connotes a lack of intention in allowing commingling to occur. Adventitious presence in our view is a broader term than contamination. Contamination refers to those situations where genes or traits are not only unintended (or adventitious) but also for some reason unwanted.

Both commercial and legal considerations make the presence of transgenically derived sequences in agricultural products problematic. Many transgenic varieties of crops in use in the United States have not been approved in other countries and their presence in imports is unlawful. In addition, many customers for U.S. exports —particularly those looking to purchase organic food or non-organic specialty products—are exhibiting a strong preference for non-genetically engineered grains and oilseeds free of some or all transgenic varieties.

Seeds in commodity agriculture

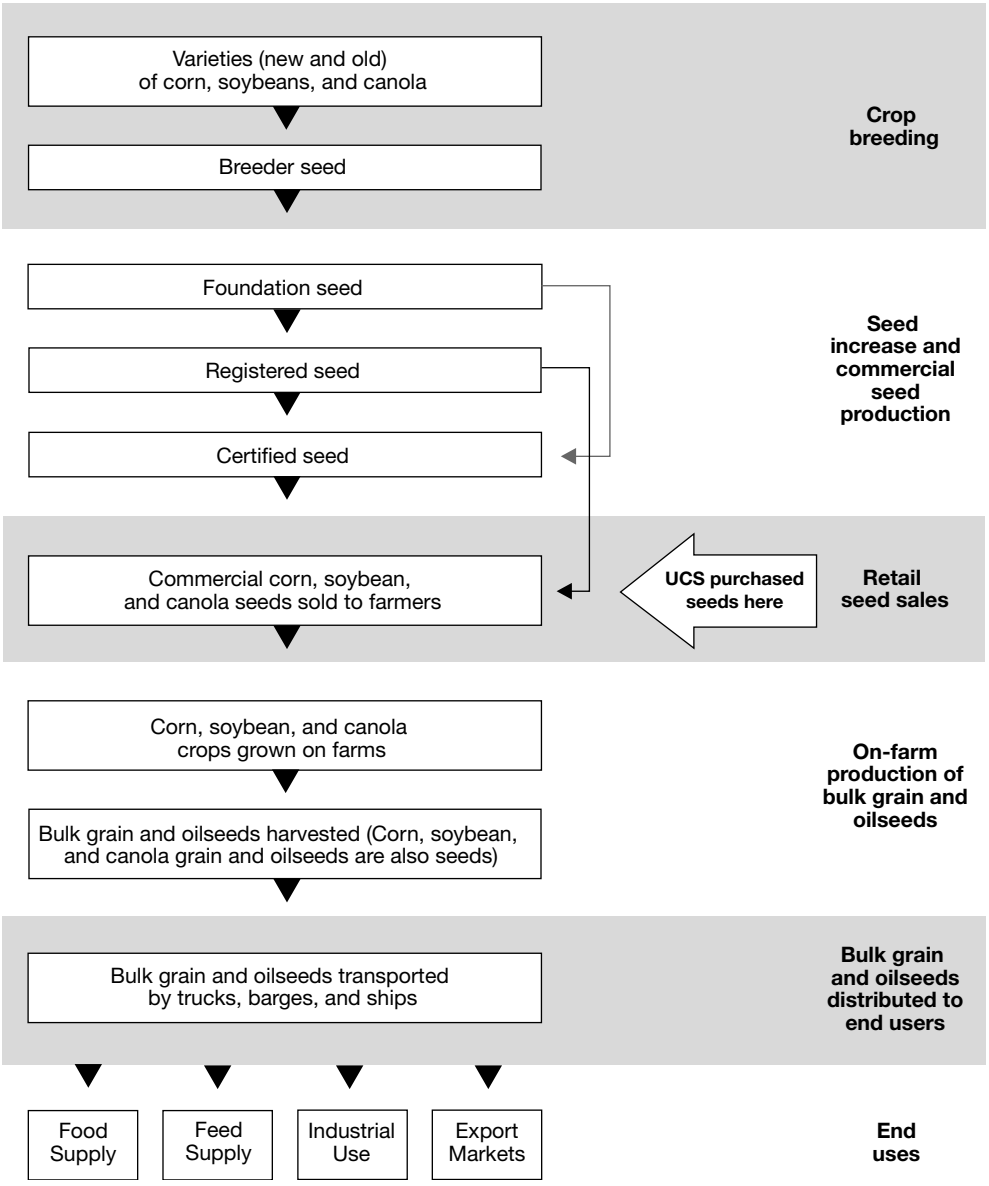
Each season, farmers plant seeds of commodity crops such as corn, canola, and soybeans to produce a crop that will be harvested and sold as bulk grain and oilseed. Figure 1-1 (p. 8) illustrates how seeds of corn, soybean, and canola varieties move through the agricultural commodity system. For a more detailed account of crop variety development and seed production, see Appendix A.

Plant breeders are constantly producing new varieties of corn, soybeans, and canola. Every year a set of varieties (old and new) is selected for commercial development and a process called seed increase is set in motion to generate sufficient quantities of seeds to be offered for sale to growers. Seed increase usually requires several rounds of planting and harvesting to meet commercial demands.

For economic reasons, seeds are grown under progressively less stringent containment conditions, which correspond to four classes of seed purity. Breeder seed, controlled by the plant breeding institution, is the purest class of seed, followed by foundation, registered, and certified seed (the least pure class). Private certifying agencies set crop-specific purity standards for each seed class. Examples of corn, soybean, and canola seed standards can be found in Appendix A.

Farmers can obtain commercial seed through retail seed stores, the Internet, and catalogs. Seeds purchased by growers are planted, the plants are tended during the growing season, and seeds are harvested and sold as bulk grain and oilseed products. Eventually these products make their way to end users for a variety of purposes including feed, food, and industrial uses. Substantial quantities of U.S. grain and oilseeds are exported to other countries. Although rarely done in the case of corn, farmers may also retain soybean or canola seed from their harvest to plant the following year.

Figure 1-1 **Seeds in Commodity Agriculture: How Seeds of Corn, Soybean, and Canola Varieties Move from Plant Breeders to End Users**



Many of these customers are rejecting grains and oilseeds containing detectable levels of transgenic varieties regardless of whether the levels or kinds of transgenic varieties render the product technically illegal. In both legal and commercial contexts, the unwanted presence of genetically modified grains or oilseeds, and sequences deriving from them, are therefore properly considered contaminants.

SEED VS. BULK CROP CONTAMINATION

As mentioned above, seed contamination, the focus of this report, is only one source of the contamination that bedevils exporters of non-engineered bulk grain and oilseeds.

Most contamination is attributable to events that occur *after the engineered and non-engineered varieties of seed are planted* (Figure 1-1). There are two types of mixing events that occur after

planting: physical mixing, such as commingling in grain elevators; and outcrossing, the movement of genes via pollen into neighboring fields of sexually compatible crops. Since both of these phenomena are difficult to control under the current systems of grain and oilseed production, transport, and storage, mixing would occur even if the seeds farmers planted were absolutely free of transgenically derived sequences. While starting with seed contaminated with transgenically derived sequences exacerbates these problems, pure seed would not alleviate them.

EARLY WARNINGS

When transgenic varieties were first allowed on the market in the United States, little attention was paid to the idea that widespread adoption of transgenic crops could lead to seed contamination of traditional varieties. In retrospect, this seems surprising. Breeders working with genetically engineered varieties continued to use the same seed purity standards that applied to traditional varieties. Those standards vary from crop to crop but allow, in the case of soybeans, for example, up to 0.6 percent of the seeds to come from other kinds of crops such as corn and up to 0.5 percent from other varieties of soybeans (Appendix A). Application of these standards made it almost inevitable that substantial cross contamination would follow the widespread adoption of genetically engineered crop varieties.

A number of factors—among them, the growing global controversy over biotechnology crops, the increasing popularity of organic foods, and regulatory regimes that vary from country to country—have led to demands for crops of far greater purity than the seed production system was geared to deliver. But awareness of this situation emerged slowly. Plant breeders, growers, and others in the agricultural establishment seemed to proceed on the assumption that even as the adoption rates of genetically engineered varieties increased, those who wanted to purchase seed free of transgenic components would be able to continue doing so.

A number of instances of seed contamination over the last seven years have called that optimistic assumption into question.

StarLink-contaminated hybrid corn seed

StarLink was an engineered corn variety approved by the U.S. government in 1997 for use in animal feed but not in human food. In September 2000, after newspapers reported that StarLink corn was showing up in consumer products, the government undertook comprehensive testing of corn-derived foods in the U.S. food supply.[8] Although planted on only 350,000 of the 80 million total U.S. corn acres (about 0.4 percent) in its most popular year,[9] genetic sequences from StarLink corn varieties were eventually detected in numerous consumer products distributed throughout the U.S. food supply and in exported corn.

By 2001, StarLink also contaminated the U.S. corn seed supply. Fearing recurrent introduction of the illegal contaminant into food via the seed supply, the USDA instituted a program to buy up corn seed that tested positive for StarLink. In June 2001, the department announced that it had already purchased $13 million worth of StarLink-contaminated seed from 63 companies and was

8 Taylor, M.R. and J.S. Tick. 2003. Post Market Oversight of Biotech Foods: Is the System Prepared? Washington, DC: Pew Initiative on Food and Biotechnology, pp. 90-105.

9 Keller, D. and D. Miller. 2000. Biotech's black eye. *Progressive Farmer* (December), p. 24; USDA NASS. No date. U.S. corn acres. On the USDA NASS website at *http://www.usda.gov/nass/aggraphs/cornac.htm*, accessed on December 2, 2003.

Almost half the organic growers surveyed recently felt that contaminated seeds represented the greatest source of contamination from engineered varieties.

considering additional expenditures of up to $5 million.[10]

Despite concerted effort, it has proved surprisingly difficult to purge the U.S. grain system of the contaminant. As recently as December 2003, StarLink was still being reported in domestic grain.[11] Part of the explanation may be that the seed supply for corn is still contaminated. It may be that inbred lines remain contaminated with StarLink genetic sequences and every time these inbreds are used to produce hybrid corn seed, the StarLink sequences are reintroduced into the seed supply. (See Appendix A for details on hybrid corn seed production.)

Contaminated foundation soybean seed

In 2002, the head of North Dakota State University's Foundation Seedstocks Program acknowledged that the program's foundation seed for non-engineered natto soybeans—the basic stock from which seeds are grown to sell to farmers—contained sequences from engineered soybeans.[12] (Natto soybeans are grown for premium food-grade products.) Three other foundation soybean seed programs—in Virginia, Missouri, and Michigan—have also recently reported genetic engineering contamination problems.[13]

Contaminated canola seed

In 1997, Monsanto, a leading biotechnology company, recalled 60,000 bags of seeds of one of its transgenic canola varieties in Canada because they were contaminated with seeds of another transgenic canola variety (RT-200), which had not been approved for marketing in that country.[14] Four years later, Monsanto detected the RT-200 contaminant again in seeds of commercial transgenic canola varieties in Canada. Even though RT-200 varieties had gained approval in Canada by that time, Monsanto withdrew the contaminated seeds from the market because the contaminating varieties had not been approved in all countries to which Canadian canola would be exported.[15]

Monsanto admitted in 2002 that RT-200 seeds might also have been contaminating U.S. canola seed supplies since 1999. Even though the company has no plans to commercialize RT-200 in the United States, it sought approval of the

10 USDA. 2001. USDA purchases Cry9C affected corn seed from seed companies. Press release, June 15, 2001. On the USDA website at *http://www.usda.gov/news/releases/2001/06/0101.htm*, accessed on November 14, 2003.

11 Fabi, R. 2002. Global updates: Exporters say Japan finds StarLink in U.S. corn cargo. Reuters, December 28; Jacobs, P. 2003. Banished biotech corn not gone yet: traces raise health, other key issues. *San Jose Mercury News* (December 1). On the *Mercury News* website at *http://www.bayarea.com/mld/mercurynews/business/7386106.htm*, accessed on December 2, 2003.

12 Pates, M. 2002. Seed contamination raises control issues, posted November 12, 2002. On the *Grand Forks Herald* website at *http://www.grandforks.com*, accessed on January 7, 2003. The article identified Monsanto's Roundup Ready soybeans as the source of contamination.

13 *The Non-GMO Source*. 2003. Concerns increase over GMO contamination of foundation seed. Volume 3, Number 6, pp. 1-2, June.

14 Rance, L. 1997. Registration suspended: Genetic mixup prompts recall of Roundup Ready canola. *Manitoba Co-Operator* (April 24).

15 Monsanto. 2001. Press statement: Quest canola seed replacement offered, April 25. On the Monsanto website at *http://www.monsanto.com/monsanto/media/01/01apr25_quest.htm*, accessed on December 18, 2001.

variety in this country that year to minimize the disruption caused by its contamination of other canola varieties.[16]

In the spring of 2000, Advanta Seeds UK acknowledged that traditional canola varieties contaminated with an engineered variety (GT-73) had been sold to several European Union (EU) countries—where it had not been approved for sale—in 1999 and 2000.[17] In 2002, Scottish scientists discovered that transgenic canola plants being tested in field trials were contaminated with a transgene not approved for testing in the United Kingdom.[18]

Organic producers struggle to find non-engineered seed

Organic food and fiber is one of the fastest-growing sectors in U.S. agriculture. Not only do many consumers expect organic food to be free of genetically engineered material, but federal standards also forbid the use of genetically engineered varieties in the production of organic foods. Organic growers seeking to meet this standard are finding it increasingly difficult to obtain non-engineered seed. Almost half the organic growers surveyed recently felt that contaminated seeds (rather than post-planting pollen drift, for example) represented the greatest source of contamination from engineered varieties.[19] The difficulty in producing pure seed has led some organic seed companies to move their seed operations outside the United States.[20]

GOVERNMENT'S FAILURE TO RESPOND

While any one of these incidents might reflect an isolated example of seed contamination, taken together they reasonably suggest a more widespread phenomenon. The prospect of broad contamination of the seed supply raises important questions for food safety, international trade, organic agriculture, and the integrity of the seed system at the base of our global food supply.

The growing evidence of seed contamination should have prompted the U.S. government to determine the extent to which seeds marketed as non-engineered are currently contaminated with engineered sequences. Indeed, the Union of Concerned Scientists (UCS) and others in the public interest community have suggested the government undertake such a study. But it has not responded.

The growing evidence of seed contamination should have prompted the U.S. government to determine the extent to which seeds marketed as non-engineered are currently contaminated with engineered sequences.

16 Hesman, T. 2002. Monsanto says gene-altered food may be in U.S. food. *St. Louis Post-Dispatch* (Business, April 16); Kilman, S. and J. Carroll. 2002. Monsanto admits unapproved seed may be in crops. *Wall Street Journal* (April 15).

17 Brown, N. 2000. Statement of the United Kingdom Minister of Agriculture, Fisheries and Food in the House of Commons, May 18. On the United Kingdom Parliament website at *http://www.publications.parliament.uk/pa/cm199900/cmhansrd/vo000518/debtext/00518-09.htm*, accessed on June 18, 2003.

18 Kelbie, P. and M. Woolf. 2002. Ministers suspend GM crop-testing. *The Independent* (August 16). Obtained from the *biotech_activists@iatp.org* mailing list server August 16, 2002, where the source was listed as *The Independent* website at *http://news.independent.co.uk/uk/environment/story.jsp?story=324776*. Apparently, the contaminated seeds, provided by Aventis (a biotechnology company now owned by Bayer Crop Science), had been planted in more than 20 test plots over a three-year period in England and Scotland.

19 Organic Farming Research Foundation (OFRF). 2003. Preliminary results from OFRF's fourth national organic farmers' survey: Section 7—GMOs and organic. On the OFRF website at *http://www.ofrf.org/press/releases/pr.051403.gmosurvey.html*, accessed on June 19, 2003.

20 *The Non-GMO Source*. 2003. Organic seed company moves corn production to Argentina to avoid GMOs. Volume 3, Number 1, p. 3, January.

So, UCS decided to conduct a pilot study of its own to assess the extent of contamination in the U.S. traditional seed supply. These seeds, along with seeds for transgenic varieties, are available from seed retailers, by mail order, and over the Internet.

As described below, our study found low levels of transgenically derived sequences in most of the samples of non-engineered corn, canola, and soybean seeds that we tested. The samples were obtained from seed sold in a number of locations around the United States. Our results suggest that the U.S. supply of seed for traditional varieties of corn, soybeans, and canola is pervasively contaminated with low levels of genetic sequences originating in transgenic varieties.

IDENTITY-PRESERVATION SYSTEMS

The purity of seed is an issue of growing interest outside the arena of genetic engineering. New efforts are under way to create value-added markets for high-value crops, including some produced by genetic engineering. High-value crops exhibit desirable traits such as increased levels of important nutrients or the ability to produce a drug or industrial chemical. Today's commodity system, which minimizes transportation, cleaning, and handling costs in part by tolerating a relatively high degree of cross-contamination, cannot meet the need for segregated, pure supplies of these high-value crops.

Spurred by market demand, individuals and companies are taking on the challenge of developing new infrastructure and delivery systems for value-added products.[21] New "identity-preserved" systems create alternative pathways between seed suppliers, growers, and customers that avoid the current commodity system and its endemic sources of cross-contamination.[22]

The U.S. government is currently exploring ways to facilitate the marketing of identity-preserved products. For example, the USDA is considering ways to reconfigure the commodity grain system to make segregation more feasible.[23] Fundamental to the new systems devised to "preserve identity" is the ability to produce and preserve the purity of seed.

REPORT OUTLINE

Chapter 2 describes how we conducted our seed study and what we found. Our analysis suggests that the contamination of commercial seed stocks is pervasive and ongoing, and that the current regulatory regimes, which were not designed to prevent such contamination, are incapable of doing so. Because seed stocks are fundamental to agriculture and the food supply, seed contamination has potential implications in a number of arenas. It is time to understand and address these implications.

We have attempted to initiate a discussion of these issues in Chapter 3, where we consider the implications of contamination in nine contexts. The most urgent of these is what many in agriculture expect to be the next big wave of biotechnology applications: crops that produce pharmaceuticals and industrial chemicals. Other contexts include food safety, the environment,

21 It is important to note that these systems are designed to respond to commercial, not safety, considerations.

22 Strayer, D. 2002. *Identity-Preserved Systems: A Reference Handbook*. Boca Raton, FL: CRC Press; Sundstrom, F.J., J. Williams, A. Van Deynze, and K.J. Bradford. 2002. Identity Preservation of Agricultural Commodities. Agricultural Biotechnology in California Series, Publication 8077. Davis, CA: University of California, Davis. On the UC Davis website at *http://anrcatalog.ucdavis.edu*, accessed on May 30, 2003.

23 USDA, Grain Inspection, Packers and Stockyards Administration (GIPSA). 2000. Request for public comments on how USDA can best facilitate the marketing of grains, oilseeds, fruits, vegetables, and nuts in today's evolving marketplace. *Federal Register* 65:21272-21273 (November 30); USDA GIPSA. 2002. Facilitating the marketing of U.S. agricultural products with new testing and process verification services. *Federal Register* 67:50853-50854 (August 6).

trade, organic food production, intellectual property, the food system, agriculture of developing countries, and seed repository integrity.

In Chapter 4, we present our conclusions and recommendations for further research and new policies.

The main text of the report is followed by a glossary and two appendices. Appendix A provides an overview of plant breeding and seed production. Appendix B lists transgenes and transgenic traits engineered into corn, soybeans, and canola for field testing purposes since 1987.

Chapter 2
Methods and Results

UCS's pilot study looked at the contamination of the traditional seed supply in three major commodity crops: corn, soybeans, and canola. The seeds tested were selected from the pool of seeds marketed by major seed companies in 2002 to growers in key agricultural states. Selection procedures were developed to ensure that, to the degree possible given our limited resources, the seeds tested were representative of a large portion of the traditional seed supply for these crops.

This chapter describes the study, its results, and its limitations. Text boxes explain the basics of plant genetic engineering and designations used in the text and tables. A glossary is found at the end of the report.

METHODS

Choosing crops

In late 2001, there were 11 crops that had cleared the regulatory hurdles for marketing in the United States.[24] Among these, only four had engineered versions that had been widely planted: canola, corn, cotton, and soybeans. We eliminated cotton because it is not used primarily for food.

Choosing varieties

The next step was to decide, given limited resources, how to sample the available seeds. To sample as large a portion of the 2002 seed supply as possible, we selected from the pool of non-engineered varieties offered by major seed companies to growers in states that have significant acreage dedicated to the three crops.

For corn and soybeans, specifically, we selected varieties from among those recommended by major seed companies to growers in Iowa and Illinois, the states with the most acreage dedicated to those two crops.[25] From the websites of four major seed companies, we obtained lists of traditional varieties recommended for various counties or zip codes in Iowa and Illinois.[26] We chose to focus on one county in each state—Polk in Iowa and Wabash in Illinois. Seed companies recommended anywhere from 2 to 40 traditional seed varieties for those two counties (or zip codes within them), and we chose two from each of three companies. That gave us six varieties of corn and six of soybeans.

Where a company recommended more than two varieties for one of those locations, we

24 Union of Concerned Scientists (UCS). 2002. Genetically Engineered Foods Allowed on the Market. On the UCS website at *http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageid=337*, accessed on August 13, 2003. The 11 crops allowed on the market were canola, corn, cotton, flax, papaya, potato, radicchio, soybean, squash, sugar beet, and tomato.

25 According to USDA National Agricultural Statistics Service (USDA NASS) data, Iowa and Illinois planted more acres with corn and soybeans than any other states in the 2002 growing season (*http://www.usda.gov/nass/aggraphs/cornacm.htm* and *http://www.usda.gov/nass/aggraphs/soyacm.htm*, accessed on May 15, 2003).

26 Major seed companies maintain websites where farmers can find the varieties recommended for their area by entering either their county name or zip code. Between December 2001 and February 2002, we obtained lists of recommended varieties for the 2002 growing season in Illinois (Wabash County; zip code 62806) and Iowa (Polk County; zip code 50011) from the following seed companies' websites: Monsanto/Asgrow at *http://www.farmsource.com*, Syngenta at *http://www.nk-us.com*, DuPont/Pioneer at *http://www.pioneer.com*, and Dow/Mycogen at *http://www.mycogen.com*.

