Transgenic Crops: An Environmental Assessment

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Executive Summary

The varieties and uses of genetically altered (transgenic) crops have grown much more rapidly than our ability to understand or appropriately regulate them. At this writing, we have only a small core of scientific information to understand the short- and long-term environmental effects of these crops. Some laboratory and field evidence is helping us to understand the potential environmental benefits and risks of the most widely used products, such as herbicide-tolerant crops and plants engineered with the insecticide *Bacillus thuringiensis* (Bt). However, assessments that account for a full range of differences in geography, weather, pests, and management have not been completed. Only small amounts of funding (approximately 4 percent of U.S. agricultural biotechnology research dollars) are available for seeing these and other studies through to completion.

The environmental effects of a transgenic crop depend on the characteristics of the organism, the environmental system in which the crop is placed, and the skill with which it is managed. In short, whether a transgenic crop will benefit or adversely affect the environment depends on the nature of the crop, where it is used, and how it is used. Hence, we may expect a range of environmental effects, some positive and some negative. The environmental impacts are shaped also by current biosafety regulation. Unfortunately, the policies for managing the varying environmental impacts are hindered by the relatively small core of scientific data with which to anticipate and develop appropriate control measures. Many commentators have come to believe that the existing regulatory framework is inadequate. In fact, a recent National Research Council report has recommended a number of actions to strengthen the regulatory process for genetically modified pest-protected plants.

Chapter One: The Environmental Effects of Transgenic Crops: What We Know Now

The rapid growth and spread of transgenic crops provides us with a context for assessing their potential environmental benefits and risks. Globally, transgenic crops were estimated to cover approximately 100 million acres in 1999. The vast majority was planted in the United States (71 percent), Argentina (17 percent), and Canada (10 percent). Overall, the estimated commercial plantings included about 40 transgenic crops in 8 developed countries and 4 developing nations. Transgenic soybeans are the most popular crop, accounting for approximately 21 percent of the acres planted with transgenic seeds across the world. Corn made up 11 percent; cotton and canola were each 3 to 4 percent. Developing nations are growing primarily transgenic cotton, corn, soybeans, and tomatoes.

Transgenic crops have been adopted rapidly by U.S. farmers in their initial phase. Since their introduction to the market in 1995, they grew to cover approximately 71 million acres in 1999, about one-quarter of U.S. cropland planted to the major crops. The U.S. expansion rate from 1998 to 1999 was 8.2 percent. Argentina followed at 2.4 percent, Canada at 1.2 percent, and China at 0.2 percent. Soybeans are leading the global growth with a 7.1 percent increase from 1998 to 1999, followed by corn at 2.8 percent and cotton at 1.2 percent. Despite the recent surge of interest within the U.S., government surveys indicate that the nation’s farmers planned to plant 3 percent fewer acres to transgenic soybeans and 8 percent fewer acres to transgenic corn in 2000 than in 1999. Cotton farmers have indicated, however, that they expected to increase their acreage of transgenic cotton from 55 to 61 percent. The differential changes affirm that transgenic crops should not be treated as a homogeneous technology.

Transgenic crops can have many possible effects on the environment. Potential environmental benefits of the technologies include the use of fewer, less toxic, or less persistent pesticides; increased crop yields (which may reduce the need to convert pasture or other lands to agricultural production); decreased water use; and reduced soil tillage. Potential risks include uncontrolled flows of genes to wild relatives; development of herbicide, insect, and virus resistance in wild relatives; reduced *in situ* crop genetic diversity; and adverse effects on organisms that are not pests, such as beneficial insects. A relatively small but expanding body of evidence exists to assess the effects. Early estimates suggest that transgenic crops will confer environmental benefits in some areas and/or in some years—for example, some crops appear to induce reduced use of toxic pesticides and slightly increased yields on average. The early experimental findings also show that using transgenic crops will, in certain circumstances, increase some environmental risks, such as gene flow and harm to species that are not pests.

Most studies of the environmental effects of transgenic crops have been confined to laboratories or small fields. The lack of detailed environmental impact data required for commercial approval and release has hindered risk and benefit assessment efforts. Some environmental scientists argue that it has been too easy to introduce some new transgenic crops without sufficient environmental assessment. Monitoring is not being conducted on the potential environmental impacts or on the interactions of multiple transgenic plants within ecosystems. Farmers likely will monitor the impacts on their farms, but usually will not extend their oversight beyond farm boundaries. Remedying the lack of environmental science will require more than simple increases in funding for current public research efforts. Research priorities will need to be changed so that crop traits potentially beneficial to the public, such as improved drought resistance, will garner more attention.