TABLE 2-1 **Traditional Varieties of Corn, Soybeans, and Canola Selected for This Study**

Crop	Company Producing Seeds of Traditional Varieties	Seeds of Traditional Varieties Purchased		
		Variety Designation Used in This Report	Company Variety Designation*	From a Seed Retailer in:
Corn	DuPont/Pioneer	1	36B08	Clarke County, VA
		2	34G13	Clarke County, VA
	Syngenta	3	N60-N2	Edwards County, IL
		4	V72-V7	Frederick County, VA
	Dow/Mycogen	5	5212	Frederick County, VA
		6	2A791	Frederick County, VA
Soybean	DuPont/Pioneer	7	94B53	Edwards County, IL
		8	93B82	Clarke County, VA
	Syngenta	9	S25-J5	Edwards County, IL
		10	S42-H1	Edwards County, IL
	Monsanto/Asgrow	11	A2869	Edwards County, IL
		12	A4922	Jefferson County, WV
Canola	Proseed	13	Topscore	Wells County, ND
		14	Canterra 1492	Wells County, ND
	Interstate	15	Hyola 330	Cass County, ND
		16	Hyola 401	Cass County, ND
	DuPont/Pioneer	17	46A65	Lake County, MT
		18	46A76	Lake County, MT

*Company seed lot designations available upon request.

randomly selected two for testing (Table 2-1). Many of the chosen varieties were recommended for other locations in Iowa or Illinois and other states. We deemed it impracticable to try to determine which varieties were the most widely recommended.[27]

For canola, we adopted a slightly different approach, focusing on varieties offered to growers in North Dakota, which accounted for 89 percent of U.S. canola acreage in 2002.[28] Seed companies' websites did not provide specific recommendations for that state, but North Dakota State University provided data on 2001 performance trials of 33 traditional canola varieties. Using these data, we selected five non-engineered varieties from three companies that performed well in the trials[29] (Table 2-1). Assuming that seeds of better-performing varieties would make up a larger proportion of the seed supply than poorly performing varieties, we believe this strategy allowed

27 Company websites are set up in such a way that it is difficult to determine how widely a particular variety is recommended. To do so would require searching for varieties recommended in every crop-growing county or zip code in the country.

28 USDA NASS. 2003. Crop Production: 2002 Summary. Publication CrPr2-1(03), p. 31. On the USDA NASS website at *http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bban/cropan03.pdf*, accessed on November 25, 2003.

29 Like many land-grant universities, North Dakota State University (NDSU) provides information to state growers on the performance of crop varieties as an aid in choosing which varieties to plant. An NDSU Extension Service publication provided data on 33 traditional varieties tested in variety trials in 2001. (NDSU. 2002. 2001 Canola Variety Trials. NDSU Extension Service publication A-1124 [revised], compiled by Duane R. Berglund. Fargo, ND: NDSU, January, p. 1.)

Basics of plant genetic engineering

Genes are functional segments of DNA located on chromosomes within the cells of organisms, including plants. An organism's DNA, comprised of thousands of genes, forms the blueprint for its inherited traits. The full set of genes and associated DNA of an organism is referred to as its **genome**.

Genes code for **proteins**,* the building blocks of organisms. Proteins, working alone or in combination, are responsible for the traits exhibited by plants (e.g., height, flower color, drought tolerance, insect resistance, nutritional makeup). **Regulatory sequences** control the process by which plant cells manufacture proteins. For example, **promoters** are regulatory sequences that operate like switches to start the manufacturing process for a particular protein. They also determine the amount of protein produced. **Genetic sequences** or **elements** refer to genes, regulatory sequences, or pieces thereof.

Genetic engineering involves the use of sophisticated molecular methods to synthesize novel combinations of regulatory sequences and genes and transfer them into an organism. These techniques may be used to transfer genetic sequences between unrelated organisms—from soil bacteria to a corn plant, for example—or to remove and rearrange genetic sequences within a species. Applying these techniques to crops, scientists create crop varieties with new traits. Various terms are used to describe plants produced by these techniques: **genetically engineered**, **genetically modified**, or **transgenic**.

A variety is a subgroup of plants within a crop whose genetic makeup and agricultural characteristics distinguish it from other varieties of that crop. Seed companies are constantly developing new varieties with traits important to growers, such as higher yield or increased resistance to insects and herbicides. These traits may be obtained through genetic engineering or traditional breeding.

To introduce a new trait through genetic engineering, scientists first assemble a **construct**, which can be visualized as a cassette of genetic sequences often taken from several different organisms. Constructs typically carry several regulatory sequences and genes.

After all the pieces of DNA are joined together, the construct is inserted as a unit into an individual plant, creating what scientists refer to as a **transformation event**, or **event** for short. Companies often use the same designation, such as GTS 40-3-2, for both the construct and the plant (and its progeny) created with that construct. A list of events relevant to this report is included below.

As a first step, scientists typically insert new constructs into plant varieties that are easily engineered.

Genetically Engineered Transformation Events

Event	Trade Name	Crop	Company	Trait
176	KnockOut NaturGard	Corn	Syngenta Dow/Mycogen	Resistant to certain insects (expresses Bt toxin)
Bt11	YieldGard†	Corn	Syngenta	Resistant to certain insects (expresses Bt toxin)
CBH-351	StarLink	Corn	Bayer	Resistant to certain insects (expresses Bt toxin)
DBT418	BtXtra	Corn	Monsanto	Resistant to certain insects (expresses Bt toxin)
GA21	Roundup Ready	Corn	Monsanto	Resistant to glyphosate herbicides
GT73	Roundup Ready	Canola	Monsanto	Resistant to glyphosate herbicides
GTS 40-3-2	Roundup Ready	Soybean	Monsanto	Resistant to glyphosate herbicides
MON810	YieldGard†	Corn	Monsanto	Resistant to certain insects (expresses Bt toxin)
NK603	Roundup Ready	Corn	Monsanto	Resistant to glyphosate herbicides
T14 and T25	LibertyLink	Corn	Bayer	Resistant to glufosinate herbicides

SOURCE: AGBIOS website (*http://www.agbios.com*), accessed on September 30, 2003.
†Both Syngenta and Monsanto use Monsanto's registered trademark YieldGard for their respective Bt corn events (Bt11 and MON810).

Transferring the new event into agronomically valuable varieties is accomplished by **traditional plant breeding**.

The diagrams to the right illustrate a generalized construct and a specific construct used to produce soybean varieties resistant to glyphosate herbicides.

GTS 40-3-2 is a construct developed by Monsanto to create Roundup Ready soybeans, which are resistant to the company's glyphosate (Roundup) herbicides. The construct contains a gene coding for a protein and three regulatory sequences: a promoter, a terminator, and a chloroplast transit peptide that directs the new protein to chloroplasts, where it functions in a particular metabolic pathway.

** Some scientists use the term gene to encompass the DNA sequences coding for regulatory sequences as well as proteins.*

A Generalized Construct Used in Genetic Engineering

Regulatory Sequences	Genes for Traits of Interest	Regulatory Sequences
Promoter	Bt insect resistance or herbicide resistance	Terminator

A Specific Construct Conferring Herbicide Resistance in Soybeans (GTS 40-3-2)

Regulatory Sequences		Gene for Herbicide-Resistance Trait	Regulatory Sequences
35S promoter from cauliflower mosaic virus	CTP (chloroplast transit peptide) from petunia	EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) gene from *Agrobacterium tumefaciens* CP4	NOS terminator from *Agrobacterium tumefaciens*

SOURCE: AGBIOS database product description, MON-04032-6 (GTS 40-3-2). On the AGBIOS website at *http://www.agbios.com/dbase.php?action+showprod&data+gts+40-3-2&frmat=long*, accessed on September 30, 2003.

us to look at a representative sample of a substantial portion of the non-engineered canola seed supply. Because of difficulties in finding seed of the better-performing varieties, we selected one variety (Topscore) that was not part of the 2001 variety trials.

Buying seeds

We bought seeds of all varieties from seed retailers just as growers do. A UCS employee or consultant ordered a bag (approximately 50 pounds) of each variety from seed sellers by phone or in person. The seed sellers shipped the seeds to UCS's Washington, DC, office or a UCS employee or consultant picked up the seeds from the sellers and shipped them by United Parcel Service or delivered them by private vehicle to UCS.

Upon arrival, bags were checked for tears (all arrived with seed bags intact) and were stored in a vacant room within secure UCS offices.

The testing laboratories

To determine whether the seeds contained genetic sequences that might have derived from commercially available engineered varieties, we sent them to two independent, well-established commercial laboratories: GeneScan USA, Inc., and Biogenetic Services, Inc. Both labs specialize in what has come to be called GMO testing—the analysis of food, feed, and other agricultural products to detect sequences from genetically modified organisms (see box, "Basics of plant genetic engineering"). We chose these two companies because of their extensive experience in

GMO testing, their scientists' detailed knowledge and expertise, and their excellent performance in the USDA Grain Inspection, Packers and Stockyards Administration proficiency tests.[30]

GeneScan USA was established five years ago in Belle Chasse, LA, as a subsidiary of GeneScan Europe, AG, which began GMO testing in 1995.[31] GeneScan Europe has a global network of genetic testing labs in North and South America, Europe, Asia, and Australia. Biogenetic Services is a small, privately owned company founded 15 years ago in Brookings, SD. Despite its small size, Biogenetic Services serves a wide array of customers: government agencies, food and seed companies, elevator operators, insurance companies, law firms, and private individuals.[32]

By submitting samples to two independent companies, we increased our confidence in our overall conclusions. Even so, that confidence is tempered by the recognition that GMO testing is still in its infancy and, unlike older, well-established areas of analysis, has neither standardized protocols and reference materials nor a uniform, worldwide system of laboratory accreditation.[33] In light of the uncertainties associated with GMO testing methods and the relatively small number of samples for each crop, our primary focus in this study was determining the presence or absence of engineered sequences. While some of the assays did provide information on the levels at which engineered sequences were found in samples, we do not believe the data are sufficiently robust to draw conclusions about the likely levels of contamination in the seed supply.

We conducted two rounds of testing. In Round One, the first laboratory (GeneScan) assayed seed samples of corn, soybeans, and canola to determine the presence of sequences derived from transgenic crops, estimate the levels of contaminants, and run controls for false positives. In Round Two, the second laboratory (Biogenetic Services) tested seeds of the three crops to confirm the first round tests and assayed a duplicate, but larger, sample of seeds to increase the chances of detecting contaminants.[34] Both laboratories employed widely used testing methods based on polymerase chain reaction (PCR) to detect and identify engineered genetic sequences in the seeds.

Testing method: polymerase chain reaction

Reduced to the simplest terms, PCR testing methods home in on particular target sequences of DNA and, using a special DNA-copying enzyme (DNA polymerase), selectively make enough copies of the target sequence to allow it to be identified and measured. In practice, PCR methods are complicated and require highly trained personnel, sophisticated machinery, and carefully

30 For more information on the USDA Grain Inspection, Packers and Stockyards Administration (GIPSA) program, see the USDA GIPSA website at *http://www.usda.gov/gipsa/biotech/proficiency-program.htm*.

31 For more information on GeneScan USA, Inc., see the GeneScan website at *http://www.gmotesting.com.*

32 For more information on Biogenetic Services, Inc., see the Biogenetic Services website at *http://www.biogeneticservices.com*. Also, see examples of Biogenetic Services' clients at: Plant Genome Database—Prototype Developing (at *http://www.nal.usda.gov/pgdic/probe/v1n3_4/ maize.html*, accessed on September 23, 2003); Progress in the Development of a Genomic RFLP Map of Cultivated Sunflower (*Helianthus annus*) (at *http://www.intl-pag.org/1/abstracts/101pg1.html*, accessed on September 23, 2003); and Conclusions from a Meeting to Discuss the Interpretation of Test Results on Seed Grown at the Affected Sites in Gisborne and Pukekohe, September 18, 2002 (at *http://www.maf.govt.nz/biosecurity/imports/plants/papers/gm-seeds/appendix-10.htm*, accessed on September 23, 2003).

33 Anklam, E., P. Heinze, S. Kay, and G. Van den Eede. 2002. Validation studies and proficiency testing. *Journal of AOAC International* 85(3):809-815.

34 Sample size is a critical factor in the capacity for PCR methods to detect and measure target DNA. Larger samples increase the chances that a given target molecule will be detected and that the amount of the target measured in the sample will be close to the actual amount in the lot from which the sample was taken. For more information on the role of sample size in GMO testing, see Fagan, J. 2004. Detection and Quantification of GMOs by DNA-Based and Protein-Based Methods. Chapter in *Handbook of Food Analysis, second edition,* Marcel Dekker, Inc., in press; Spiegelhalter, F., F.-R. Lauter, and J.M. Russell. 2001. Detection of genetically modified food products in a commercial laboratory. *Journal of Food Science* 66:634-640; USDA GIPSA. 2000. Sampling for the Detection of Biotech Crops. On the USDA GIPSA website at *http://www.usda.gov/gipsa/biotech/sample2.htm*, accessed on November 13, 2001.

Designations for regulatory sequences and genes

CTP2/EPSPS CP4	Sequences characteristic of various glyphosate-resistant (Roundup Ready) crops (see the figure, "A Specific Construct Conferring Herbicide Resistance in Soybeans," p. 17)
hmgA	High-mobility group A, a corn-specific gene
le1	Lectin, a soybean-specific gene
nptII	An antibiotic-resistance gene often used as a selective marker in plant engineering
P35S	A promoter from the cauliflower mosaic virus; widely used in transgenic plants
PFMV	A promoter from the figwort mosaic virus
pepC	Phosphoenol pyruvate carboxylase, a canola-specific gene
T-NOS	A terminator sequence (nopaline synthase) widely used in engineered plants

SOURCE: AGBIOS website (*http://www.agbios.com*).

designed tests incorporating many controls and reference standards to ensure accurate and reproducible results.[35]

Primers, or primer sets, are a key feature of PCR testing methods; they "find" the targeted DNA in a mixture of DNA molecules. Primers are short pieces of DNA synthesized to match sequences at the beginning and end of a segment of targeted DNA. When added to a mixture of DNA molecules extracted from a seed sample, the primers bind to the corresponding beginning and ending segments of the target DNA, thereby marking the exact segment to be copied by the DNA polymerase.

The next step, copying the target DNA, involves a series of different reactions, each requiring a different temperature. Thermocyclers subject mixtures of sample DNA, primer sets, DNA polymerase, and other reagents to a carefully controlled regimen of temperature changes—allowing each of the required reactions to proceed under optimal conditions. Each cycle through the temperature regimen doubles the number of target DNA segments, leading quickly to billions of copies.[36]

Companies use thermocyclers in conjunction with other analytical equipment to generate useful information about the accumulated DNA copies and, by extrapolation, the original sample. GeneScan employed both a qualitative PCR system that determined whether engineered sequences were present or absent in seed samples and a quantitative PCR system to estimate the level of engineered DNA in a sample. Biogenetic Services used a semi-quantitative PCR system that simultaneously detected and estimated the proportion of engineered sequences.

Background on testing strategy

In the study, PCR methods were used for three purposes: to screen for the presence of transgenically derived sequences in the traditional seed samples, to identify the specific transgenic events that were the likely sources of the contaminants, and to estimate the level at which transgenic sequences were present.

Screening for transgenically derived sequences. Screening tests were conducted to determine whether any sequences derived from genetically

35 For more detail on PCR techniques, assay design, controls, reference standards, and interpretation of results, see Fagan, J. 2004 and Spiegelhalter, F. et al. 2001.

36 Spiegelhalter, F. et al. 2001. Theoretically, after 32 cycles, a single target molecule would yield just over one billion copies. In actuality, more cycles would be required because each cycle, for various reasons, usually yields less than a doubling.

engineered crops were present in the seed samples. Most of the corn and soybean events currently on the market were engineered with—and therefore likely to contain—either P35S or T-NOS (see box, "Designations for regulatory sequences and genes," p. 19), so primers for those regulatory sequences were used in the initial screen. By probing for those common regulatory sequences, the tests cast a wide net for potential contaminants.

In contrast to corn and soybean events, not all canola events contain P35S and/or T-NOS, so additional primer sets were used to canvas for the presence or absence of canola constructs. In addition to P35S and T-NOS, GeneScan used nptII and CTP2/EPSPS CP4, and Biogenetic Services used PFMV.

Identifying specific transgenic events. In samples testing positive for transgenically derived sequences in the screening assays, subsequent tests were undertaken to identify the specific engineered events. Our approach for identifying these events was slightly different in different crops.

In soybeans, only one commercial event was likely to have contaminated traditional seeds: Monsanto's Roundup Ready soybeans. Even though the U.S. government has allowed two other engineered soybean events on the market (Bayer's glufosinate-resistant soybeans and DuPont's altered-oil soybeans), these events are planted on little, if any, acreage and are less likely to contaminate traditional soybeans. In first-round screening assays, we assumed the genetic sequences detected in soybean samples using primers for P35S and T-NOS came from Roundup Ready (event GTS 40-3-2). Quantitative tests conducted in the first round confirmed that assumption.

Canola seeds testing positive for transgenically derived sequences were assayed for the presence of only one engineered canola event—Monsanto's Roundup Ready (event GT73)—even though other events have been commercialized. Neither lab had the primer sets necessary to assay Bayer's LibertyLink and SeedLink or Monsanto's Laurical.

Primer sets for many Bt corn events are available to laboratories. The corn samples testing positive for transgenically derived sequences were subjected to additional PCR tests to identify which commercial engineered corn events might be the source of the contaminating DNA. The two laboratories in this study used primer sets recognizing specific commercial corn events such as 176, Bt11, and MON810.

The identification of specific events in this study helped confirm that the genetic sequences detected in screening tests did indeed originate in engineered varieties and ruled out "other seeds" (for example, corn seeds in bags of soybean seed) as major sources of false positive results.

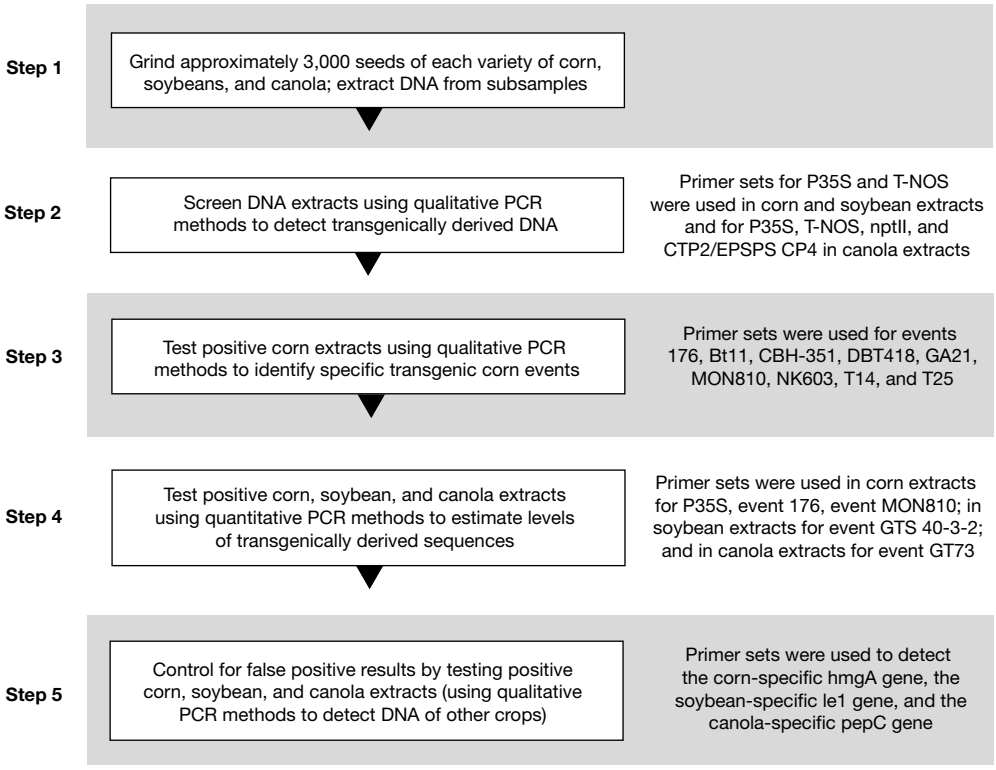
Estimating the levels of transgenically derived sequences. GeneScan and Biogenetic Services provided data on the percentage of genomes in the samples that carried transgenically derived sequences (i.e., the number of genomes containing target DNA detected in comparison to the total number of crop genomes detected in a seed sample times 100). For example, a PCR test detecting 2,000 genomes of Roundup Ready varieties and 1,000,000 genomes of soybean DNA in a sample would report 0.2 percent Roundup Ready DNA.[37]

Round One testing

In Round One, GeneScan tested seed samples from each of six varieties of corn, soybeans, and canola. We weighed, packaged, and shipped approximately 2.5 pounds of seeds of each variety, taking special precautions to prevent cross-contamination of varieties.

37 For more information on quantifying DNA, see Spiegelhalter, F. et al. 2001.

Figure 2-1 **Round One: Detecting and Estimating the Levels of Transgenically Derived DNA (3,000-Seed Samples)**



Detecting transgenically derived DNA. The laboratory ground approximately 3,000 seeds[38] of each variety, extracted DNA from a subsample of the ground material, and used qualitative PCR methods to screen DNA samples. As shown in Figure 2-1, Step 2, primer sets for P35S and T-NOS were used to screen corn and soybean samples, and P35S, T-NOS, nptII, and CTP2/EPSPS CP4 were used to screen canola samples (at a detection limit of approximately 0.1 percent[39]).

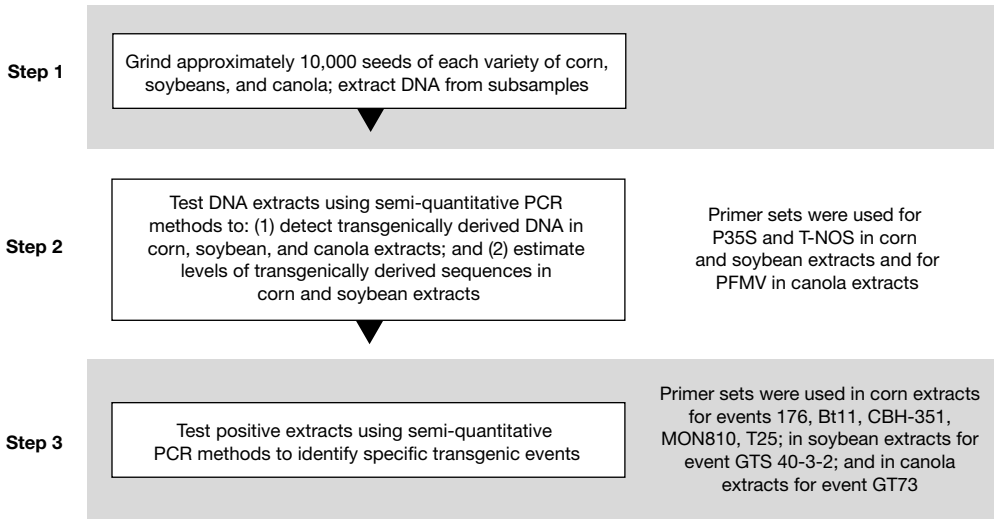
Determining specific transgenic events. For samples testing positive for transgenically derived sequences, the laboratory used qualitative PCR methods to determine which specific events might be the source of the contaminating DNA. As explained above, positive corn samples were subjected to further PCR testing to distinguish among a number of commercial engineered events (Figure 2-1, Step 3), and we assumed positive soybean extracts were contaminated with DNA from Roundy Ready (event GTS 40-3-2) soybeans. Canola extracts were subjected to PCR using a primer set for one canola event: GT73 (Roundup Ready).

Estimating the levels of transgenically derived sequences. After determining the presence or absence of regulatory and gene sequences, the

38 The company weighed the equivalent of approximately 3,000 seeds, based on data on weights of aliquots of known numbers of seeds.

39 A 0.1 percent detection limit means that the methods could not reliably detect target DNA if it were present in the samples at less than a 0.1 percent level.

Figure 2-2 **Round Two: Detecting and Estimating the Levels of Transgenically Derived DNA (10,000-Seed Samples)**



laboratory used quantitative PCR methods to estimate the percentage of genomes that carried transgenically derived sequences in positive seed samples (typically at an approximate quantification limit of 0.05 percent[40]). Figure 2-1, Step 4 (p. 21) shows the primer sets used in each crop.

Reducing false positive results. Genetically engineered varieties of crops other than the one being tested are potential sources of false positive results. For example, a false positive result in soybean seeds might be the result of contamination with engineered corn seed. We attempted to eliminate this possibility by visually inspecting the samples for seeds of other crops before shipping. Nonetheless, contaminating seeds or pieces of seed remained a possibility.

To determine whether the seed samples were contaminated by engineered sequences derived from other crops, the laboratory assayed positive samples for the presence of DNA from two other crops for which transgenic varieties have been allowed on the market. Using primers for genes unique to each crop, corn samples were tested for the presence of canola and soybean DNA, soybean for corn and canola DNA, and canola for corn and soybean DNA. (See Figure 2-1, Step 5, p. 21, for primer sets used to detect crop-specific DNA.)

In addition, naturally occurring plant viruses in canola seeds may yield positive results for P35S. The laboratory avoided this potential outcome by using primers for sequences in addition to P35S when testing canola (Figure 2-1, Step 2, p. 21).

Round Two testing

Biogenetic Services tested additional and larger samples of corn, soybean, and canola seeds taken from the same 50-pound bags used in the first round of tests. These second-round tests were undertaken to confirm GeneScan's results and to determine whether larger samples of seeds would increase the likelihood of obtaining a positive

40 A 0.05 percent quantification limit means that the methods could not reliably measure target DNA if it were present in the samples at less than a 0.05 percent level.

Table 2-2 **Round One Results: Presence and Levels of Transgenically Derived DNA**

Crop	Variety Designation*	Transgenically Derived DNA Detected	Transgenic Events Detected	% of Total Genomes Containing Transgenically Derived DNA**
Corn	1	No	None	None
	2	No	None	None
	3	Yes	MON810 (YieldGard)	Less than 0.05%
	4	No	None	None
	5	Yes	MON810 (YieldGard)	0.1%
	6	Yes	176 (KnockOut/NaturGard) MON810 (YieldGard)	Less than 0.2% Less than 0.05%
Soybean	7	No	None	None
	8	No	None	None
	9	Yes	GTS 40-3-2 (Roundup Ready)	Less than 0.05%
	10	Yes	GTS 40-3-2 (Roundup Ready)	Less than 0.05%
	11	Yes	GTS 40-3-2 (Roundup Ready)	Less than 0.05%
	12	No	None	None
Canola	13	Yes	GT73 (Roundup Ready)	Less than 0.05%
	14	Yes	GT73 (Roundup Ready)	0.05%
	15	Yes	GT73 (Roundup Ready)	0.05%
	16	Yes	GT73 (Roundup Ready)	0.1%
	17	Yes	GT73 (Roundup Ready)	0.1%
	18	Yes	GT73 (Roundup Ready)	Less than 0.05%

*See Table 2-1, p. 15.
**Limit of quantification = 0.05% except for event 176 (0.2%).

result from any one 50-pound bag, thus providing a more accurate picture of the extent of contamination.

We weighed, packaged, and shipped approximately nine, seven, and three pounds of seeds of each variety of corn, soybeans, and canola, respectively, to the second laboratory using the same protocol, except for sample size, as with the first laboratory. We shipped enough seeds to grind 10,000 seeds of each variety (compared with the 3,000 seeds ground by the first laboratory). The seeds of each variety sent to the second laboratory were scooped from the same bag sampled for first-round testing.

Detecting and estimating the levels of transgenically derived sequences. Biogenetic Services ground approximately 10,000 seeds[41] of each variety of corn and soybeans and extracted DNA from a subsample of the ground material. Using semi-quantitative PCR methods, the laboratory screened DNA samples with primer sets for the common regulatory sequences P35S and T-NOS and estimated the levels of transgenically derived sequences in positive samples (at detection and quantification limits of approximately 0.1 percent). The same process was followed for canola seeds, except the laboratory screened with primer sets for PFMV and did not estimate the levels of transgenically derived sequences (Figure 2-2, Steps 1 and 2).

Determining specific transgenic events. To determine which specific events might be responsible for the contamination, positive samples of corn, soybean, and canola seeds were subjected

41 The company weighed the equivalent of approximately 10,000 seeds, based on data on weights of aliquots of known numbers of seeds.

Table 2-3 **Round Two Results: Presence and Levels of Transgenically Derived DNA**

Crop	Variety Designation*	Transgenically Derived DNA Detected	Transgenic Events Detected	% of Total Genomes Containing Transgenically Derived DNA**
Corn	1	Yes	Bt11 (YieldGard) MON810 (YieldGard)	Between 0.5 and 1.0%
	2	Yes	176 (KnockOut/NaturGard) MON810 (YieldGard) T25 (LibertyLink)	Approximately 1.0%
	3	Yes	176 (KnockOut/NaturGard) Bt11 (YieldGard) MON810 (YieldGard)	Approximately 1.0%
	4	No	None	None
	5	Yes	176 (KnockOut/NaturGard) Bt11 (YieldGard) MON810 (YieldGard)	Approximately 1.0%
	6	Yes	176 (KnockOut/NaturGard) MON810 (YieldGard)	Approximately 1.0%
Soybean	7	Yes	GTS 40-3-2 (Roundup Ready)	Between 0.5 and 1.0%
	8	No	None	None
	9	Yes	GTS 40-3-2 (Roundup Ready)	More than 1.0%
	10	Yes	GTS 40-3-2 (Roundup Ready)	More than 1.0%
	11	Yes	GTS 40-3-2 (Roundup Ready)	More than 1.0%
	12	Yes	GTS 40-3-2 (Roundup Ready)	Between 0.1 and 0.5%
Canola	13	Yes	GT73 (Roundup Ready)	QND***
	14	Yes	GT73 (Roundup Ready)	QND
	15	Yes	GT73 (Roundup Ready)	QND
	16	Yes	GT73 (Roundup Ready)	QND
	17	Yes	GT73 (Roundup Ready)	QND
	18	No	None	QND

*See Table 2-1, p. 15.
**Limit of quantification = 0.1%. Estimates were made of the total transgenically derived DNA detected using P35S and T-NOS, not of individual events.
***Quantification not done.

to additional semi-quantitative PCR tests (Figure 2-2, Step 3, p. 22). This time, primers for specific engineered events were used (at a detection limit of approximately 0.1 percent).

RESULTS

Overall, the pilot study showed that seeds of traditional varieties of corn, soybeans, and canola are contaminated at a high incidence with low levels of genetic sequences derived from transgenic crop varieties.

Incidence of contamination

Round One results. Transgenically derived sequences were detected in seeds of three of six traditional varieties (50 percent) of corn and soybeans and in all six traditional varieties (100 percent) of canola (Table 2-2, p. 23). Monsanto events were detected in all three crops: MON810 (YieldGard) in the three contaminated corn varieties, GTS 40-3-2 (Roundup Ready) in the three contaminated soybean varieties, and GT73 (Roundup Ready) in all six contaminated canola varieties. Syngenta's event 176 (KnockOut/NaturGard) was detected in one contaminated corn variety.

Round Two results. Transgenically derived sequences were detected in seeds of five of six traditional varieties (83 percent) of all three crops (Table 2-3). Of the five contaminated corn varieties, three

Table 2-4 **Combined Results of Rounds One and Two: Presence and Levels of Transgenically Derived DNA***

Crop	Variety Designation**	Transgenically Derived DNA Detected		Transgenic Events Detected		% of Total Genomes Containing Transgenically Derived DNA**	
		Round 1	Round 2	Round 1	Round 2	Round 1***	Round 2****
Corn	1	No	Yes	None	Bt11 (YieldGard) MON810 (YieldGard)	None	Between 0.5 and 1.0%
	2	No	Yes	None	176 (KnockOut/NaturGard) MON810 (YieldGard) T25 (LibertyLink)	None	Approximately 1.0%
	3	Yes	Yes	MON810 (YieldGard)	176 (KnockOut/NaturGard) Bt11 (YieldGard) MON810 (YieldGard)	Less than 0.05%	Approximately 1.0%
	4	No	No	None	None	None	None
	5	Yes	Yes	MON810 (YieldGard)	176 (KnockOut/NaturGard) Bt11 (YieldGard) MON810 (YieldGard)	0.1%	Approximately 1.0%
	6	Yes	Yes	176 (KnockOut/ NaturGard) MON810 (YieldGard)	176 (KnockOut/NaturGard) MON810 (YieldGard)	Less than 0.2%*** Less than 0.05%	Approximately 1.0%
Soybean	7	No	Yes	None	GTS 40-3-2 (Roundup Ready)	None	Between 0.5 and 1.0%
	8	No	No	None	None	None	None
	9	Yes	Yes	GTS 40-3-2 (Roundup Ready)	GTS 40-3-2 (Roundup Ready)	Less than 0.05%	More than 1.0%
	10	Yes	Yes	GTS 40-3-2 (Roundup Ready)	GTS 40-3-2 (Roundup Ready)	Less than 0.05%	More than 1.0%
	11	Yes	Yes	GTS 40-3-2 (Roundup Ready)	GTS 40-3-2 (Roundup Ready)	Less than 0.05%	More than 1.0%
	12	No	Yes	None	GTS 40-3-2 (Roundup Ready)	None	Between 0.1 and 0.5%
Canola	13	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	Less than 0.05%	QND*****
	14	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	0.05%	QND
	15	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	0.05%	QND
	16	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	0.1%	QND
	17	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	0.1%	QND
	18	Yes	No	GT73 (Roundup Ready)	None	Less than 0.05%	QND

*3,000 and 10,000 seeds of each variety were tested in Round One and Round Two, respectively.
**See Table 2-1, p. 15.
***Limit of quantification = 0.05% except for event 176 (0.2%).
****Limit of quantification = 0.1%.
*****Quantification not done.

contained three transgenic events and two contained two events. Monsanto events were detected in all three crops: MON810 (YieldGard) in the five contaminated corn varieties, GTS 40-3-2 (Roundup Ready) in the five contaminated soybean varieties, and GT73 (Roundup Ready) in the five contaminated canola varieties. Syngenta events 176 (KnockOut/NaturGard) and Bt11 (YieldGard) were detected in four and three contaminated corn varieties, respectively. Bayer event

T25 (LibertyLink) was detected in one corn variety.

Combined results. The positive results in the first round were largely confirmed and extended by second-round tests (Tables 2-4, p. 25, and 2-5). The second laboratory, which used a larger seed sample (10,000 versus 3,000), found a higher incidence of engineered contaminants in corn and soybeans and a lower incidence in canola. In addition, the second laboratory found a larger number of contaminating events in corn varieties than the first. The most conservative expression of the combined results is that transgenically derived DNA was detected in 50 percent of the corn, 50 percent of the soybeans, and 83 percent of the canola varieties tested.

Table 2-5 **Combined Results of Rounds One and Two: Percentage of Tested Varieties Containing Transgenically Derived DNA**

	Number and % of Tested Traditional Varieties Containing Transgenically Derived DNA*			
	Round 1 (3,000 seeds)		Round 2 (10,000 seeds)	
Crop	Number	%	Number	%
Corn	3 of 6	50	5 of 6	83
Soybean	3 of 6	50	5 of 6	83
Canola	6 of 6	100	5 of 6	83

*See text and Table 2-4, p. 25, for more detail.

Estimated levels of contamination

Round One results. In contaminated corn varieties, MON810-derived sequences were estimated at levels ranging from 0.1 percent to less than 0.05 percent of the corn genomes present and event 176 was found in one variety at less than 0.2 percent. In all three contaminated soybean varieties, GTS 40-3-2 was estimated to be less than 0.05 percent of the soybean genomes present. The six canola varieties were contaminated with GT73 at estimated levels ranging from 0.1 percent to less than 0.05 percent of the canola genomes present. All Round One assays had a quantification limit of 0.05 percent except for event 176, for which the limit was 0.2 percent (Table 2-2, p. 23).

Round Two results. The second laboratory estimated the levels of transgenically derived sequences in corn and soybean samples based on the total transgenically derived DNA detected by primers for common regulatory sequences. It did not, however, quantify individual events in corn as did the first laboratory (Table 2-3, p. 24).

In four of five contaminated corn samples, approximately one percent of the corn genomes present contained transgenically derived sequences, while the fifth sample was slightly less contaminated, at less than one percent but more than 0.5 percent of the corn genomes present. In soybeans, the laboratory determined that more than one percent of the soybean genomes in three varieties contained transgenically derived sequences. The remaining two varieties had lower levels of transgenic genome contamination, ranging between 0.1 and 1 percent. All Round Two assays had a quantification limit of 0.1 percent. The second laboratory did not run quantitative assays for contaminants in canola.

Combined results. In the samples where transgenically derived DNA was detected, the percentage of total genomes containing transgenically derived sequences ranged from less than 0.05 percent to approximately one percent in corn, less than 0.05 percent to more than one percent in soybeans, and less than 0.05 to 0.1 percent in canola.

Overall, the estimated levels of transgenically derived sequences in contaminated traditional seeds of the three crops ranged from less than 0.05 percent of the total genomes present in the samples to more than one percent. As discussed above, PCR methodology is still in its infancy and lacks standard protocols and methods. As a result, it is difficult to combine data from different laboratories. While we have presented data from quan-

Table 2-6 **Round One Tests for False Positives**

Crop	Designations of Varieties Testing Positive for Transgenically Derived DNA*	Presence (+)/Absence (-) of Other-Crop DNA
Corn	3	Soybean - Canola -
	5	Soybean - Canola -
	6	Soybean - Canola -
Soybean	9	Corn - Canola -
	10	Corn + Canola -
	11	Corn + Canola -
Canola	13	Corn - Soybean -
	14	Corn - Soybean -
	15	Corn - Soybean -
	16	Corn - Soybean -
	17	Corn - Soybean +
	18	Corn - Soybean -

*See Table 2-1, p. 15.

titative and semi-quantitative analyses of the seed samples we had tested, we do not believe these data are robust enough to draw conclusions about the levels of contamination in the seed supply.

We note that the second laboratory, which tested 10,000 rather than 3,000 seeds of each variety, reported higher levels of contamination in corn and soybeans than the first laboratory (Table 2-4, p. 25), but we believe different methods and samples make it impossible to interpret this difference. Even preliminary conclusions on the levels of contamination must await a larger study and the development of a standard testing methodology.

Potential false positive results

Of the 12 varieties testing positive for transgenically derived sequences in the first round, three contained the DNA of other crops: two soybean varieties were contaminated with corn DNA and one canola variety was contaminated with soybean DNA (Table 2-6). Therefore, it is possible that engineered seeds from other crop varieties could have contributed to the positive test results on incidence.

However, that source of contamination could not have accounted for all the engineered genetic sequences detected in the tests because assays with specific primers provided independent evidence that contamination originated in varieties of the tested crop. In the two soybean varieties contaminated with corn DNA, some of the transgenic sequences may have come from corn. But PCR methods used to estimate the levels of engineered genetic sequences relied on a primer set specific for transgenic soybean (the Roundup Ready soybean event GTS 40-3-2). That primer set would not have recognized any commercial engineered corn events.

Similarly, in the canola variety contaminated with soybean DNA, the quantitative PCR testing in Round One was conducted with a primer set specific for transgenic canola (the Roundup Ready canola event GT73). That primer set does not recognize the Roundup Ready soybean event.

UNDERSTANDING THE RESULTS

Extent of contamination

As Tables 2-4 (p. 25) and 2-5 show, one laboratory found engineered contaminants in half the corn and soybean varieties and all the canola varieties. The second laboratory found five of six, or 83 percent, of the varieties of all three crops were contaminated with engineered sequences. Although the sample size is small, the sampling methodology we used suggests that the contamination of the traditional seed supply is likely to be pervasive.

The 18 varieties we selected were marketed to farmers in states planting the most corn, soybean,

and canola seeds in the United States. Four of the six seed companies from which we purchased seed are among the biggest in the country, controlling a substantial portion of the U.S. traditional seed supply. So it is likely that these 18 varieties represent a substantial portion of the 2002 traditional seed supply for these three crops.[42]

It seems improbable that all or most of the other varieties we did not test were free of transgenic contaminants.

Expression of new traits

Not all the contaminants detected by the PCR methods in this study would lead to the expression of engineered traits in the plants grown from these seeds. In general, only those seeds containing intact constructs (i.e., the full complement of regulatory and gene sequences needed to confer the trait) will produce a plant exhibiting new characteristics.

Transgenic constructs may fragment and/or rearrange once they are within a plant genome,[43] leading in some instances to separation of regulatory and gene sequences. Genes alone would produce new protein only in the unlikely event that they were positioned in the neighborhood of a resident regulatory sequence. Regulatory sequences by themselves would not be able to produce novel functional proteins. On the other hand, if they were located in proximity to resident genes, the transgenically derived regulatory sequences may be able to alter the level of expression of those genes and perhaps confer new traits.

Routes of contamination

It is worth emphasizing that this study provides no information on how or when the commingling that led to the contamination occurred. The genetic sequences detected in this study could have moved into traditional seeds by either physical mixing or outcrossing, which could have occurred last year or several years ago. The lack of information on the mode and timing of commingling makes it difficult to speculate on just how extensive the contamination is or where in the production or handling of seeds intervention could have prevented it.

Nevertheless, the study does provide one insight into the role of physical mixing. We initially assumed gene flow rather than physical mixing was the likely primary cause of contamination and predicted that transgenic sequences would most likely show up in corn and canola—crops with outcrossing rates well above that of the predominantly self-pollinating soybeans. The results, however, show all but one traditional soybean variety contaminated with transgenically derived DNA, suggesting that seed mixing during seed production and handling—at planting, harvest, processing, storage, or transport—may be able to produce widespread contamination.

Illustration of low levels of contamination

As stated earlier, we are not suggesting this study provides a basis for determining overall levels of contamination. The fact that we detected transgenic sequences in so many samples, however, makes it appropriate to consider what low levels of contaminants in the traditional seed supply might mean in practical terms.

To do that, we converted the percentage of total genomes carrying transgenically derived sequences into a percentage of contaminated seeds and then attempted to visualize contamination in

42 Companies do not release sales data on individual varieties to the public, so we could not determine which varieties were the most widely planted in 2002.

43 Svitashev, S.K., W.P. Pawlowski, I. Makarevitch, D.W. Plank, and D. Somers. 2002. Complex transgene locus structures implicate multiple mechanisms for plant transgene rearrangement. *The Plant Journal* 32(4):433-445. On the Blackwell-Synergy website at *http://blackwell-synergy.com/links/doi/10.1046/j.1365-313X.2002.01433.x*, accessed on November 6, 2003.

Table 2-7 **Illustration of Low Levels of Seed Contamination**

Crop	Estimated number of seeds of transgenic varieties contaminating seeds of traditional varieties at a level of:		Estimated number of 50-pound bags required to hold seeds of transgenic varieties contaminating seeds of traditional varieties at a level of:		Estimated number of large tractor-trailer trucks* required to hold seeds of transgenic varieties contaminating seeds of traditional varieties at a level of:	
	0.1%	1%	0.1%	1%	0.1%	1%
Corn**	1.6 billion	16 billion	25,000	250,000	24	240
Soybean***	4.4 billion	44 billion	32,000	320,000	31	308
Canola****	270 million	2.7 billion	47	470	Less than 1	Less than 1

*We assumed that a large tractor-trailer truck would have a 26-ton carrying capacity. (Iowa Department of Transportation. 1994. Compare cargo capacity. On the Silos and Smokestacks National Heritage Area website at *http://silosandsmokestacks.org/resources/images/scans/comparedot.gif*, accessed on February 11, 2003.)
**Based on estimates of the number of traditional corn seeds (1.6 trillion) planted in the United States in 2002. See text for more detail.
***Based on estimates of the number of traditional soybean seeds (4.4 trillion) planted in the United States in 2002. See text for more detail.
****Based on estimates of the number of traditional canola seeds (270 billion) planted in North Dakota in 2002. See text for more detail.

three ways: the number of contaminating seeds and the number of 50-pound bags and large (26-ton) tractor-trailer trucks needed to hold the seeds (Table 2-7; Figure 2-3, p. 30; Figure 2-4, p. 31).

For the sake of convenience, we assume that the percentage of genomes translates directly into the percentage of seeds carrying genetically engineered sequences.[44] This study reports percentages of total genomes containing transgenically derived sequences ranging from less than 0.05 percent to more than one percent. For the purposes of this exercise, these numbers translate into a range of less than 0.05 percent to more than one percent of the total seeds carrying transgenic sequences in the samples tested.

These levels may appear low, and may lead some to believe that the quantities of seed they represent are small. But that would be a mistake. To emphasize this point, we have estimated the number of contaminating seeds and the number of 50-pound bags and large tractor-trailer trucks required to hold the seeds that 0.1 and 1 percent levels of contamination would represent of the seeds planted with traditional corn, soybean, and canola varieties. For our calculations, we used data on the acreage planted with traditional varieties of each crop in 2002.

Illustrating low levels of contaminants in corn and soybean seeds. Using USDA data on the acreage of traditional crop varieties planted and published information on planting rates (number of seeds per acre), we estimated the number of seeds of traditional varieties of corn and soybeans planted in the United States in 2002 to be roughly 1.6 trillion for corn and 4.4 trillion for soybeans.[45]

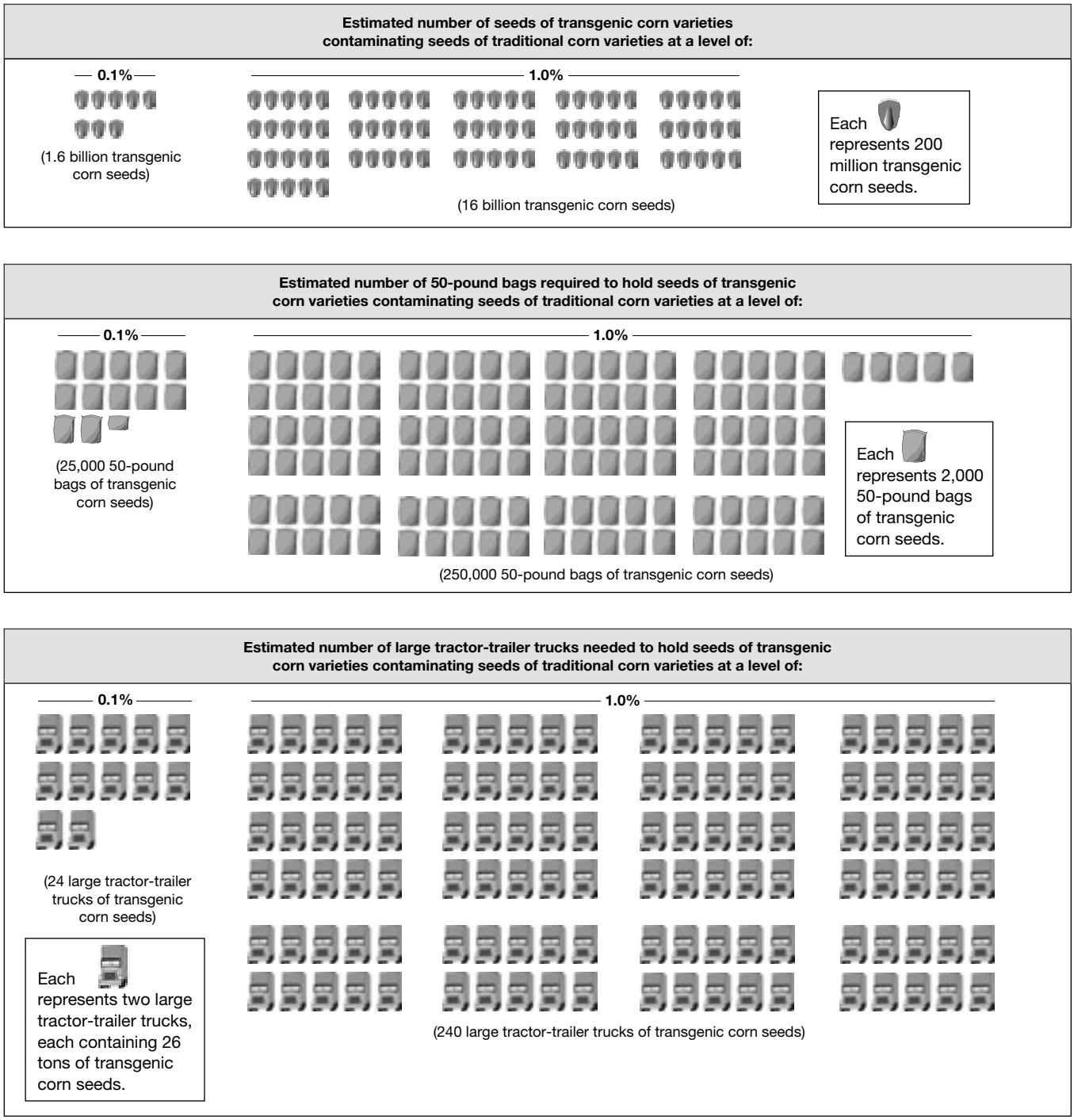
We then calculated the number of seeds carrying transgenic sequences that would have

continued on page 32

44 The conversion of percentage genomes into percentage seeds contaminated is not straightforward because of issues like ploidy (the number of genomes per cell) and zygosity (whether genetic elements were contributed by one or both parents), some of which may be taken into account by GMO testing companies' adding particular PCR controls.

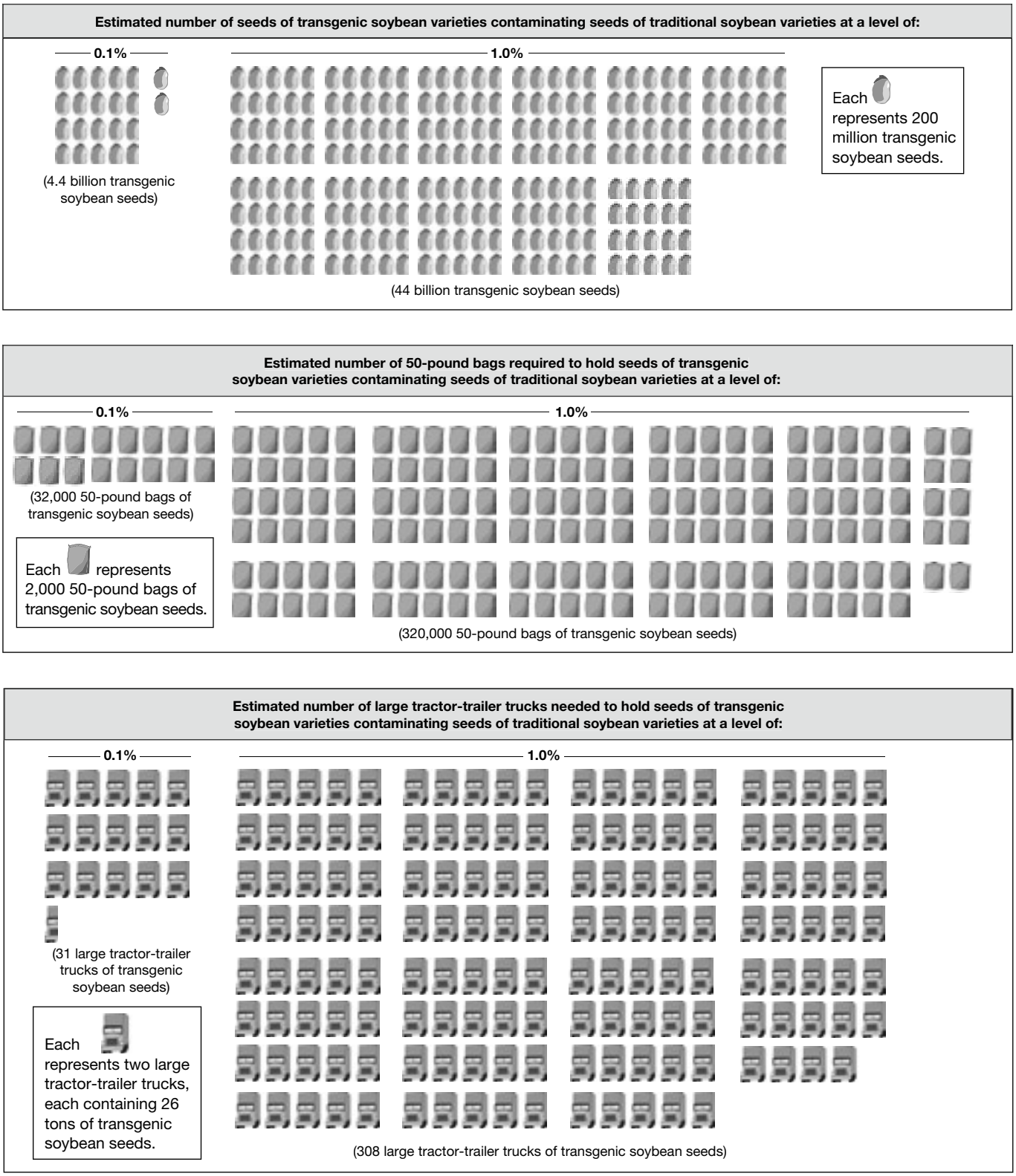
45 According to USDA NASS data, 79,054,000 acres were planted with corn (*http://www.usda.gov/nass/aggraphs/cornacm.htm*) and 73,758,000 acres were planted with soybeans (*http://www.usda.gov/nass/aggraphs/soyacm.htm*) in the United States in 2002 (USDA NASS website accessed on May 15, 2003). Approximately 52 million acres, 66 percent of the total corn acreage, were planted with traditional varieties. Approximately 18 million acres, 25 percent of the total soybean acreage, were planted with traditional varieties in 2002 (USDA NASS website at *http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bbp/pspl0303.pdf* accessed on August 15, 2003). We calculated estimates of planting rates for corn (30,400 seeds per acre) and soybeans (243,000 seeds per acre) from data in Hoeft, R.G., E.D. Nafziger, R.R. Johnson, and S.R. Aldrich. 2000. *Modern Corn and Soybean Production*. Champaign, IL: MCSP Publications, pp. 90-94. Multiplying the traditional acreage for each crop by the estimated planting rate, we arrived at roughly 1.6 trillion and 4.4 trillion seeds of corn and soybean, respectively, planted in traditional varieties in 2002.

Figure 2-3 **Graphic Illustration of Low Levels of Seed Contamination in Corn**



Calculations based on U.S. acreage planted with traditional varieties of corn in 2002. See text and Table 2-7, p. 29, for more detail on calculations.

Figure 2-4 **Graphic Illustration of Low Levels of Seed Contamination in Soybeans**



Calculations based on U.S. acreage planted with traditional varieties of soybeans in 2002. See text and Table 2-7, p. 29, for more detail on calculations.

continued from page 29

been planted in fields of traditional corn and soybean varieties if all traditional seed planted in the United States in 2002 had been contaminated at levels of 0.1 or 1 percent (Table 2-7, p. 29, and Figures 2-3, p. 30, and 2-4, p. 31).

At the 0.1 percent contamination level, 1.6 billion corn seeds carrying transgenic sequences would have been planted in fields of traditional varieties of corn in 2002. At the same contamination level, 4.4 billion soybean seeds carrying transgenic sequences would have been planted in fields of traditional varieties of soybeans.

According to our estimates, it would take about 25,000 50-pound bags (the standard size bought by farmers) or 24 large tractor-trailer trucks to hold the 1.6 billion contaminating corn seeds and 32,000 50-pound bags or 31 large tractor-trailer trucks to hold the 4.4 billion contaminating soybean seeds.[46]

At one percent contamination, 16 billion contaminating corn seeds (or 250,000 50-pound bags or 240 large tractor-trailer trucks) and 44 billion contaminating soybean seeds (or 320,000 50-pound bags or 308 large tractor-trailer trucks) would have been planted along with seeds of traditional varieties.

Illustrating low levels of contaminants in canola seeds. Since the USDA does not publish national data on acres planted with traditional and engineered canola varieties, but that information was available for North Dakota, we limited our estimates of traditional canola seeds planted to that state. Based on North Dakota State University estimates of traditional acreage and published information on canola planting rates, we estimated the number of seeds of traditional canola varieties planted in North Dakota in 2002 to be approximately 270 billion.[47]

We similarly estimated the number of canola seeds carrying transgenic sequences that would have been planted in fields of traditional canola varieties in North Dakota in 2002 at a contamination level of 0.1 or 1 percent. Finally, we estimated the number of 50-pound bags[48] or large tractor-trailer trucks that would be required to hold the contaminating seeds (Table 2-7, p. 29).

At a 0.1 percent contamination level, North Dakota farmers would have planted an estimated 270 million canola seeds containing transgenic sequences, or 47 50-pound bags (less than one tractor-trailer truck), in fields of traditional canola varieties. At a one percent contamination level, 2.7 billion contaminating canola seeds, or 470 50-pound bags (less than one tractor-trailer truck), would have been planted. The 270 million and 2.7 billion canola seeds would weigh approximately 1.2 and 12 tons, respectively.

STUDY LIMITATIONS

This pilot study was limited in three important ways.

First, the study tested for only a subset of the genetic sequences present in engineered varieties of corn, soybeans, and canola. As discussed

46 To calculate the numbers of 50-pound bags and 26-ton tractor-trailer trucks required to hold the corn and soybean seeds, we estimated 1,300 seeds per pound for corn (the National Corn Growers Association website at *http://www.ncga.com/education/main/faq.html#kernels*) and 2,750 seeds per pound for soybeans (Hoeft, R.G. et al. 2000, p. 93).

47 Berglund, D.R. 2003. Personal communication, August 15. D.R. Berglund is a professor and extension agronomist at North Dakota State University. Since the USDA does not publish information on the percentage of canola acres planted with engineered and non-engineered varieties in the United States, we relied on data from North Dakota State University (NDSU). (North Dakota accounted for nearly 90 percent of the total U.S. canola acreage in 2002.) According to Dr. Berglund, approximately 400,000 (or 31 percent) of North Dakota's total of 1,300,00 acres of canola were planted with non-engineered varieties in 2002. We calculated an estimated planting rate for canola of 678,000 seeds per acre from data published by University of Minnesota [UM] Extension Service. 1999. Canola Variety Trials. Publication MR-7348-GO. On at the UM Extension Service website at *http://www.extension.umn.edu/distribution/cropsystems/DC7348.html*, accessed on August 5, 2002. Multiplying the traditional acreage by the estimated planting rate, we arrived at roughly 270 billion seeds of traditional canola varieties planted in North Dakota in 2002.

48 We used an estimate of 113,000 seeds per pound for canola (UM Extension Service, 1999).

above, GMO testing laboratories can only test for sequences for which they have primer sets, and can only obtain or synthesize primer sets for certain engineered events (primarily those that have been used commercially).

The two laboratories tested for some of the most common transgenic sequences, such as the cauliflower mosaic virus promoter and genes for popular herbicide- and insect-resistance events. However, as noted above, there are other events and regulatory sequences allowed in corn, soybeans, and canola for which the testing laboratories did not have primers. Beyond that, there are many transgenes that are either still undergoing, or have undergone, field tests for which primers are unavailable. To the extent that our study did not test for all possible engineered contaminants, it underestimates the degree of contamination.

The field testing of transgenic corn, soybeans, and canola represents a potentially major source of contaminants not assessed by this study. Since 1987, the USDA has received more than 5,500 applications and notifications of field trials for these three crops—and has denied few. Appendix B contains a list of transgenes and transgenic traits from USDA records of field tests allowed in corn, soybeans, and canola during the last 16 years.

Many, if not most, of the crop-transgene combinations listed in Appendix B will not be commercialized, but they are nevertheless potential sources of contaminating transgenes. The total acreage devoted to field testing is difficult to estimate because one USDA record for a field trial may include tests of multiple transgenes at multiple locations over several years. Since plot sizes typically range from a tenth of an acre to hundreds of acres, however, overall acreage over the past decade and a half is likely to have involved thousands of acres. Many of these tests have been carried out in areas of the country where seed production occurs. Thus, it is possible that transgenes from field test plots have migrated to nearby seed production fields in the past and are still doing so today.

Second, the study looked at the commercial seed supply for traditional varieties of only three crops. It did not include other crops such as cotton and squash, which have engineered varieties in commercial use for which laboratories might have obtained primers. To the extent that seeds for traditional varieties of the crops beyond the three we tested are also contaminated, the overall problem is underestimated by our study.

Third, the study methods do not rule out false positives, or contaminants from other engineered crops. The two corn and two soybean varieties that tested positive for transgenically derived sequences in Round Two but not Round One were not tested for contamination by other crops. Since common regulatory sequences were used by Biogenetic Services to estimate the levels of contaminating DNA in samples, these tests might have picked up genetic sequences contributed by other engineered crops, thereby potentially overestimating the level of genetic sequences contributed by engineered events of the original crop.

Because we did not test for DNA sequences from all the crops with commercially approved transgenic varieties, including cotton and squash, there remains a small possibility that some contaminants in positive samples may have come from those crops.

SUMMARY

For this study, UCS staff bought seeds of traditional varieties of three major commodity crops—corn, soybeans, and canola—and had them tested for genetic sequences originating in transgenic crops. In 18 varieties (six of each crop), we looked for evidence of both regulatory sequences such as promoters, which control gene

expression, and genes, which confer herbicide resistance or insect resistance (Bt), from engineered varieties. We found pervasive, low-level contamination from transgenically derived sequences in the seeds of traditional varieties of all three crops.

Although we expected to detect some contamination, we were surprised to find transgenic sequences in most of the varieties tested. The varieties we tested were selected to represent a substantial portion of the 2002 seed supply for the traditional varieties of the three crops. That is, the 18 varieties we selected were marketed by major seed companies to farmers in the two states planting the most acres of corn and soybeans and the one state planting the most canola acres in the United States. Therefore, we tentatively conclude that seed contamination in those three crops is not limited to pockets of the seed supply, but is pervasive.

Although they are preliminary, the results of this study suggest the existence of an easy path for the movement of transgenes into the seed supply—one impeded little by current regulations or the standard confinement procedures in commodity crop seed production.

Chapter 3
Implications

Our pilot study suggests that the commercial seed stocks of non-engineered (traditional) commodity corn, soybean, and canola varieties are pervasively contaminated with low levels of sequences originating in genetically engineered varieties. The genes and genetic sequences we detected came from popular transgenic varieties currently allowed on the market in the United States.

Although the study sheds little light on how the contamination occurred, there is no reason to assume that the traits detected in this study were the only engineered traits moving into the traditional seed supply. We would not be surprised if further examination revealed additional traits contaminating a greater number of crop varieties. Until we know otherwise, it is minimally prudent to assume that *any* transgenes or transgenically derived sequences being produced and field tested in the United States could move into the seed supply of corn, soybeans, canola, or any other crops with engineered varieties. The vulnerability of the seed production system to contamination is due primarily to its design and standard operating procedures. Contamination is likely to continue unless that system is changed.

Assuming this report's conclusions are borne out by further study, its implications are broad. Seeds are fundamental to agriculture and the food supply, and continued seed contamination can have a potential impact in a number of arenas. We briefly address nine of these below: pharmaceutical and industrial crops, food safety, the environment, trade, organic food production, intellectual property, the food system, the agriculture of developing countries, and seed repositories. In Chapter 4, we present our conclusions and recommendations.

AREAS OF CONCERN

1. Pharmaceutical and industrial crops

The possibility of seed contamination for food crops heightens concerns about pharmaceutical and industrial crops.

Will drug-producing crops end up contaminating our seed and food supplies? Our results suggest reasons for concern. In the near term, this may be the most important implication of our findings.

Agricultural biotechnology is entering a new age. No longer are researchers concentrating only on inserting genes that result in plants with traits like herbicide and insect resistance that make crops cheaper or easier for farmers to grow. Now they are inserting genes to create plants that produce drugs and industrial chemicals—in essence turning the crops into biological factories. The developers of the new pharmaceutical-producing "pharm" crops especially promise compelling benefits: new drugs that would otherwise be unavailable, and decreased production costs leading to lower consumer drug prices.[49]

A wide variety of genes has been engineered into plants for pharmaceutical and industrial purposes. For more information, see the box,

49 Whether the technology can deliver on these promises remains uncertain. Production costs, for example, are just one factor in consumer drug prices, and drug companies often use patents on popular products to charge high prices unrelated to the costs of production and testing.

What kinds of substances are being engineered into pharm and industrial crops?

The following is a list (gleaned from public sources including industry websites) of experimental pharmaceutical and industrial substances that have been produced in engineered crops. Many of them are bioactive and/or toxic. Currently, no drugs produced in genetically engineered plants are on the market.

Pharmaceuticals or drugs: Proteins for healing wounds and treating conditions such as anemia, liver cirrhosis, and cystic fibrosis; anticoagulants; blood substitutes; hormones; and enzymes to treat Fabry's and Gaucher's diseases.

Antibodies: Substances that home in on disease-causing molecules with great specificity. Examples include antibodies to fight cancer and tooth decay.

Vaccines: Substances to be injected or given orally to humans and animals to confer immunity to diseases, including non-Hodgkin's lymphoma, rabies, cholera, piglet diarrhea, and foot-and-mouth disease. So-called "edible" vaccines are fruits and vegetables engineered to contain vaccines that will be delivered by ingestion. Currently being developed to fight diseases such as hepatitis B, measles, and polio, as well as various types of viral diarrhea, edible vaccines were originally envisioned in whole foods such as tomatoes that can be eaten raw, but dosing and quality control considerations have led most developers to consider at least minimal processing of foods and batch production.

Industrial chemicals: Compounds used in the manufacture of products such as paper, plastics, personal care items, and laundry detergents. Examples are trypsin and laccase.

Research chemicals: Substances used in investigative and diagnostic laboratories. Examples include avidin and beta-glucuronidase.

SOURCES: Pew Initiative on Food and Biotechnology (PIFB). 2001. Harvest on the Horizon: Future Uses of Agricultural Biotechnology. Washington, DC: PIFB, pp. 53-63 and references therein; Union of Concerned Scientists (UCS). 2003. Pharm and Industrial Crops: the Next Wave of Agricultural Biotechnology. Washington, DC: UCS, pp. 3-4 and references therein, on the UCS website at *http://www.ucsusa.org/publication.cfm?publicationID=538*, accessed June 19, 2003.

"What kinds of substances are being engineered into pharm and industrial crops?" Many crops containing these genes have been tested in the open environment. Corn is the crop most widely tested for use as a pharm crop, but other food and feed crops including rice, potatoes, soybeans, tomatoes, and canola are also being used. Appendix B includes a list of transgenes from USDA field test records, among which are a number of transgenes intended for pharmaceutical use. Many other pharm crop transgenes have been tested but their identities are withheld from the public as confidential business information.

The production of drugs and industrial chemicals in corn and other food crops presents obvious risks.[50] If genes find their way from pharm crops to ordinary corn, they or their products could wind up in drug-laced corn flakes. In addition, crops that unintentionally contain drugs or plastics could also prove harmful to domestic animals that eat contaminated feed; to deer, mice, birds, and other wildlife that feed in pharm crop fields; or to organisms living in the soil.

The prospect of pharmaceutical genes contaminating the seeds we depend on for our food supply is genuinely troubling. If seeds are contaminated

50 Union of Concerned Scientists (UCS). 2003. Pharm and Industrial Crops: the Next Wave of Agricultural Biotechnology. Washington, DC: UCS, pp. 9-11 and references therein, on the UCS website at *http://www.ucsusa.org/publication.cfm?publicationid=538*, accessed on June 19, 2003.

with genes for drugs, farmers will unknowingly plant and harvest what could be very dangerous crops. The fact that many pharm crops will be planted on small acreage does not assuage the concern.[51] The StarLink incident described in Chapter 1 involved crops planted on less than 0.5 percent of U.S. corn acreage, yet the product ended up contaminating grain throughout the food system. Also affected were the seed stocks of at least 63 small and medium-sized seed companies—more than one-fifth of those contacted by the USDA in the course of the department's seed buyback.[52] StarLink genes may still contaminate the seed supply.

The likelihood that seeds would become contaminated with genes from pharm crops is difficult to assess. It will depend on how the seed contamination occurs (by physical mixing or outcrossing) and a number of other factors, such as whether fields intended for seed production or seed increase for food and feed crops are located close to areas where pharm crops are grown. More study is needed to understand how often seeds are contaminated and where in the seed production process contamination occurs. At this point, we do not have the information to be assured that pharmaceutical genes have not already moved into our food system.

Pharm and industrial crops, for the most part, remain in the early phases of development. At this point, we should still be able to control the risks of this technology by imposing a strong new regulatory system. Now that we recognize that seeds could become contaminated with pharm or industrial products during the field testing phase and that these genes could make their way into commercial agricultural production, we need to ensure that the seed supply for food crops is explicitly protected in the development of such regulations.

2. Food safety

The prospect of pervasive seed contamination raises food safety concerns for the future, although the particular genes detected in this study do not set off alarms.

There is no reason to believe that genetic sequences originating in transgenic crops *per se* render food unhealthful. Only if the genes or their products cause problems on ingestion is there a food safety hazard, a determination that needs to be made on a case-by-case basis.

The transgenically derived sequences detected in seeds of traditional varieties in this study include both regulatory sequences (e.g., promoters) and genes conferring the traits of interest from the two most popular kinds of transgenic products on the market today. These varieties have passed through the government oversight system for food safety, although only the Bt crops were formally approved for food use by a federal agency—the Environmental Protection Agency (EPA).[53]

Within the limits of that system, we have no evidence that these transgenically derived sequences are not safe and we do not believe

51 Field trials conducted before commercialization usually start with very small plots (less than 1 acre to 10 acres) but can increase dramatically as products get closer to market. At commercialization, some of these products—therapeutic vaccines and certain research chemicals, for example—will likely require only tens of acres to meet the specific demands of those particular markets. Other products, however, will necessitate much larger plantings, ranging up to hundreds of thousands of acres.

52 U.S. Department Agriculture (USDA). 2001. USDA purchases Cry9C affected corn seed from seed companies. USDA News Release, June 15, on the USDA website at *http://www.usda.gov/news/releases/2001/06/0101.htm*, accessed on November 14, 2003.

53 The EPA formally approves crops that are engineered to produce plant-incorporated protectants (PIPs) such as the Bt toxin. The agency does not regulate herbicide-resistant crops as PIPs. The Food and Drug Administration (FDA) does not formally approve genetically engineered crops; it merely encourages developers to engage in a voluntary consultation process after which the agency affirms that it has no questions about a biotechnology company's determination of product safety. (FDA. 1992. Statement of policy: foods derived from new plant varieties. *Federal Register* 57:22984-23005.)

their detection in this study raises food safety alarms. Given the lack of monitoring systems in the United States, lack of reported incidents is not strong evidence of lack of effect, but food ingredients made from these products have been consumed for several years without the emergence of overt problems connected to their origin via genetic engineering.

We do, however, have reservations about the safety of genetically modified food. Our concerns are related less to known problems with the products currently on the market than the lack of scientific rigor in the system evaluating their safety. We have long stressed the need for a mandatory system that would provide a government-backed finding of safety, and have urged the government to undertake or support new basic research to evaluate the potential hazards of genetically modified food (e.g., in the area of allergenicity).[54] As it stands now, the Food and Drug Administration (FDA) has little power to compel companies to submit food safety data and does not carry out independent, scientifically rigorous reviews of new transgenic food products.[55]

We do, however, have reservations about the safety of genetically modified food. Our concerns are related less to known problems with the products currently on the market than the lack of scientific rigor in the system evaluating their safety.

A new, stronger system would inspire a higher degree of public confidence in the safety of engineered foods, particularly those products that will be brought to market in the future. The system should be based on more rigorous science and include more tests for unexpected effects, as recommended recently by the Codex Alimentarius Commission, an international body that sets food safety standards under the auspices of the Food and Agriculture Organization and the World Health Organization.[56] The U.S. National Academy of Sciences recently conducted a study on the hazards and unintended impact of engineered food on human health, and is preparing a report expected to contain recommendations for improving the food safety assessment process.[57]

While most novel gene products will probably prove safe to consume as food and feed, such products are not inherently safe. For gene products that turn out to be harmful, the general concern in the seed contamination context is that the products will make their way into non-engineered seed varieties and be perpetuated in those crops by successive breeding cycles. The new products might not be readily identified as harmful because

54 Allergenicity is one of the major challenges in the evaluation of a genetically modified food's safety. Scientists currently have only limited ability to predict the allergenicity of a particular protein on the basis of its biophysical characteristics. As a result, the protocols used to screen for allergens on the basis of such characteristics are necessarily imperfect. The StarLink variety of Bt corn was denied approval for food uses because its Bt toxin failed screens for digestibility and heat stability. StarLink raises the question of whether other Bt toxins that passed the screens might nevertheless be allergens. It is difficult to resolve this question without a better understanding of food allergenicity. The failure to identify and remedy such a critical research need is a major flaw in the U.S. system overseeing genetically engineered food.

55 Gurian-Sherman, D. 2003. Holes in the Biotech Safety Net: FDA Policy Does Not Assure the Safety of Genetically Engineered Foods. Washington, DC: Center for Science in the Public Interest (CSPI), on the CSPI website at *http://cspinet.org/new/pdf/fda_report__final.pdf*, accessed on February 5, 2003.

56 Haslberger, A.G. 2003. Codex guidelines for GM foods include the analysis of unintended effects. *Nature Biotechnology* 21:739-741 (July).

57 National Academy of Sciences (NAS). 2003. Project title: unintended health effects of genetically engineered foods. Project Identification Number: BBXX-K-00-02-A. On the NAS website at *http://www4.nationalacademies.org/cp.nsf/projects+_by+_pin/bbxx-k-00-02-a?opendocument*, accessed on December 18, 2003.

they would occur sporadically in products not recognized as genetically engineered.

The degree of concern about potential contaminants of food and feed crops varies with their regulatory status and intended use. Transgenic products that have undergone government scrutiny for use in or as food and feed (e.g., for herbicide and insect resistance) tend to raise the least concern. These products were developed for human and animal consumption and have at least been evaluated at some level and screened for obvious problems.

Transgenic products that have not undergone food safety review but have been and are still being field tested raise more concern. Under the U.S. regulatory system, agencies do not analyze genetically modified crops for food safety until after they have undergone years of field testing. This means that transgenic crops are potentially available to contaminate the seed supply long before a decision has been made about their safety. Examples of engineered crops that have been field tested but not evaluated for food safety include rice resistant to fungal diseases and corn with modified oils, starches, and proteins.[58] Although not necessarily harmful, transgenic crop varieties that have not been scrutinized are of greater concern than scrutinized products because they have undergone no screen to remove dangerous transgenes.

Finally, gene products that are not intended for use in food raise the highest level of concern. They are unlikely to be reviewed for food safety at all, and many, such as pharm and industrial crops, are likely to produce bioactive and toxic compounds.

Ad hoc accumulation of several novel genes raises food safety concerns. In seed production systems that allow new genes to move into seeds via cross-pollination, every season offers new opportunities for the introduction of new traits. Single plants could accumulate and propagate several different novel traits over time, especially if they offer selective advantages. For example, in the short time that herbicide-resistant canola has been grown in Canada, genes for resistance to three different herbicides have accumulated in individual canola plants—whose offspring show up as weeds in fields planted with canola and other crops. Two of the resistance traits originated in engineered canola varieties and one came from a traditionally bred variety.[59]

Whatever food safety dangers may accompany the presence of single novel genes, combinations of genes raise new concerns. The combinations of traits would not likely have been reviewed by agencies for food safety and may present synergistic or otherwise unpredictable effects. Accumulation (or the natural stacking) of traits is most likely to occur in crops whose seeds are routinely saved and planted. Parental lines of hybrid crops or true-breeding crops such as canola or soybeans fit in this category.

3. The environment

The additional risk posed by a transgene contaminating traditional varieties of a crop is likely to be small where the transgene is already present in widely planted commercial varieties of the same crop. Seed contamination, however, offers new routes by which transgenes might make their way surreptitiously to new environments—with unknown effects.

Just as with food safety, the presence of engineered traits in the supply of traditional seeds is not *necessarily* a problem from an environmental

58 Information Systems for Biotechnology (ISB). 2003. Field Test Releases in the U.S. Blacksburg, VA: Virginia Polytechnic Institute and State University. On the ISB website at *http://www.isb.vt.edu/cfdocs/fieldtests1.cfm*, accessed on October 14, 2003.

59 Hall, L., K. Topinka, J. Huffman, L. Davis, and A. Good. 2000. Pollen flow between herbicide-resistant *Brassica napus* is the cause of multiple-resistant *B. napus* volunteers. *Weed Science* 48:688-694.

perspective. Nothing about genetic engineering suggests that in and of itself, gene products derived from transgenic crops constitute an environmental threat or that engineered sequences inevitably render non-engineered plants dangerous to the environment.

But, again, neither are all such crops inherently safe; some do present environmental risks. The nature and degree of these risks depend on the traits added, the plants to which they are added, and the environment within which the plants are situated. Environmental risks are complex in nature and highly context-dependent.

We address the risk issue here within the framework of our earlier report, *The Ecological Risks of Engineered Crops*.[60] That book organized the risks of genetically engineered crops around the notion of weeds—a generic term for plants unwanted by humans, whether in agricultural or nonagricultural settings. In this context, weeds include not only those plants that compete with crops but also those plants that degrade environments of value to humans. Thus, purple loosestrife that decreases the usability of a pond ecosystem by ducks, duckweed that clogs water channels, and kudzu that kills trees are all weeds.

The main environmental risk of genetically engineered crops is that they would become weeds or transfer traits to wild relatives that would become weeds. Whether crops become or give rise to weeds depends on the genes they carry and, importantly, where they are grown. Crops cannot contribute genes to wild and weedy relatives if none exist nearby.

One question here is what additional risk to the environment is posed by a transgene present as a contaminant in traditional varieties of a crop beyond the risks posed by the growth of commercial varieties containing the transgene already permitted in commerce. In general, as long as the level of contamination remains low, where the transgenes at issue have been allowed on the market and the varieties containing them are widely adopted, the increased exposure due to the contaminants in the seed supply is unlikely to substantially increase exposure to the transgenes or the overall risk. The increase in the levels of Bt toxin coming from contaminated corn seed, for example, will not add much to the overall pressure on the environment resulting from the stream of Bt toxins already in the environment due to commercial Bt products.[61]

In most cases, neither seed sellers nor farmers would be aware of the contaminant, which would undermine their ability to effectively manage for environmental risks.

On the other hand, seed contamination offers genes and gene products surreptitious paths to new environments. In most cases, neither seed sellers nor farmers would be aware of the contaminant, which would undermine their ability to effectively manage for environmental risks. The greatest risks would be associated with untested or disallowed genes, but even allowed genes might be a problem.

For example, transgenic salt-tolerant rice might be commercialized under conditions designed to keep the plants from invading coastal wetlands.

60 Rissler, J. and M. Mellon. 1996. *The Ecological Risks of Engineered Crops*. Cambridge, MA: MIT Press.

61 Contamination is also generally unlikely to reduce the performance of the crop. For example, a small amount of seed of a drought-tolerant variety planted along with seed of a non-drought-tolerant variety will not interfere with the field production of the non-tolerant variety.

If the transgenes for salt tolerance were to contaminate the traditional rice seed supply, however, their presence would not be known and no precautions taken. The contaminated rice seeds, finding their way to wetlands, could upset a delicate and important ecosystem. Furthermore, if the traits conferred a selective advantage, this would increase the prevalence of the transgenes in the new system.

It is also possible that plants from the transgenic contaminating seeds could breed with wild plants, transferring new traits into wild populations. The effects of such transfers depend on the traits, the receiving populations, and environmental pressures and stresses. But harmful effects are certainly possible.[62] The possibility that some of the large number of transgenes that have already been field tested in more than 40 food and feed crops may already be moving into wild plant populations is troubling.

In contrast to food and feed safety concerns, the relatively low level of contaminating transgenes found in any particular seed batch is not a limit on the amount of harm these transgenes can do in the environment. Considerations of ecological risk must take into account the ability of favorable environments to select for and increase the proportion of harmful transgenes in plant populations.

Contamination with transgenes from pharm and industrial crops raises environmental issues of special concern. These genes may be the sources of toxins that harm wildlife. In addition, toxin production is a common strategy by which plants protect themselves from predators, and pharm genes may provide selectable advantages in wild plant populations. If such transgenes are transferred from pharm crops to weedy relatives or used in crops that have tendencies to become weeds, they may enable crops to become weeds or make existing weeds more resilient and difficult to control.

For example, aprotinin, a cow protein that has human medical uses but is also an insect toxin, has been produced in engineered corn plants.[63] If aprotinin genes were to move from aprotinin-producing pharm crops into weedy relatives, the new genes might make the weeds hardier by enhancing their ability to withstand insect predation. The likelihood of pharm genes establishing themselves in weedy populations is enhanced where the pharm genes confer an advantageous trait such as insect resistance.

In contrast to food and feed safety concerns, the relatively low level of contaminating transgenes found in any particular seed batch is not a limit on the amount of harm these transgenes can do in the environment.

Seeds contaminated with Bt insect-resistance transgenes could also undermine the effectiveness of so-called resistance-management refuges. Refuges are non-engineered crops planted in the

62 Ellstrand, N.C., H.C. Prentice, and J.F. Hancock. 2002. Gene Flow and Introgression from Domesticated Plants into Their Wild Relatives. In *Horizontal Gene Transfer*, second edition, ed., M. Syvanen and C.I. Kado, 217-236. London: Academic Press.

63 Zhong, G.-Y., D. Peterson, D.E. Delaney, M. Bailey, D.R. Witcher, J.C. Register III, D. Bond, C.-P. Li, L. Marshall, E. Kulisek, D. Ritland, T. Meyer, E.E. Hood, and J.A. Howard. 1999. Commercial production of aprotinin in transgenic maize seeds. *Molecular Breeding* 5:345-356. A joint commercial research venture involving Pioneer Hi-Bred (a major seed company), Prodigene (a pharm crop company), and Eli Lilly (a major pharmaceutical company) has successfully engineered corn to synthesize aprotinin.

In general, seed contamination provides an avenue for release into the environment of genes and gene products that have not been evaluated or allowed in commerce and whose presence is unknown to farmers, regulators, or scientists. These may cause problems that are difficult to identify and remedy.

proximity of engineered Bt crops to slow the evolution of insect pests resistant to the Bt toxin. In theory, refuges work by allowing populations of susceptible pests to survive and mate with the relatively rare resistant pests. If the refuges are contaminated with Bt-producing plants, they would likely kill some susceptible pests, thereby aiding the emergence of Bt-resistant insects. Whether the presence of Bt transgenes in traditional varieties of crops would affect the efficacy of refuges would depend on the levels of contamination. Low levels of contamination would be unlikely to have much effect.

In general, seed contamination provides an avenue for release into the environment of genes and gene products that have not been evaluated or allowed in commerce and whose presence is unknown to farmers, regulators, or scientists. These may cause problems that are difficult to identify and remedy.

Finally, just as we noted about food safety, our concerns about the environmental risks of engineered crops are exacerbated by the federal government's weak regulatory oversight, its lack of scientific rigor in risk assessments, and its failure to adequately address unintended consequences. The National Academy of Sciences, in recent reports, has criticized both the USDA and the EPA—the two agencies charged with environmental oversight—for failing to develop strong, rigorous regulatory programs.[64]

4. Trade

Seed contamination exacerbates the difficulty of providing non-engineered products to demanding import customers.

Corn and soybeans are major export crops. The United States produces far more of these crops than its own economy can absorb, so it sells aggressively to the rest of the world. While engineered crops are popular among U.S., Argentinean, and Canadian farmers,[65] they are highly controversial in other parts of the world, most importantly among some of our major trading partners such as the European Union, Japan, and South Korea.[66]

Resistance in these and other countries has led to a complex set of serious problems for U.S. exporters,[67] most of which are the result of the

64 National Research Council. 2000. *Genetically Modified Pest-Protected Plants: Science and Regulation*. Washington, DC: National Academy Press; National Research Council. 2002. *Environmental Effects of Transgenic Plants: the Scope and Adequacy of Regulation*. Washington, DC: National Academy Press.

65 International Service for the Acquisition of Agri-biotech Applications (ISAAA). 2003. Global Status of GM Crops: Global Area of GM Crops in 2002. On the ISAAA website at *http://www.isaaa.org/kc/bin/gstats/briefs.htm*, accessed on June 17, 2003. The United States planted two-thirds of the global acreage of genetically engineered crops in 2002. Four countries accounted for 99 percent of the total: United States (66 percent), Argentina (23 percent), Canada (6 percent), China (4 percent).

66 The causes of this resistance are many and complicated. Some resistance stems from consumer concerns and some from desires to protect markets. In addition, genetic engineering has often been presented as an "our way or the highway" proposition, stirring up resentment in parts of the world concerned about looming U.S. hegemony. Finally, there are legal implications to contamination with products that have not been approved in other countries.

67 For more information on trade implications of genetically engineered contaminants, see Taylor, M.R. and J.S. Tick. 2003. Post Market Oversight of Biotech Foods: Is the System Prepared? Washington, DC: Pew Initiative on Food and Biotechnology, pp. 58-84.

United States' failure to supply non-engineered bulk products sufficiently free of transgenically derived sequences. This inability is somewhat surprising, considering that the United States, like any good marketer in a competitive industry, should want to satisfy customer demands and capture market share.

The United States grows substantial quantities of non-engineered and organic products that face no customer resistance anywhere in the world and which, in many cases, even command premium prices. But much of the non-engineered grain and oilseed is contaminated with varying levels of genetic sequences derived from engineered varieties. This would not matter if U.S. export customers tolerated contamination with engineered sequences to the same degree they tolerate contamination with other varieties or even other crops, but that is not the case. Many customers want grain or oilseed free of transgenic sequences, especially genes or gene products that have not been approved in their countries.[68] Meeting this demand has proved a difficult challenge.[69]

Most of the contamination of bulk grain and oilseed products is the result of physical mixing that occurs routinely within the infrastructure of trucks, ships, and grain elevators that moves commodity crops to market. In addition, the outcrossing of pollen from engineered plants into neighboring fields is unavoidable. The existing commodity infrastructure was never intended to transport different segregated streams of grain and oilseed from farms to food and feed processors. As long as the United States grows substantial acreages of engineered crops and does not alter its commodity infrastructure, it will not be able to readily provide uncontaminated commodity grain or oilseed product.

Seed contamination exacerbates the difficulty of keeping engineered genetic sequences out of non-engineered grain and oilseed. Even if growers seeking to export highly pure non-engineered commodity crops could start with pure seed, unreviewed or unwanted transgenic sequences could move into their products via mixing or outcrossing. But, when farmers start with contaminated seed, even the most innovative systems for moving segregated products to market are doomed. Such systems represent new market opportunities and are currently the focus of substantial investments.

It should also be noted that customer preferences are moving targets. If international customers grow more accepting of engineered grain and oilseed, the intermixing inevitable within the current commodity system would cause fewer problems for U.S. exports, and the importance of seed contamination as a contributor to trade problems would be diminished.

Global resistance to genetic engineering, on the other hand, could continue to stiffen and perhaps reach a point where the United States would have to retool parts of its commodity grain and oilseed infrastructure to enable the segregation of uncontaminated non-engineered products. As discussed earlier, the trend in U.S. agriculture is toward identity-preserved systems.[70] In this scenario, the value of pure non-engineered seed to U.S. exports would increase.

68 Demetrakakes, P. 2000. Processors are trying to gauge the meaning of the backlash against genetically modified crops. *Food Processing Magazine* (March 1). On the *Food Processing Magazine* website at *http://www.foodprocessing.com/web_first/fp.nsf/articleid/meat-4l8nvb*, accessed on November 14, 2003; McMillan, D. 1999. We must provide what customers want. *Western Producer* (September 2). On the *Western Producer* website at *http://www.producer.com/articles/19990902/market_quotas/opmcmillan.html*, accessed on November 14, 2003. Growers can have similar problems in the domestic U.S. market with demanding customers such as baby food manufacturers, many of which also prefer foods free of transgenically derived sequences.

69 *The Non-GMO Source*. 2001. Export buyers concerned about US ability to provide non-GMO. Volume 1, Number 3, pp. 1-3 (June). The inability to supply the products customers demand has lost the United States important markets, most notably in the European Union, but also in Japan.

70 Strayer, D. 2002. *Identity-Preserved Systems: A Reference Handbook*. Boca Raton, FL: CRC Press.

5. Organic food production

The contamination of traditional seed supplies undermines the future of organic agriculture.

Food products that bear the federal organic seal and label have met the U.S. government's standards for the growing and handling of organic food. The core organic standards restrict the use of synthetic pesticides and prohibit the use of irradiation, municipal sludge, and engineered seeds and other engineered inputs in food production. The combination of comprehensive and stringent standards and management systems that enable farmers to meet these standards comprises a holistic approach to food production that works in concert with the environment.

Food that meets organic standards generally commands a premium price in the marketplace. In fact, organic food has sufficient appeal that it is one of the few sectors of U.S. agriculture that is maintaining long-term, double-digit annual growth rates.[71] U.S. certified organic cropland and pasture more than doubled between 1992 and 2001, from fewer than one million acres in 1992 to 2.3 million acres in 2001.[72] Because the organic market offers a value-added product especially important for small and medium-sized farms, the potential loss of this market is of growing importance to U.S. agriculture.

Many organic buyers, processors, and consumers, like many U.S. export customers, are demanding a product free of transgenically derived sequences.[73] To the extent that U.S. organic farmers cannot meet that demand, consumers will go elsewhere or perhaps refuse to pay premium prices. The U.S. government, which touts its organic label as the equivalent of a label indicating the absence of genetically engineered sequences, also has an interest in helping organic growers meet the demand.

As discussed above, organic farmers are struggling to find uncontaminated seed. If they cannot purchase seed free of transgenically derived sequences or control post-planting outcrossing—neither of which is completely within their control—they will be unable to meet their own or larger societal demands for non-engineered food. Although it is only one part of the solution, the availability of seed free of engineered substances is essential to meeting consumer demand and preserving an increasingly important sector of U.S. agriculture.

Although it is only one part of the solution, the availability of seed free of engineered substances is essential to meeting consumer demand and preserving an increasingly important sector of U.S. agriculture.

71 Dimitri, C. and C. Greene. 2002. Recent Growth Patterns in the U.S. Organic Foods Market. USDA Economic Research Service (ERS), Market and Trade Economics Division and Resource Economics Division, Agriculture Information Bulletin Number 777 (September). On the USDA ERS website at *http://www.ers.usda.gov/publications/aib777/aib777.pdf*, accessed on December 15, 2003.

72 Dimitri, C. and C. Greene. 2002; Greene, C. and C. Dimitri. 2003. Organic agriculture: gaining ground. *Amber Waves: the Economics of Food, Farming, Natural Resources, and Rural America* (February). On the USDA ERS website at *http://www.ers.usda.gov/amberwaves/feb03/findings/organicagriculture.htm*, accessed on December 15, 2003.

73 Yates, S. 1999. Exported corn chips tainted with GMOs. *Natural Foods Merchandiser* (April). On the New Hope Natural Media website at *http://exchange.healthwell.com/nfm-online/nfm_backs/apr_99/cornchips.cfm*, accessed on May 10, 2003; *The Non-GMO Source*. 2002. Organic farmers report increasing problems with GMO contamination. Volume 2, Number 12, pp. 1-2 (December). Although organic standards do not strictly require a product free of genetic engineering, organic farmers are in a bind because they cannot control the contamination caused by outcrossing originating in their neighbors' fields. They can and have been severely penalized in the marketplace when, through no fault of their own, their harvested products contained traits they did not plant.

6. Intellectual property

Contamination of non-engineered seeds subjects farmers who have never purchased engineered seeds to the intellectual property laws.

The pervasive contamination of seeds may also have patent implications for farmers who inadvertently plant and harvest seed containing transgenically derived sequences. Under U.S. intellectual property laws, genes, gene products, and engineered crops are now considered patentable subject matter—just like windshield wipers or clocks.[74] Where patents apply, it is illegal for others to make, use, or sell the invention during the term of the patent without permission from the patent holder. To do so could subject the infringer to lawsuits and stiff penalties.

An important feature of the patent law is that infringement does not require intent. Farmers who use genes or seeds patented by others can be sued even if they did not know they were using the invention. While the law is murky, pervasive seed contamination would appear to put farmers at risk of unknowingly infringing the patents held by biotechnology companies. The threat of patent holders pursuing infringement claims against farmers who inadvertently purchased contaminated seed seems counterintuitive, but it is not impossible. Monsanto, for example, has not been shy about bringing suits against farmers for patent infringement, despite having provoked widespread anger and resentment in rural America.[75]

7. The food system

Seeds contaminated with transgenically derived sequences add a new source of potential food system disruption to the already difficult problems posed by bulk contamination.

The presence of unapproved genes and gene products would of course play havoc with the food system if the traits they confer proved to be harmful, but this could be the case even if they were not harmful. In general, food handlers and processors are not allowed to sell food considered to be adulterated under the provisions of the Federal Food, Drug and Cosmetic Act (FFDCA). Food may be considered adulterated for many reasons, including the presence of either pesticidal substances for which the government has not set a tolerance[76] or unapproved food additives.[77] Products of genetic engineering could fall in either category.

The StarLink episode discussed in Chapter 1 illustrates just how disruptive the presence of an unapproved pesticidal product in the grain and food system can be. The EPA had approved StarLink (a variety of corn engineered to contain a pesticidal Bt toxin) for animal feed but not human food in 1997. The announcement that StarLink corn had been found in taco shells in 2000 set into motion widespread product recalls. Without a tolerance set by the EPA, the presence of the Bt pesticide rendered food adulterated under the FFDCA and therefore illegal.[78] The

74 Diamond v. Chakrabarty, 447 U.S. 303 (1980).

75 Monsanto still suing Nelsons, other growers. Cropchoice.com (May 21). On the Cropchoice.com website at *http://www.cropchoice.com/leadstry.asp?recid=326*, accessed on June 23, 2003.

76 21 U.S.C. 342(a)(2), 346.

77 21 U.S.C. 342(a)(2), 348.

78 21 U.S.C. 346a(a)(1).

recalls set off an expensive chain of events as grain sellers and food handlers had to test and divert contaminated lots of grain.[79]

The sources of transgenes that may move into the food supply and trigger similar disruptive events include food crops grown for non-food purposes (for example, corn used as a pharm crop) and engineered crop varieties in the early stages of development prior to commercialization. Transgenes from these sources might be physically mixed with or outcross into food crops destined for the food system, where they could cause widespread disruption including recalls and lawsuits if discovered.

Seed contamination would exacerbate this problem by making it even more difficult for growers and food companies to know the exact composition of the products they buy and sell.

8. Agriculture of developing countries

Contamination of non-engineered seed in the United States may increase the unpredictability of agriculture in developing countries and may lead to or exacerbate contamination of traditional crop varieties, landraces, and wild progenitors in centers of diversity.

There are two ways that seeds contaminated with engineered sequences could make their way to developing countries: as seeds for planting or as bulk products, which are made up of viable seeds. In developing countries, it is highly likely that seeds purchased as commodity products will be planted by farmers as seeds.

Unsuspecting purchasers of potentially contaminated traditional seed in developing countries will take no precautions to prevent the flow of transgenes into nearby crops and wild and weedy relatives via outcrossing. Since U.S. seeds could be contaminated with many kinds of genes, the consequences of gene movement are difficult to predict. Transgenes that confer fitness benefits on plants can become fixed in plant populations and increase in frequency in successive generations.[80] Thus, seed contamination could become a conduit for new genes—some of which may be harmful to human health or the environment—into wild and weedy plants.

Unsuspecting purchasers of potentially contaminated traditional seed in developing countries will take no precautions to prevent the flow of transgenes into nearby crops and wild and weedy relatives via outcrossing.

In general, the most unsettling aspect of seed contamination for producers in the developing world is that there is no way to evaluate, monitor, or avoid such movements because they would occur surreptitiously. Where transgenes move into other varieties or landraces,[81] they could lead to unpleasant—and expensive—surprises. For example, if herbicide-resistance genes move into crop varieties, farmers may find that costly

79 The StarLink-related losses for food recalls, lost sales, payments to farmers and grain elevators, and seed buybacks amounted to hundreds of millions of dollars. The USDA ended up bailing out seed companies involved in the effort to contain the contaminants. Demand for U.S. corn abroad plummeted. (Gillis, J. 2003. Little oversight of altered crops. *Washington Post* [April 25]; Howie, M. 2003. Non-StarLink growers reach class action settlement. *Feedstuffs* [February 24], p. 23; Lambrecht, B. 2001. *Dinner at the New Gene Café.* New York, NY: St. Martin's Press, pp. 51-55; Taylor, M.R. and J.S. Tick. 2003, pp. 90-105.)

80 Ellstrand, N.C. et al. 2002. Where gene flow is recurrent, even traits with detrimental effects can persist in a plant population.

81 Landraces are plants selected by traditional farmers from wild populations.

herbicides do not work. Or, if seeds of traditional corn varieties are contaminated with the Bt toxin gene, farmers may find that the crop unexpectedly kills beneficial insects.

The impact of contaminated seed must be considered against the backdrop of genetically engineered varieties that enter a country legally and fully disclosed as a bulk commodity product. It is likely, for example, that Bt transgenes in Bt crop varieties diverted for use as seed would flow through pollen into neighboring crop varieties, landraces, and wild relatives. For popular transgenes such as Bt, the seed diverted from transgenic varieties of commodity crops is likely to be a greater source of novel genes in developing countries than those same transgenes occasionally contaminating seeds of traditional varieties.

The 2001 discovery that landraces of corn in Mexico are contaminated with genetic sequences that originated in engineered corn varieties from the United States underscores the difficulty of confining transgenes used in agriculture.[82] Subsequent studies have confirmed and extended those findings.[83] It is not clear how the genes traveled to Mexico—whether seeds unapproved in Mexico were sold on the black market or bulk products imported from the United States[84] were diverted and used as seed. The Mexican government is attempting to assess the causes and consequences of this finding.[85]

The unexpectedly rapid dispersal of transgenes to Mexico only a few years after their first commercial use in the United States deserves immediate attention from the scientific community because Mexico is the center of diversity[86] for corn, one of the world's most important food crops. Teosinte, the crop's wild progenitor, can be found growing in Mexican cornfields, and whatever novel genes are found in Mexican landraces are also likely to be transferred into teosinte plants via pollen. While it is impossible with our current level of knowledge to assess the impact of novel genes on teosinte populations, the potential contamination of such important populations of wild plants points to the need for additional research.[87]

The ongoing situation in Mexico highlights the ease with which novel genes and traits can move through agricultural varieties into wild plant populations, including the vital populations that are the centers of diversity for important crops.

9. Seed repositories

If transgenes continue to move into the commercial seed supply of traditional crop varieties, seed repositories may also become pervasively contaminated with a variety of novel genes.

Ongoing contamination of the commercial seed supply could gradually undermine the quality of our communal genetic storehouse

82 Quist, D. and I. Chapela. 2001. Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico. *Nature* 414:541-543 (November 29).

83 Alvarez-Morales, A. 2002. Transgenes in maize landraces in Oaxaca: Official report on the extent and implications. Abstract of presentation at the 7th International Symposium on the Biosafety of Genetically Modified Organisms, Beijing. On the 7th International Symposium website at *http://www.worldbiosafety.net/title%20paper.htm*, accessed on August 14, 2003.

84 Weiner, T. 2002. In corn's cradle, U.S. imports bury family farms. *New York Times* (February 26). Mexico imports about one-fourth of its corn from the United States.

85 Alvarez-Morales, A. 2002.

86 Centers of diversity are regions around the world that harbor populations of free-living relatives of crops. These populations serve as reservoirs of genes that can be moved into crops by traditional breeders.

87 Sánchez-González, J. 2002. Concerns about the effect of transgene introgression in maize landraces and teosinte. Abstract of presentation at the 7th International Symposium on the Biosafety of Genetically Modified Organisms, Beijing. On the 7th International Symposium website at *http://www.worldbiosafety.net/title%20paper.htm*, accessed on August 14, 2003.

for agricultural crops. Nothing is more fundamental to the future of our agriculture and food system than a continued supply of safe, high-quality seed.

The prowess of genetic engineers notwithstanding, seeds cannot be made from scratch. They must be produced generation after generation through highly complex, natural biological processes. The value to food and fiber production embodied in the seeds entrusted to our generation cannot be overstated.

Plant genetic storehouses are maintained through dynamic processes that involve saving, selecting, and storing seeds.[88] A number of groups and institutions are involved in this process. First, as we discussed above, commercial seed companies develop and sell seeds for crop varieties destined for fields or home gardens, in some cases in cooperation with farmers, gardeners, and scientists.[89]

Public-sector plant breeders also develop new varieties, although their role has diminished over the last several decades.[90] Despite the overall decline in university and other public-sector breeding programs, there are new projects under way in land-grant university systems, including the Public Seed Initiative, a joint venture among Cornell University, the USDA, and two organic farming groups.[91]

Farmers also continue to be active in seed selection and preservation. In fact, most of the world's farmers do not have access to commercial seed products and save seeds every season for planting the next season.

In addition to seed stores that are actively managed by companies, scientists, and farmers, some seeds are gathered and kept in repositories called seed banks. Some of the most important seed banks house collections managed by international organizations such as the Consultative Group on International Agricultural Research.[92] These seeds contain genes for valuable traits and combinations of traits that have been selected in a process spanning countless generations. Seed banks are not static collections; the seeds are often removed and planted, and their progeny returned to the seed bank.

Although motley and uneven in its importance to different farmers and gardeners, the sprawling network of seed repositories is vital to the quality and resilience of our food supply. Its importance suggests that we should be highly conservative in our judgment about potential threats to its integrity.

Contamination of seed repositories by transgenically derived sequences is not theoretical. The Charles M. Rick Tomato Genetics Resource Center at the University of California, Davis, recently reported that its seed stock had become contaminated with transgenes originating in a tomato variety engineered to alter processing characteristics. Seed bank officials moved immediately to recall contaminated seed samples that had been sent to researchers in the United States and 14 other countries since 1996.[93]

The magnitude of the threat posed by transgenically derived sequences is not known at this

88 Periodic planting and seed harvesting to replenish stores and increase viability provides opportunities for contamination.

89 Wheat breeding is a good example of companies, farmers, and university scientists working together.

90 Knight, J. 2003. A dying breed. *Nature* 421:568-570 (February 6).

91 See the Public Seed Initiative website at *http://www.plbr.cornell.edu/psi*.

92 For more detail, see the Consultative Group on International Agricultural Research website at *http://www.cgiar.org/research/res_genebanks.html.*

93 University of California (UC), Davis. 2003. Tomato seed from seed bank found to be genetically modified. Press release, UC Davis News and Information, December 18, on the UC Davis website at *http://www.news.ucdavis.edu/search/printable_news.lasso?id=6833&table=news*, accessed on December 19, 2003.

point. As we discussed above, engineered traits *per se* are not necessarily a problem from either an environmental or human health standpoint. Agricultural scientists do not knowingly create harmful varieties (other than, perhaps, for pharm and industrial crops.) Eventually, if engineered varieties are used for a long period without ill effect, seeds from certain engineered varieties will likely be added to seed collections intentionally.

Our experience with transgenic crops to date seems encouraging, but it is limited to a few traits in a few commodity crops. Pharm and industrial crops and other new products[94] dramatically different from Bt and herbicide-resistant products are on the cusp of development, and these engineered crops will exhibit new traits and other features that may warrant a higher level of concern than the first generation of transgenic crops.

At this juncture, there remains the remote possibility that the current assurances of safety may be proven wrong—that interfering with natural genetic systems could be setting something seriously amiss. We may be violating rules we do not know exist, passing transgenic sequences into food crops that are in some way generally debilitating, but that we have not yet noticed. Such effects may be accumulating gradually or may need to reach some threshold to manifest themselves.

Until we gain a better understanding of genetic engineering, it is premature to allow transgenically derived DNA and transgenic seeds to creep unobserved into seed repositories.

94 For a discussion of potential new kinds of engineered crops, see Wolfenbarger, L., ed. 2002. Proceedings of a Workshop on Criteria for Field Testing of Plants with Engineered Regulatory, Metabolic and Signaling Pathways, June 3-4, 2002. Blacksburg, VA: Information Systems for Biotechnology (ISB), Virginia Polytechnic Institute and State University. On the ISB website at *http://www.isb.vt.edu/proceedings02/the_proceedings02.pdf*, accessed on August 14, 2003.

Chapter 4

Conclusions and Recommendations

CONCLUSIONS

The results of the pilot study presented in this report suggest that seeds of traditional varieties of corn, soybean, and canola sold to growers in the United States contain low levels of genetic sequences that originated in engineered crops. Because we tested seeds of varieties representative of a substantial portion of the 2002 traditional seed supply, we believe that contamination is not an isolated phenomenon but is endemic to the system.

Widespread contamination with genetically modified sequences suggests that production systems for seed sold in the United States are porous—that is, as currently designed and operated, these systems routinely allow contamination by other crop varieties, including engineered varieties. Unless these standard procedures are tightened, there is little reason to believe that the current level of contamination will decrease. Business-as-usual seed production ensures the perpetuation of contamination and a probable increase in the level and extent of contamination. This is a critical moment for the growers, traders, and food companies who are bearing the managerial costs of testing and segregation, and who will incur liability if incidents similar to StarLink occur again.

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In percentage terms, the reported levels of contamination are very low. Nevertheless, as illustrated in Chapter 2, such levels could result in tons of genetically engineered seed being planted each year intermixed with non-engineered seed.

Current concerns: food safety, environment, trade

Today, there is no reason to believe that low-level contamination of non-engineered food crops with genetic sequences from the two kinds of transgenic crops (Bt and herbicide-resistant) detected in the study represents a major threat to human health or the environment. The crops have undergone federal review, and while we agree with the National Academy of Sciences reports indicating that the U.S. regulatory system is not as rigorous as it should be, we do not believe this report justifies raising alarms about the currently unresolved food safety or environmental issues surrounding these crops. Since genetically engineered crops expressing these traits already represent a substantial portion of the grains and oilseeds produced in the United States, the additional presence of contaminants in non-engineered versions of those crops probably represents a marginal increase in dietary or environmental exposure.

Any assurances about food, feed, and environmental safety, of course, apply only to transgenes that can be detected through testing.

Unfortunately, for practical reasons, many transgenes—including those that have not survived the development process—cannot be detected with PCR-based tests. There are hundreds of such transgenes, some known to the public and some whose identities have been withheld as confidential business information. Field tests of these genetically engineered crops have been conducted for more than a decade in geographic regions where seed production occurs, and the transgenes in these tests represent a potentially large source of contamination.

This study's results should intensify the concerns of consumers who want to avoid genetically engineered foods for ethical, religious, or other reasons. In the United States, where purveyors of food need not disclose the presence of genetically engineered components, such consumers are already deeply frustrated by the lack of information in the marketplace. Contamination of traditional crop varieties with genetically engineered seeds and transgenic sequences only increases the difficulties consumers face.

In the trade arena, the study underscores the point that as long as the United States grows substantial acreages of engineered crop varieties and does not alter its commodity system (including the seed production system), it will not be able to provide uncontaminated commodity grain or oilseed products for any purpose. The lack of this capacity limits the attractiveness of U.S. products in the international marketplace.

Future concerns: pharm/industrial crops

The most urgent concern arising from this study does not relate to the current generation of products but to future products, in particular pharm and industrial crops. Many of these gene products would obviously be harmful if they were to appear at high levels in food or the environment. If, as the study suggests, the current seed production process is porous to contaminants, it offers a wide conduit through which the genes for pharm and industrial products may find their way into our food and feed systems or environment.

Industry and policy makers interested in pharm and industrial crops should receive this pilot study's message as a wake-up call: The seed supply for major food crops in the United States is vulnerable to contamination with drugs and industrial substances.

The result of such dangerous substances moving from seeds to consumers could be a disaster for human health. In addition, the economic impact of such an incident would ripple through the U.S. food chain, affecting millers, crushers, and retailers. The possibility that exported grain could be contaminated with substances such as drugs or plastics would further unnerve already wary foreign customers. In short, a contamination crisis similar to StarLink but involving drugs or industrial chemicals could set back, and perhaps even permanently derail, the U.S. agricultural biotechnology industry.

Industry and policy makers interested in pharm and industrial crops should receive this pilot study's message as a wake-up call: The seed supply for major food crops in the United States is vulnerable to contamination with drugs and industrial substances. Until we begin to address the problem of seed contamination, we must assume that pharm and industrial genes introduced into crops could become low-level contaminants of non-engineered seeds (or even other

genetically engineered seeds). As time passes and more transgenes for drugs and industrial chemicals are engineered into plants and tested in the environment, seeds may accumulate higher levels and a greater variety of these foreign genes and sequences.

Time to act

The current government approach to the contamination of bulk grain and oilseed products, landraces, or seeds appears ostrich-like: putting heads in the sand and hoping the phenomenon will go away.

But it will not.

Potential buyers of U.S. export products care about engineered contaminants for a number of legal, cultural, and other reasons and have plenty of other sellers to whom they can turn if the United States cannot meet their demands. From a health and environment standpoint, concerns cannot be written off simply because the levels of transgenically derived sequences are low; novel bioactive substances synthesized in transgenic pharm crops can do damage even at low levels. Moreover, transgenes that escape from the agricultural setting can be propagated in the environment and, in some cases, their levels could increase as a result of natural selection.

The fact—and possible consequences—of contamination can no longer be ignored. These concerns, especially where untested, unapproved substances intended as drugs or industrial chemicals are involved, hang like an ominous cloud over the future of agricultural biotechnology and the global food system.

RECOMMENDATIONS

The contamination of seeds of traditional crop varieties with transgenically derived DNA sequences must be addressed right away. The Union of Concerned Scientists recommends the following actions:

1. The USDA should sponsor a full-scale investigation of the extent, causes, and impacts of contamination of the traditional seed supply by transgenically derived DNA sequences.

The USDA should follow up this pilot study with a full-scale investigation of the extent, causes, and impacts of contamination of the traditional seed supply by DNA sequences originating in genetically modified organisms. This government-sponsored investigation should include traditional varieties of cotton, corn, canola, soybeans, and wheat, as well as fruits and vegetables for which genetically engineered varieties have been field tested. Although it has not been commercialized, genetically engineered wheat has been extensively field tested without stringent measures in place to guard against seed contamination. The USDA should look for contaminants originating in

The fact—and possible consequences—of contamination can no longer be ignored. These concerns, especially where untested, unapproved substances intended as drugs or industrial chemicals are involved, hang like an ominous cloud over the future of agricultural biotechnology and the global food system.

transgenic crop varieties that are being field tested, as well as in those that have been commercialized.

The investigation should encompass a sufficient number of samples taken from many seed sources in many parts of the country to ensure that its results will be representative of the general state of the traditional seed supply. The sample sizes should be large enough to provide reliable estimates of the extent and levels of contamination.

To address and eventually control contamination of the traditional seed supply by transgenically derived sequences, it is important to know why and where contamination occurs. There are basically two potential sources of contamination: physical mixing and outcrossing, both of which can occur at a number of points within the seed production process. New research should assess how mixing and outcrossing contribute to seed contamination across the entire spectrum of activities associated with seed production.

Special attention should be paid to understanding the points at which seed production would be vulnerable to contamination by pharm and industrial crops. That will allow scientists to devise strategies to control and prevent contamination in the future (see Recommendation 2).

The needed research is extensive. It must encompass seed production of major commodity crops at corporations, universities, on farms, and among national and international institutions. We recommend that the USDA fund the National Academy of Sciences Standing Committee on Agricultural Biotechnology, Health, and the Environment for the purpose of convening an expert panel to develop the scope and agenda for this research.

2. The USDA, FDA, EPA, and appropriate coordinating elements of the federal government should amend the regulations for transgenic pharm and industrial crops to ensure that the seed supply for food and feed crops is not contaminated at any level with drugs, vaccines, plastics, or related substances.

Protection of U.S. food and feed crops, as well as bulk food products, should be given the highest priority by the federal government in the coming year. We recommend that the USDA, FDA, EPA, and appropriate coordinating elements of the government amend pharm and industrial crop regulations to ensure that the seed supply for food and feed crops is completely protected against contamination with non-food transgenes and transgene products such as drugs, vaccines, plastics, and related substances.

This is a rigorous standard that is best achieved if pharm and industrial crops are regarded as a drug-manufacturing activity rather than a sideline of commodity crop production. Complete protection of the food supply against pharm and industrial crop contamination may not be achievable if food crops continue to be used as pharm and industrial crops.

Pharm and industrial crops have been planted without adequate control for more than a decade now, and only recently has the federal government awakened to the need for stronger regulation. The USDA recently imposed more rigorous containment procedures on the growing of pharmaceutical and industrial crops, but these new regulations do not even mention, much less address, the issue of seed supply contamination.

The USDA must amend existing pharm and industrial crop rules to deal with this issue and establish new restrictions based on an understanding of the points at which the seed production system is vulnerable to contamination. Such understanding will be the fruit of the additional studies recommended above. In the meantime, we recommend that the USDA immediately require short-term protections for the seed supply, such as

requirements that pharm and industrial crops not be grown on or near farm operations that also produce seed.

3. The USDA should establish a reservoir of seeds for non-engineered varieties of major food and feed crops free of transgenically derived sequences.

If the seed supply for major crops continues to be contaminated with genetic sequences derived from transgenic crops, it will become increasingly difficult to remove them from food, feed, or industrial systems should that become necessary or desirable. We believe the minimally prudent course is to have the USDA establish a reservoir of seeds for non-engineered varieties of major food and feed crops free of engineered sequences.

The appeal of a seed reservoir is that we would not be committing ourselves to a single path before we are sure it is the right one. If something does go wrong with genetic engineering, we will be able to shift onto a new course. Moreover, as discussed earlier, there are now and will likely continue to be trade and marketing advantages in our ability to reliably produce non-engineered products, but this will require the availability of uncontaminated seed for traditional crop varieties.

Setting up a reservoir of traditional seeds virtually free of engineered contaminants a decade and a half after the introduction of transgenic crops will be a challenge, but it is achievable. With careful attention to seed sources and strict new protocols for seed production, it should be possible to create breeder seed supplies that are free of genetically engineered sequences. Even if restoring the seed supply to a completely pristine state proves impossible, it will still be important to set up a seed reservoir with the lowest achievable amounts of contamination. The quantity of contamination matters; low levels of one or two transgenes are far better than high levels of hundreds of transgenes, especially pharm and industrial genes.

We recommend that the USDA develop a program that would ensure an uncontaminated supply of seeds for a long enough period to give us confidence in this new technology. Although any number is arbitrary, we suggest that 30 years might be appropriate.

4. The USDA and land-grant (agricultural) universities should reinvigorate the public plant breeding establishment to help ensure a supply of pure seed of traditional crop varieties.

One of the major trends of the last century has been the transformation of plant breeding from a publicly supported activity to a private one. Since private breeding is now conducted primarily by a handful of transnational companies, and those companies have switched almost completely to genetically engineered varieties of crops, a reinvigorated public plant breeding establishment is vital to the continued development of non-genetically modified varieties for commodity crops.

For public plant breeding to flourish, the USDA and land-grant universities must acknowledge the importance of plant variety development outside the confines of private corporations. They need to support genetic engineers who want to investigate crops and pursue projects that do not receive industry support. Even more urgently, the USDA needs once again to train classical breeders —as well as the soil scientists, plant pathologists, and agronomists on whom they depend—to provide the expertise necessary for the continued provision of non-genetically engineered seed. Public plant breeders would assist and cooperate with the Consultative Group on International Agricultural Research, international plant breeding institutions, farmer groups, and the many

volunteer "seed savers" who also participate in the global seed-producing enterprise.

5. The Association of Official Seed Certifying Agencies (AOSCA) should establish a national standard for breeder and foundation seed of traditional crop varieties: no detectable level of contamination by transgenes and associated sequences originating in genetically engineered crops.

Breeder and foundation seeds for commercial crops are key elements of our food and feed system. To give farmers opportunities to meet the demands of diverse domestic and global marketplaces, and to help create a national reservoir of non-engineered seed, it is important for the seed industry to establish standards assuring seed purchasers that non-transgenic seeds free of modified sequences are available.

We therefore recommend that the AOSCA establish a national standard of no detectable transgenically derived sequences in the breeder and foundation seeds for non-engineered varieties of major crops. The standard should specify appropriate tests such as PCR or other state-of-the-art methodologies.

6. The USDA, the organic agriculture community, land-grant universities, and plant breeders should develop new policies and programs to provide organic agriculture with pure seeds of traditional crop varieties.

Organic farming is one of the fastest-growing sectors of American agriculture, leading the way in the development of value-added food systems and providing new and growing opportunities for all sizes of farm operations. If organic agriculture is to reach its maximum potential, the USDA, land-grant universities, plant breeders, and the organic agriculture community itself should develop policies and programs that will ensure food and feed meet federal and international organic standards and any additional demands imposed by buyers of organic grain.

Essential to that effort is a guaranteed supply of uncontaminated seed for traditional crop varieties. The best way to provide this seed is in the context of partnerships among growers, public plant breeders, and agricultural scientists put together to select, test, and propagate seed tailored to the needs of organic agriculture. Promising initiatives along these lines are under way at Cornell and a handful of other universities mentioned in Chapter 3. We recommend adding the provision of seed for organic producers to the mission of these enterprises, and giving them the resources to accomplish this task.

Of course, while necessary, the provision of uncontaminated seed for organic agriculture is not sufficient to guarantee organic food and feed free of genetically engineered contaminants. That requires additional measures to address the problem of pollen inflow from engineered crops on neighboring fields. Individual organic farmers cannot stop this unwelcome arrival of pollen, which can degrade the quality of their products and put their certification as organic growers in jeopardy.

In the meantime, we recommend that consumers continue to purchase organic foods and support organic agriculture. Despite their best efforts, some organic producers may occasionally end up with products containing low levels of genetically engineered sequences, but this is the exception, not the rule. Organic producers are working hard to control sources of contamination and certified organic food remains the best marketplace option by far for consumers who demand uncontaminated products.

7. The USDA, the organic and biotechnology industries, and national growers' associations,

among others, should sponsor a series of meetings to begin addressing how those sectors of U.S. agriculture that have adopted transgenic crops and those threatened by contamination with transgenically derived DNA sequences from those crops can coexist.

Widespread use of transgenic crops will inevitably result in the transfer via pollen of engineered sequences and traits to compatible crops in nearby fields. If the growers of those nearby crops are attempting to harvest a product free of genetically engineered sequences, this unwanted contamination can have serious economic consequences. Whether facing an exacting customer in South Korea or an organic certifier, farmers in the receiving fields risk losing money if they try to market their contaminated crop.

This situation creates tension among producers. Who will accept responsibility and/or legal liability for the economic losses? Who will be accountable for the predictable results of choosing particular varieties? What sort of testing is currently done by growers and is there a way of spreading the costs of that testing?

European countries have identified the coexistence of agriculture sectors affected by the use of transgenic crops (both positively and negatively) as an important step to a prosperous and safe future, and set up a series of workshops to address these problems. Coexistence issues extend beyond seed production, but a series of similar conferences encompassing seed production would also have great value in the United States, particularly if they were sponsored by stakeholder groups including the organic community, national growers' associations, land-grant universities, and the USDA.

8. Private seed companies in the United States should periodically test their seed stocks, especially breeder and foundation seed and parental inbred lines, for the presence of transgenically derived DNA sequences. They should then make public the extent to which the seeds of the traditional varieties they market are free of transgenically derived contaminants.

Private seed companies in the United States could play a leading role in the effort to cleanse the seed supply for traditional varieties of crops by periodically testing their own breeder and foundation seed and parental inbred lines for the presence of transgenic seeds and transgenically derived sequences. In conjunction with that effort, these companies should then publicize their results.

The aggregate of the published results would provide a rough indication of the extent to which the U.S. supply of seeds for traditional varieties is contaminated and the progress being made in reducing contamination. Companies whose foundation and breeder seed stocks and parental inbred lines are free of transgenically derived DNA sequences should be proud to make that fact public.

Appendix A

Plant Breeding and Seed Production in Corn, Soybeans, and Canola

Below is a brief discussion of plant breeding and seed production in corn, soybeans, and canola.[95] See Figure 1-1 (p. 8) for a simplified diagram of the steps involved in the breeding and commercial seed production of a new crop variety.

DEVELOPING NEW COMMERCIAL VARIETIES

Until roughly the last 100 years, most plant breeding in the United States was undertaken by farmers, and in much of the world, farmers remain the plant breeders for important crops. Even in the United States, where commercial breeding is well established, plant breeding by farmers and gardeners continues to flourish.[96]

Early on in agriculture, farmers selected plants with favorable characteristics and saved their seed to plant in subsequent growing seasons. These farmer-selected plant types are called landraces.

Modern plant breeders, capitalizing on dramatic advances in genetics in the twentieth century, have raised plant breeding to a new level of sophistication. With the ability to identify, categorize, and characterize the genetic material of plants, breeders can select plants that have valuable new characteristics, cross-breed them with other varieties that have important agronomic traits, and find among the offspring plants exhibiting new combinations of desirable traits—in some cases, traits better than either parent. Promising offspring are tested and those that perform well in the field are sent into commercial seed-production processes. While still an art in some ways, traditional plant breeding has proved to be immensely successful and is responsible, to a great extent, for the significant productivity gains achieved in agriculture in the last century.

Sources of new traits

Farmers and commercial breeders rely primarily on the natural recombination resulting from sexual reproduction as the source of new traits for their breeding work. Sexual reproduction in plants involves the production of offspring through the combination of pollen from the male parent and eggs from the female parent. This process mixes genetic sequences from different parents, and every generation produces new combinations, some of which result in valuable traits such as increased yield or synchronous growth. Plants expressing these new traits are the raw material for a breeding program.

During the last two decades, genetic engineering techniques have begun to provide plant breeders with another source of new traits: genes taken from unrelated organisms. Methods such as mutagenesis, which induce changes in plant genes using chemicals or radiation, have been tried in the past but are rarely used anymore. Promising new approaches involving combinations of breeding and sophisticated genomic analysis,

95 We are grateful to Dr. Kendall Lamkey, professor, Department of Agronomy, Iowa State University, for helpful information on breeding and seed production, particularly in corn. For additional information, see Wych, R.D. 1988. Production of Hybrid Seed Corn. In *Corn and Corn Improvement*, agronomy monograph 18, ed., G.F. Sprague and J.W. Dudley, 565-607. Madison, WI: American Society of Agronomy; and Fehr, W.R. 1987. Breeding Methods for Cultivar Development. In *Soybeans: Improvement, Production, and Uses*, agronomy monograph 16, ed., J.R. Wilcox, 249-293. Madison, WI: American Society of Agronomy.

96 See Seed Savers Exchange at *http://www.seedsavers.org/wholepgs/Mainpgs/aboutus.htm* and Seed Savers Network at *http://www.seedsavers.net*.

though in the early stages of development, may become important in the future.

Testing new commercial varieties

Though some early steps in the breeding process of crops such as wheat and oats can be done in greenhouses, most breeding of traditional varieties of crops including corn and soybeans—which are not amenable to breeding in greenhouses—is done in the field. When transgenic varieties are being developed, the genetic engineering phase must of course be done in the laboratory, but once the genetic engineers have a plant expressing a transgenic construct, traditional breeders take over and complete the variety development process.

Breeders evaluate the new plant material in field tests, which may run from one to hundreds of acres and may be conducted in several different geographic locations to determine whether the varieties perform well under a range of environmental conditions. The varieties that perform the best in these field tests go into the commercial seed-production process.

PRODUCING SEED FOR NEW COMMERCIAL VARIETIES

In general, the seed industry produces seeds for two kinds of varieties: pure-line and hybrid. Pure-line varieties closely resemble their parent lines, and can be harvested and planted year after year with the expectation that plants with desirable characteristics typical of the parent variety will re-emerge each year. By contrast, hybrid offspring are strikingly different from their parents, and the seeds they produce cannot be saved and planted without losing desirable traits.

Virtually all commercial corn seed in the United States is hybrid—the product of controlled pollination. Soybean and canola seeds are sold in both pure-line and hybrid varieties, with most being pure-line. Although the major stages in seed production are the same for both, there are important differences discussed below.

Seed production may occur in the United States or abroad. Companies often want to take advantage of seasonal differences above and below the equator to produce seeds between growing seasons in North America. Nevertheless, much of the seed production takes place in the same region as commercial production of the crop. Nestled among the fields growing commodity corn and soybeans in Iowa and Illinois, for example, are fields devoted to corn and soybean seed production. Substantial canola seed production occurs in North Dakota, the site of most commercial U.S. canola production.

Pure-line seed production: soybeans and canola

Producing seed for non-hybrid varieties is a straightforward multiplication process beginning with small amounts of highly pure breeder seed and culminating two or three generations later with large quantities of seed to sell to farmers. For economic reasons, each generation of seed is grown under containment conditions less stringent than the preceding generation, resulting in a final commercial class of seed that is less pure than the original breeder seed.

Each step is given a class name that indicates to seed specialists and farmers the stringency under which the seed was produced and, hence, the purity of the seed. As noted in the following section on seed purity, certifying agencies set specific, numerical purity standards (and the procedures needed to achieve those standards) for each class in various crops. (See Table A-1 for examples of corn, soybean, and canola seed standards.)

Seed production for a new variety begins with breeder seed, which is produced and controlled by the plant breeding institution that developed the

new variety. Breeders take great care during seed production to prevent contamination.

The next step is to produce foundation seed. A small amount of breeder seed is planted and grown under less stringent controls to generate a larger amount of foundation seed. This seed may be used to produce additional foundation seed or the next class of seed: registered. Though some companies sell registered seed to farmers, more often they go one step further and produce larger amounts of certified seed. Companies may contract with farmers to grow foundation, registered, and certified seed.

The final stage in the production of commercial seed for farmers involves the following steps: sowing the seed, maintaining the crop during the growing season, harvesting the seed, then transporting, drying, cleaning, bagging, and storing the harvested seed until it will be shipped to seed retailers.

Hybrid seed production: corn

Hybrid seed production requires a more complicated approach in order to produce seeds exhibiting what is known as "hybrid vigor." This term refers to the superior traits exhibited by the offspring (hybrids) of two parents that lack those traits. This phenomenon is quite common in corn, which is one reason why hybrid seed is now the norm in corn seed production. Hybrid vigor is lost if seeds harvested from the hybrids are saved and planted the next year.

To generate commercial seeds with hybrid vigor, corn seed producers must plant large acreages of the two different parental lines, called inbreds. Producing enough seeds for the inbred lines begins with breeders. Once they have developed the new inbred lines for the new hybrid corn variety, they generate breeder seed for these lines under strict confinement measures.

Using breeder seed, the next step is to increase the amount of inbred seed. The new generation of inbred corn seed is termed foundation seed and, like the foundation seed of pure-line varieties, is typically produced under conditions less stringent than those for breeder seed. Foundation seed is then used in subsequent growing seasons to increase the amount of foundation inbred seed. Some companies refer to this process as parent seed production because foundation inbred seeds are the parents of hybrid seeds.

Once a company has enough foundation inbred seed, it begins producing hybrid seed in commercial quantities. Companies must ensure that all the seed produced during this stage results from the combination of two selected parents. To

Table A-1 **Association of Official Seed Certifying Agencies (AOSCA) Standards for Classes of Corn, Soybean, and Canola Seed***

	Hybrid Corn	Soybeans			Canola		
	Certified**	Foundation	Registered	Certified	Foundation	Registered	Certified
Pure seed (minimum)	98.0%	No standards	98.0%	98.0%	99.0%	99.0%	99.0%
Contaminant:							
Inert matter (maximum)	2.0%	No standards	2.0%	2.0%	1.0%	1.0%	1.0%
Weed seed (maximum)	0.0%	0.05%***	0.05%***	0.05%***	7 per lb.***	16 per lb.***	25 per lb.***
Total other crop seed (maximum)	No standards	0.2%	0.3%	0.6%	0.05%	0.1%	0.25%
Other varieties (maximum)	0.5%	0.1%	0.2%	0.5%	0.05%	0.1%	0.25%

*Adapted from AOSCA. 2001. Genetic and Crop Standards, pp. 2-29, 2-36, and 2-98. On the AOSCA website at *ftp://www.aosca.org/geneticstandards.pdf*, accessed on September 24, 2003.
**AOSCA recognizes only one class (certified) for hybrid corn seed.
***Includes zero tolerance for certain weeds.

begin, the parental inbreds are planted near one another, but the female parent must be prevented from pollinating itself by eliminating its ability to produce pollen. This is accomplished by mechanically removing its pollen-producing organs (tassels) or rendering it genetically sterile. The female inbred parent may then be wind-pollinated by the nearby male inbred parent or hand-pollinated.

The rest of the hybrid seed production process is very similar to that for pure-line varieties: at the end of the growing season, the hybrid seed is harvested, transported, dried, shelled, cleaned, bagged, and stored.

Contamination during seed production

Whether the result is hybrid or non-hybrid seeds, the process of variety development and seed production offers numerous opportunities for commingling of seeds and traits. This can occur through both physical mixing and cross-pollination.

Physical mixing opportunities arise during the planting of parent lines and the harvesting, sorting, handling, storage, or cleaning phases of seed production. Cross-pollination between plants can occur during the propagation of the parental lines and at several steps in the production of hybrid or pure-line seed. When stray pollen finds its way to receptive plants, the seeds produced may carry unwanted genetic sequences.

SEED PURITY STANDARDS

In the United States, the Association of Official Seed Certifying Agencies (AOSCA) establishes standards for seed purity that vary according to the kind of contaminant involved, the crop in which the contaminant is found, and the level of purity needed. For example, zero-tolerance standards apply to weed seeds in certified hybrid corn seed, while low levels of contaminating seeds of other crops (0.2 to 0.6 percent) are allowed in soybean seeds, depending on the class of seed (Table A-1, p. 59).

AOSCA recognizes the four levels of purity, or seed certification classes, mentioned above (breeder, foundation, registered, and certified) and sets specific procedures under which each level can be achieved during the seed production process.[97] These procedures typically involve restrictions on crops previously grown in seed production fields, minimum distances between seed production fields and nearby crops, and inspections of fields and seeds. The levels of purity achieved for each class vary from crop to crop and are set specifically for each crop. Not all classes exist for all crops; for example, there is only one class of hybrid corn: certified.

Although genetically modified varieties of a crop that are allowed on the market can be considered seed contaminants to the same extent as any other variety, engineered sequences in traditional seed are not currently considered contaminants for which standards have been set.

97 Association of Official Seed Certifying Agencies (AOSCA). 2001. Genetic and Crop Standards. On the AOSCA website at *http://www.aosca.org/genetic standards.pdf*, accessed on September 24, 2003. The website offers more information on AOSCA and the procedures required for various classes of certified seed in a variety of crops.

Appendix B

Transgenes and Transgenic Traits Listed in USDA Records of Field Tests of Genetically Engineered Corn, Soybeans, and Canola

Commercialized varieties of genetically engineered crops are not the only sources of seed contamination. Prior to commercialization, transgenic varieties are tested for several years in open fields, a practice that offers many opportunities for seed mixing and outcrossing.

Tables B-1 through B-6 list many transgenes and transgenic traits that have been field tested in the United States and may have moved into the seed supply. The identities of many other transgenes and traits that have also been field tested and may have moved into the seed supply are not listed because companies are allowed to withhold that information from the public as confidential business information (CBI).

Since 1987, corporations and university researchers have conducted thousands of field trials of genetically engineered plants in the United States. The U.S. Department of Agriculture (USDA), which oversees the tests, makes information on the trials available to the public through a database maintained by the Information Systems for Biotechnology (ISB) at Virginia Polytechnic Institute and State University.[98] Currently, that database contains nearly 10,000 records of field tests of engineered plants.

Each record consists of a number of fields containing information about the trials, including the recipient crop, the transgenes engineered into the crop, the traits conferred by those transgenes, the institution sponsoring the tests, and the states where the tests have been or are to be conducted. The records are compiled from information submitted to the USDA by those companies or universities seeking to conduct trials. Depending on the nature of the crop-gene combination and the intended use of the engineered crop, these submissions are either notifications of intent or requests for permission to conduct field tests.

Of the nearly 10,000 records on transgenic crops, more than half (5,528) concern field tests of the three crops that are the subject of this report. As of December 15, 2003, the USDA had acknowledged notifications or permitted field tests for 4,312 corn submissions, 711 soybean submissions, and 185 canola submissions (listed as rapeseed in the database).

Tables B-1 through B-6 list the transgenes and transgenic traits documented in USDA records of all tests of transgenic corn, soybeans, and canola that have been acknowledged or permitted by the department since 1987.[99] The information in the tables (which do not include records of submissions that are pending or have been withdrawn, denied, or voided) is taken directly from USDA records available on the

98 Information Systems for Biotechnology (ISB). 2003. Field Test Releases in the U.S. Blacksburg, VA: Virginia Polytechnic Institute and State University. On the ISB website at *http://www.isb.vt.edu/cfdocs/fieldtests1.cfm*, accessed on December 15, 2003.

99 We are grateful to the ISB staff for conducting special searches on December 15, 2003, that provided the information for the tables in this appendix.

ISB website, and is complete as of the access date (December 15, 2003).

As mentioned above, in a substantial portion of the records, the submitter has withheld information—including the names of the transgenes being tested—as CBI. As a result, the tables are far from a complete listing of the transgenes that have been field tested and may have moved into the seed supply. The percentage of records withholding the names of one or more transgenes is indicated below the tables that list transgenes in corn (Table B-1), soybeans (Table B-2), and canola (Table B-3).

Table B-1 **Transgenes Listed in USDA Records of Field Tests of Genetically Engineered Corn**

3-ketothiolase	Delta-12 desaturase antisense	Nopaline synthase
ACC synthase	Dihydrodipicolinate synthase	NptII
Aceto acetyl-CoA reductase	Dihydrodipicolinate synthetase	Nucleosome assembly factor A silencing
Acetolactate synthase	DNA adenine methylase	Nucleosome assembly factor C silencing
Acetyl CoA carboxylase	DNA methyltransferase	Nucleosome assembly factor D silencing
Acetyl CoA carboxylase antisense	DNA methyltransferase silenced	O-methyltransferase
Adenine methylase	Drug resistance protein (MRP29) antisense	Opaque 2
ADP glucose pyrophosphorylase	Enterotoxin subunit B	P regulatory gene
Albumin	EPSPS	P transcriptional activator
Aldehyde dehydrogenase	Esterase	P1 regulatory gene
Alpha-hemoglobin	Fertility restorer gene (rf2a)	P1 transcription factor
Amino polyol amine oxidase	Fertility restorer gene 2a	Phosphinothricin acetyl transferase
Amylase	Flavin amine oxidase	Polycomb group protein gene silenced
Anthocyanin regulatory gene	Flavonol 3-hydroxylase	Polycomb protein enhancer gene silenced
Anti-mutator gene B	Fructosyl transferase	Polyhydroxybutyrate synthase
Antibody (common cold)	G glycoprotein	Procollagen
Antibody (tooth decay)	Global transcription factor A silenced	Prolamin binding factor
Antifungal protein	Global transcription factor C silenced	Protein kinase
Aprotinin	Global transcription factor E silenced	Proteinase inhibitor I
Aspartokinase	Glucanase	Proteinase inhibitor II
B cell lymphoma related gene X (Bcl-xl)	Glutamate dehydrogenase	Pyruvate decarboxylase
B-glucuronidase	Glutathionine transferase	R gene transcription factor
B-Peru anthocyanin regulatory gene	Glutenin	R regulatory gene
B-Peru transcription factor-silenced	Glycogenin	Recombinase
B1 regulatory gene	Glycogenin antisense	Red fluorescent protein
B1 transcription factor	Glyphosate oxidoreductase	Replicase
Barnase	gp120 (glycoprotein 120)	Retinoblastoma 1 tumor suppresor antisense
Barstar	Green fluorescent protein	Retinoblastoma-related protein-silenced
Beta-hemoglobin	Helper protein mudrB	Ribonuclease
Branching enzyme (TB1)	Helper protein mudrB antisense	Ribosome inactivating protein
Brazzein	Histone acetylase gene silenced	Saccharopine dehydrogenase
Bromodomain protein gene silenced	Histone acetyltransferase gene silenced	Seed storage protein
C1 regulatory gene	Histone deacetylase	Self incompatibility
C1 transcription factor	Histone deacetylase silenced	Serum albumin
C1 transcriptional activator	Histone H1 gene silenced	SET domain protein gene silenced
CBI*	Homeotic regulatory gene (glossy 15)	Starch branching enzyme II
Cecropin	Homoserine dehydrogenase	Starch branching enzyme II antisense
Chitinase	Hygromycin phosphotransferase	Starch debranching enzyme
Chromatin remodeling complex-silenced	Isoamylase-type starch debranching enzyme	Starch synthase
Chromodomain protein gene silenced	Knotted-1	Starch synthase antisense
Citrate lyase	Laccase	Storage protein
Coat protein	Lectin	Sucrose phosphate synthase
Cry	Levansucrase	Sucrose synthase
Cry1F	Luciferase	Surface antigen
Cry9C	Lysine ketoglutarate reductase	T-URF13 mitochondrial
CryIA	Male sterility protein	Transcription regulator silenced
CryIA(b)	Methyl binding domain protein gene silenced	Transcriptional activator
CryIA(c)	Microtubule-associated protein (MAP4)	Transposon Mu1
CryIH	Mu transposable element	Transposon MuDR
CryIIA	Mu-1 transposable element	Transposon MuDR antisense
CryIIIA	Mu-A transposable element	Transposon Tn5
Cyclin dependent kinase	Mu-B transposable element	UDP glucose dehydrogenase
Cyclin dependent kinase inhibitor-silenced	MyB-IF35 transcription factor	Wheat germ agglutinin
Cystathionine synthase	N-terminal acetyl transferase silenced	Xylanase antisense
Cysteine proteinase inhibitors	Negative C transcription activator	Zein storage protein
Dehydroascorbate reductase	Negative R transcription activator	

***Confidential business information: 72% of the records do not disclose the names of one or more transgenes**

Table B-2 **Transgenes Listed in USDA Records of Field Tests of Genetically Engineered Soybeans**

10 kDa protein	Delta-15 desaturase	Omega 6 desaturase antisense
Acetolactate synthase	Delta-15 desaturase antisense	Oxalate oxidase
ACP acyl ACP thioesterase	Dihydrodipicolinate synthase	Oxygenase
Acyl-ACP thioesterase	Dihydrodipicolinate synthetase	Palmitoyl thioesterase
Aspartokinase	EPSPS	Palmitoyl thioesterase antisense
Aspartokinase II-homoserine dehydrogenase	Fluorescent protein	Phosphinothricin acetyl transferase
B-glucuronidase	Galactanase	Phosphoglucomutase
Calmodulin	Galactinol synthase	Protease
Casein	Glycinin	Protein kinase
CBI*	Homoserine dehydrogenase	Rps1-k resistance gene
Chitinase	Hygromycin phosphotransferase	Saccharopine dehydrogenase
Coat protein	Inositol hexaphosphate phosphohydrolyase	Seed storage protein
Conglycinin	Isoflavone synthase	Stearoyl ACP desaturase
CrylA(c)	Luciferase	Storage protein
Cyanamide hydratase	Lysine ketoglutarate reductase	Thioesterase
Cystathionine beta-lyase	Lysine ketoglutarate trypsin inhibitor	Transposon Tn5
Cystathionine synthase	Lysophosphatidate acyltransferase	UDP glucose glucosyltransferase
Delta-6 desaturase	NptII	UDP-glucose 4'epimerase
Delta-9 desaturase	Omega 3 desaturase	Zein storage protein
Delta-12 desaturase antisense	Omega 3 desaturase antisense	
Delta-12 saturase	Omega 6 desaturase	

***Confidential business information: 49% of the records do not disclose the names of one or more transgenes**

Table B-3 **Transgenes Listed in USDA Records of Field Tests of Genetically Engineered Canola**

Acetolactate synthase	CrylA(c)	Green fluorescent protein
Acetyl CoA carboxylase	Delta-9 desaturase	Hygromycin phosphotransferase
ACP acyl ACP thioesterase	Delta-9 desaturase antisense	Ketoacyl-ACP synthase
ACP thioesterase	Delta-12 desaturase	Ketoacyl-ACP synthase antisense
Acyl ACP antisense	Delta-12 desaturase antisense	Lysophosphatidic acid acetyl transferase
Acyl ACP desaturase	Delta-12 saturase	Lysophosphatidyl choline acetyl transferase
Acyl ACP desaturase antisense	Delta-12 saturase antisense	Nitrilase
Acyl CoA reductase	Delta-15 desaturase	NptII
Alanine aminotransferase	Delta-15 desaturase antisense	O-acyl transferase
B-glucuronidase	Desaturase 15 antisense	Oleayl-ACP thioesterase
B-ketoacyl-CoA synthase	Diacylglycerol acetyl transferase	Phosphinothricin acetyl transferase
B-ketoacyl-Coenzyme A synthase antisense	Dihydrodipicolinate synthase	Proteinase inhibitor I
Barnase	Elongase	Proteinase inhibitor II
Barstar	EPSPS	Reductase
CBI*	Fatty acid elongase	Sucrose phosphate synthase
Chitinase	Glucanase	Thioesterase
Coat protein	Glycerol-3-phosphate acetyl transferase	Thiolase
Cold regulated gene binding factor (CBF)	Glyphosate oxidoreductase	Trypsin inhibitor
CrylA(b)		

***Confidential business information: 47% of the records do not disclose the names of one or more transgenes**

Table B-4 **Transgenic Traits Listed in USDA Records of Field Tests of Genetically Engineered Corn**

Altered amino acid composition	Fusarium ear rot resistant	Oil profile altered
Altered maturing	Fusarium ear rot susceptible	Oil quality altered
Altered morphology	Fusarium resistant	Pharmaceutical proteins produced
Altered plant development	Gene expression altered	Phosphinothricin tolerant
Alternaria resistant	Germination increased	Photosynthesis enchanced
Animal feed quality improved	Glucuronidase expressing	Phytate reduced
Anthocyanin produced in seed	Glyphosate tolerant	Pigment composition altered
Anthracnose resistant	Grain processing improved	Pigment metabolism altered
Anthracnose susceptible	Gray leaf spot resistant	Polymer produced
Antibiotic produced	Gray leaf spot susceptible	Processing characteristics altered
Antibody produced	Growth rate altered	Protein altered
Aspergillus resistant	Growth rate increased	Protein levels increased
Botrytis resistant	Helminthosporium resistant	Protein lysine level increased
Capable of growth on defined synthetic media	Herbicide tolerance	Protein quality altered
Carbohydrate level increased	Imidazole tolerant	Protoporphyrinogen oxidase inhibitor tolerant
Carbohydrate metabolism altered	Imidazolinone tolerant	Recombinase produced
Carotenoid metabolism altered	Increased phosphorus	Rhizoctonia resistant
CBI	Increased stalk strength	Salt tolerance increased
Cell wall altered	Increased transformation frequency	Seed color altered
Cercospora resistant	Inducible DNA modification	Seed composition altered
Chloroacetanilide tolerant	Industrial enzyme produced	Seed methionine storage increased
Cold intolerant	Isoxaflutole resistant	Seed quality altered
Cold tolerant	Isoxazole tolerant	Seed size increased
Coleopteran resistant	Kanamycin resistant	Seed weight increased
Color altered	Leaf blight resistant	Selectable marker
Color pigment restored	Leaf spot resistant	Senescence altered
Color sectors in seeds	Lepidopteran resistant	Septoria resistant
Colorado potato beetle resistant	Lignin levels decreased	Smut resistant
Colored sectors in leaves	Lipase expressed in seeds	Southern rust susceptible
Common rust susceptible	Lysine level alterered	Southern corn leaf blight resistant
Corn earworm resistant	Lysine level increased	Southern corn leaf blight susceptible
Cre recombinase produced	Male sterile	Southwestern corn borer resistant
Cyanamide tolerance	Male sterile nuclear	Starch level increased
Cyanamide tolerant	Male sterile reversible	Starch metabolism altered
Dalapon tolerant	Maturity altered	Starch reduced
Development altered	MCDV resistant	Stewart's wilt susceptible
DNA synthesis altered	MCMV resistant	Storage protein
Drought tolerant	MDMV resistant	Storage protein altered
Ear mold resistant	MDMV-B resistant	Stress tolerant
Endosperm DNA synthesis altered	Metabolism altered	Sugar cane borer resistant
Environmental stress reduced	Methionine level increased	Sulfonylurea tolerant
Epidermal cells increased on juvenile leaves	Modified growth characteristics	Transposon elements inserted
European corn borer resistant	Mutator transposon suppressed	Transposon inserted
Expression optimization	Mycotoxin degradation	Transposon movement supressed
Eyespot resistant	Mycotoxin production inhibited	Tryptophan level increased
Fall armyworm resistant	Nitrogen metabolism altered	Visual marker
Fertility altered	Northern corn leaf blight resistant	Visual marker inactive
Flowering time altered	Northern corn leaf blight susceptible	Vivipary increased
Fumonisin degradation	Novel protein produced	Western corn rootworm resistant
Fungal post-harvest resistant	Nutritional quality altered	Yield increased

Table B-5 **Transgenic Traits Listed in USDA Records of Field Tests of Genetically Engineered Soybeans**

2,4-D tolerant	Fusarium resistant	Phytate reduced
Altered amino acid composition	Glyphosate tolerant	Phytophthora resistant
Altered maturing	Grain processing improved	Pollen visual marker
Altered plant development	Growth rate altered	Polymer produced
Animal feed quality improved	Imidazole tolerant	Protein altered
Antibody produced	Imidazolinone tolerant	Protein quality altered
Antiprotease producing	Increased protein levels	Recombinase produced
BPMV resistant	Increased transformation frequency	Salt tolerance increased
Bromoxynil tolerant	Industrial enzyme produced	SbMV resistant
Carbohydrate metabolism altered	Isoxaflutole resistant	Sclerotinia resistant
CBI	Isoxazole tolerant	Secondary metabolite increased
Cold tolerant	Kanamycin resistant	Seed composition altered
Coleopteran resistant	Lepidopteran resistant	Seed methionine storage increased
Cyanamide tolerant	Lysine level increased	SMV resistant
Development altered	Male sterile nuclear	Stanol increased
Dicamba tolerant	Methionine level increased	Sterols increased
Drought tolerant	Nitrogen metabolism altered	Storage protein altered
Ear mold resistant	Novel protein produced	Transformation frequency increased
Fatty acid level altered	Nutritional quality improved	Visual marker
Fatty acid metabolism altered	Oil profile altered	White mold resistant
Feed properties altered	Oil quality altered	Yield increased
Fumonisin degradation	Oleic acid content altered in seed	
Fungal susceptibility	Phosphinothricin tolerant	

Table B-6 **Transgenic Traits Listed in USDA Records of Field Tests of Genetically Engineered Canola**

Altered amino acid composition	Fungal post-harvest resistant	Oil quality altered
Bromoxynil tolerant	Glyphosate tolerant	Pharmaceutical proteins produced
CBI	Industrial enzymes produced	Phoma resistant
Cold tolerant	Lepidopteran resistant	Phosphinothricin tolerant
Coleopteran resistant	Lysine level increased	Polymer produced
Cylindrosporium resistant	Male sterile	Sclerotinia resistant
Erucic acid altered	Male sterile reversible	Seed composition altered
Fatty acid metabolism altered	Nitrogen metabolism altered	Sulfonylurea tolerant
Fertility altered	Nutritional quality altered	Visual marker
Fertility restored	Oil profile altered	Yield increased

Glossary

Biotechnology
Term referring to practical uses of living organisms. "Old" biotechnologies typically include processes such as fermentation (to make foods such as yogurt, cheese, bread, and beer), animal and **plant breeding**, and food and fiber production from plants and animals. "New" biotechnologies include modern techniques such as genetic engineering and cloning. The term biotechnology is often used interchangeably with the terms **genetic engineering** and **genetic modification**.

Breeder seed
Seed held most closely by breeders of new plant **varieties**. Breeder seed is the class of **certified seed** with the highest standards for purity and is the source for production of **foundation seed**.

Bt crop
Insect-resistant crop **variety** engineered to produce an insect toxin originally found in the soil bacterium *Bacillus thuringiensis.* YieldGard, NaturGard, KnockOut, and StarLink are trade names of some Bt-corn varieties.

Bt toxin
Insecticidal toxin produced by *Bacillus thuringiensis* bacteria. The **gene** for Bt toxin has been engineered into a number of **biotechnology** crops.

Center of diversity
Locale where the relatives of crops have the greatest genetic diversity in the form of **traditional varieties** and/or wild relatives.

Certified seed
Generically, seed that has been subject to certification by a seed-certifying agency. Classes of certified seed, listed from most to least pure, are **breeder**, foundation, registered, and certified.

Specifically, that particular class of certified seed typically produced from **registered seed**, but which also may be produced from **foundation seed** or other certified seed. Certified seed is usually the class of seeds sold to farmers and is typically the least genetically pure of the four classes of certified seed.

Construct
Assemblage of **genetic sequences** spliced together into a unit easily moved around by genetic engineers. Constructs typically include one or more **genes** for new traits (such as herbicide resistance and insect resistance) as well as **regulatory sequences** such as **promoters** and **terminators**.

Crop gene pool
All the **genes** in all the **varieties** of a crop, plus the genes of **landraces** and wild relatives that interbreed with the crop.

Cross-pollination
see **outcrossing**

Detection limit
Lowest level at which target **DNA** can exist in a sample and be reliably detected by **polymerase chain reaction (PCR)** methods. In this report, the detection limit is typically expressed as a percentage: the ratio of the number of transgenically derived **genomes** to the number of crop genomes times 100 percent.

DNA
Deoxyribonucleic acid, the linear macromolecule that makes up the genetic material of most organisms. DNA usually exists as a double-stranded helix.

Engineered construct
see **construct**

Event
Line of plants resulting from the insertion of a transgenically derived **construct** into the **genome** of a plant. Each insertion results in a different event, even when containing the same **gene**. Most of the events discussed in this report represent different constructs.

Expression
see **gene expression**

Fertilization
Combining male sex cells carried within **pollen** grains with female sex cells (eggs) to produce plant embryos. Fertilization triggers the formation of seeds, which contain embryos.

Foundation seed
Class of **certified seed** produced from **breeder seed** or other foundation seed under conditions that maintain high standards of genetic identity and purity. Foundation seed is the source of certified seed, either directly or as the source of **registered seed** that is then used to produce certified seed.

Gene
Functional unit of hereditary material (**DNA**) usually carried on chromosomes and passed from parent to offspring. A gene codes for proteins (the molecules that are responsible, alone or in combination, for traits exhibited by plants such as seed color and shape, height, and insect resistance).

Gene expression
Production of proteins coded for by **genes**.

Gene flow
The successful movement of **genes** from one population of plants to another, usually via **pollination**.

Gene product
Protein resulting from **gene expression**.

Gene splicing
see **genetic engineering**

Genetic element
see **genetic sequence**

Genetic engineering
Molecular-level techniques capable of combining **genes** and **regulatory sequences** and transferring them into an organism. These techniques, which may be used to transfer genes between unrelated organisms or to remove and rearrange genes within a species, are also called **transgenic**, **gene splicing**, and **genetic modification** techniques.

Genetic modification
Strictly speaking, any mode of altering the genetic composition of organisms. The term, especially in Europe, has come to refer more narrowly to modern gene transfer techniques and is used interchangeably with **transgenic**, **gene splicing**, and **genetic engineering** techniques.

Genetic sequence
Segment of **DNA** that codes for proteins or regulates their function.

Genetically engineered organism
Organism (or progeny of an organism) whose **genetic sequences** have been modified using molecular-level techniques. Such organisms are also referred to as **genetically modified** or **transgenic**.

Genetically modified organism (GMO)
see **genetically engineered organism**

Genome
The full set of **genes** and associated **DNA** characteristic of an organism.

GMO testing
Use of sophisticated biochemical methods to analyze food, feed, and other agricultural products for **genetic sequences** originating from engineered **varieties** (i.e., **genetically modified organisms**).

Herbicide-resistant variety
Plant **variety** resistant to the otherwise toxic effects of herbicides.

Hybrid variety
Offspring of two parent plants that differ from one another in one or more **genes** and often exhibit **hybrid vigor.** Such varieties typically do not breed true.

Hybrid vigor
Phenomenon whereby the offspring exhibit traits more desirable than either of the parents.

Identity-preserved (IP) system
Carefully controlled production and distribution system that segregates high-value crops from the time of planting to delivery to the end user.

Inbred crop
Pure-breeding line of plants that has undergone controlled **pollination** for a number of generations.

Landrace
Improved plants selected and maintained by farmers and typically found where crops have been grown for many generations. Landraces are not the products of modern **plant breeding** or **genetic engineering**.

Limit of detection
see **detection limit**

Limit of quantification
see **quantification limit**

Novel gene
see **transgene**

Outcrossing
Sexual reproduction between two different individual plants.

Pharm crop
Crop engineered to produce pharmaceuticals.

Plant breeding
Scientific discipline for producing new crop **varieties** using sophisticated, field-based selection and mating techniques.

Pollen
Dust-like material, produced by the male parts of flowers, that contains male sex cells.

Pollination
Transfer of **pollen**, most frequently accomplished by wind or insects, from the male part of a plant flower to the female part. If the pollen is compatible with the female part of the flower to which it has been transferred, pollination is followed by **fertilization**.

Pollination is sometimes used as shorthand for both pollen transfer and fertilization.

Polymerase chain reaction (PCR)
Technique used to determine whether a sample of plant tissue contains a particular **DNA** sequence. PCR relies on **primer sets** that home in on a particular target DNA sequence and a special DNA-copying enzyme (DNA polymerase) that makes enough copies of the target sequence for identification and measurement. See also **qualitative PCR**, **quantitative PCR**, and **semi-quantitative PCR**.

Primer set
Short pieces of **DNA** added to **polymerase chain reaction (PCR)** mixtures to "find" the pieces of target DNA that will be copied. Primer sets are synthesized to match sequences at the beginning and end of the target DNA, thereby defining the exact segment to be subsequently duplicated by a DNA-copying enzyme.

Promoter
Regulatory sequence of **DNA** that controls the process by which **genes** are translated into proteins. In addition to initiating the process, such sequences can also determine the amount of protein produced. The 35S promoter derived from the cauliflower mosaic virus, for example, is the most widely used promoter in crop **genetic engineering**.

Pure-line variety
Plants that are genetically identical and typically breed true (i.e., the progeny of **self-pollinating** pure-line varieties are indistinguishable genetically and in appearance from the parent **varieties**).

Qualitative PCR
Polymerase chain reaction (PCR) methods that determine the presence or absence of a specific target **DNA** sequence at a particular level of detection.

Quantification limit (QL)
Lowest level at which the amount of a target **DNA** sequence in a sample can be reproducibly measured. In this report, the quantification limit is typically expressed as a percentage: the ratio of the number of transgenic **genomes** to the number of crop genomes times 100 percent.

Quantitative PCR
Polymerase chain reaction (PCR) methods that estimate the relative amount of a target **DNA** sequence in a mixture of DNA molecules (at a particular level of quantification).

Registered seed
Class of **certified seed** generally produced from **foundation seed** under conditions that maintain certain standards of identity and purity. These standards are lower than those for foundation seed but higher than those for certified seed. Registered seed is generally a source of certified seed.

Regulatory sequence
Segment of **DNA** that controls the process by which cells manufacture proteins. **Promoters** and **terminators** are the most common regulatory sequences used in **genetic engineering**.

Self-pollination
Transfer of **pollen** from the male part of a plant flower to the female part of a flower on the same plant. After **pollination**, male and female cells combine to form embryos (**fertilization**). Soybean is a predominantly self-pollinating crop, while corn and canola are predominantly **cross-pollinating**.

Semi-quantitative PCR
Polymerase chain reaction (PCR) methods designed to determine in one analysis the presence or absence of a target **DNA** sequence and an estimate of its relative amount in a mixture of DNA molecules.

Stacked gene
One of two or more **transgenes** expressed in a genetically engineered **variety**, such as a cotton plant engineered to produce both a **Bt** toxin and a protein that enables the plant to resist glyphosate herbicides.

Terminator
Regulatory sequence of **DNA** that stops the process by which a protein is produced from a **gene**. The NOS terminator from the bacterium *Agrobacterium tumefaciens*, for example, is the most widely used terminator sequence in plant **genetic engineering**.

Traditional breeding
see **plant breeding**

Traditional variety
Crop **variety** with no history of **genetic engineering**. Traditional varieties are produced through **plant breeding** techniques that rely on selecting and mating parent plants possessing promising traits and repeatedly selecting for superior performance among their offspring.

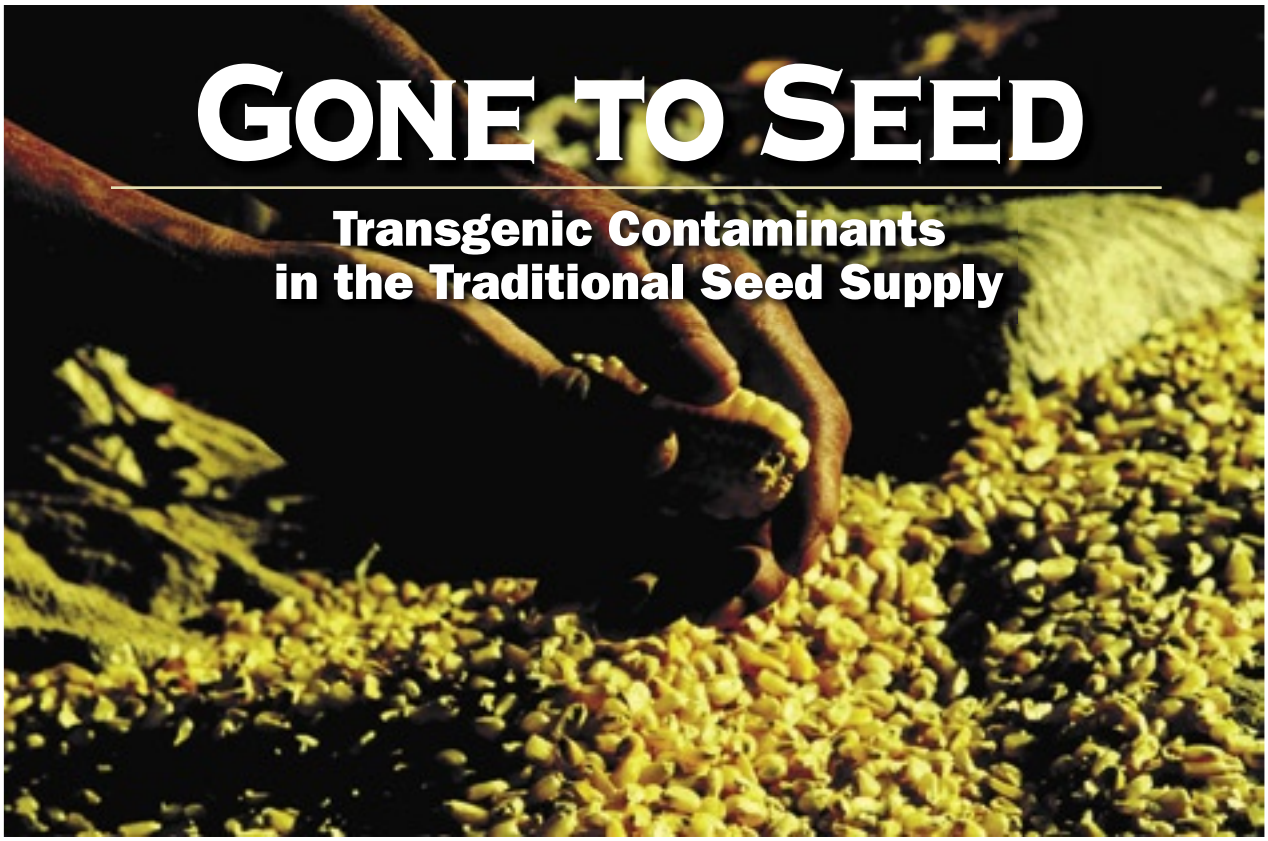
Transformation event
see **event**

Transgene
Gene transferred to an organism through **genetic engineering**.

Transgenic
see **genetic engineering**

Transgenically derived sequence
DNA sequence originating from a plant produced as a result of **genetic engineering**.

Variety
Subgroup of plants within a species whose genetic makeup and characteristics distinguish it from other varieties of the species. Crop varieties are often called cultivars, especially by agricultural scientists.



Gone to Seed

Transgenic Contaminants in the Traditional Seed Supply

Nothing is more fundamental to agriculture and our food supply than seeds. The variety, abundance, and safety of foods all depend on the availability and quality of seeds.

In *Gone to Seed*, the Union of Concerned Scientists (UCS) examines a new phenomenon that may threaten the quality of the traditional seed supply: contamination by DNA sequences used in genetic engineering. UCS conducted a small pilot study of seeds of traditional varieties of corn, soybeans, and canola purchased from the same retailers used by U.S. farmers. Laboratory testing showed the seeds are contaminated with low levels of DNA originating in genetically engineered varieties of those crops.

This report addresses the implications of seed contamination in several regulatory and policy contexts, including pharmaceutical-producing crops, trade, and organic food production. It then offers recommendations—to the federal government, seed companies, and agricultural universities, among others—for confronting this problem before it is too late.

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