Chapter Two: Biosafety Regulation

The approval process for release of transgenic crops differs dramatically between the United States and the European Union. U.S. policy has been permissive in approving transgenic plants for market release; EU policy has been quite restrictive. The difference lies not in the science used—which is fundamentally the same—but in differing social values and political conditions for agriculture. The U.S. regulatory structure uses a “science-based” risk approach, which essentially means that a transgenic crop will be approved for the market if there is no firm evidence that it causes harm. The EU’s “precautionary” approach reverses the priorities: a transgenic plant can be approved for market only if there is firm evidence that it does not cause harm.

Basic criticisms of the U.S. regulatory system center on the need to (1) increase the role of ecological scientists involved in the regulatory process, (2) designate an environmental agency to lead the ecological assessment of transgenic plants, (3) improve the public transparency of the regulatory process, and (4) include ethical values and socioeconomic factors—the so-called “fourth criterion”—in decision processes. An example of the importance of social values comes from the United Kingdom. Its decision to delay transgenic crop commercialization likely is not based on fears of excessive human health risks due to weak regulation, since the U.K. public has readily adopted biotechnology medicines. Rather, the U.K. and other EU citizenry may fear, among other things, that transgenic crops will have a negative impact on their prized countrysides, by fostering a more homogeneous agriculture and a subsequent loss in biological and cultural diversity.

Chapter Three: The Business of Biotechnology

Two policy changes involving intellectual property rights (IPR) have played key roles in propelling the agricultural biotechnology revolution and raising environmental issues. First, a narrow 1980 U.S. Supreme Court decision provided the legal basis for granting intellectual property protection for living organisms, in the form of invention patents. Invention patents give the inventing firms strong exclusion rights to using certain biotechnologies. If a close substitute is not available, the invention patents give monopoly power to the firms marketing the biotechnology product. Second, under the 1980 Bayh-Dole Act, public universities and other institutions receiving federal research funds also can patent biotechnology inventions and license them for revenues.

Research on the net social benefits of IPR is inconclusive, despite the common belief that they create social value by fostering innovation and by making the patented material publicly available after 17 or more years. The IPR changes likely have influenced the trajectory of biotechnology development, encouraging investment in products with the greatest profit potential, perhaps at the expense of investment in products that provide benefits to the public, such as improved environmental quality. The increase in biotechnology investment likely has crowded out R&D on chemical-based products and other alternative production systems.

The IPR changes may contribute also to a more concentrated industry structure, resulting in less competition and product innovation. For example, some firms have created transgenic crops tied exclusively to their pesticides. The short- and long-term environmental effects of such shifts in pesticide use are not well documented. If future biotechnologies are to fulfill their promise of a more environmentally sustainable agriculture, the institutions governing IPR require assessment to ensure that the public will benefit sufficiently.

Market forces may cause changes in transgenic crop plantings and thereby limit or expand their environmental benefits and risks. A growing number of consumers in countries other than the U.S. are unwilling or reluctant to purchase foods containing transgenic crops. Evidence on the underlying causes of public responses, including human health, environmental, and ethical concerns, is sparse. This trend is most apparent in many EU countries, but also in Japan and Brazil. It is not clear that U.S. consumers are following this pattern. Recent surveys indicate a modest rise in concern, although the majority of U.S. consumers is still not troubled about foods made with ingredients from transgenic crops.

With governments unable to reassure a growing portion of the public about foods made with transgenic ingredients, especially in the EU countries, market forces may play a critical role. If markets are to reliably reflect consumer values regarding the environment, credible information must be provided. Product labels are one way to do so, and their form, content, and responsibility are key policy choices. Scholars generally agree that labeling is desirable to inform consumer choice. Negative labeling (that is, labeling designating a food as “biotechnology-free,” or free of genetically modified organisms, “GMO-free”) appears to be preferable, because it causes less disruption to the larger conventional food supply chain than would labels declaring that a product “contains biotech ingredients.” It also has the potential to stimulate the growth of “biotech-free” markets. However, assigning responsibility to those who wish to market “biotech-free” products would impose higher costs on them. The decision to label or not to label genetically modified foods is currently the industry’s prerogative, as the U.S. Food and Drug Administration (FDA) does not require it.

Most people agree that consumers should have the right to know and choose products based on their personal values. The role of labels in helping to highlight consumer preferences for environmental protection related to transgenic crops, and then conveying those signals to farmers, has not been researched. Increasing the potential impact of consumer preferences in the environmental management of transgenic crops is, however, consistent with the “fourth criterion”—that is, the inclusion of a broader set of ethical and social values in decisions about biotechnology.

Proponents of transgenic plants often argue that if they are adopted globally, they will eventually foster a second Green Revolution of high-yield crops. The argument continues that by reducing pressure to convert land to agricultural purposes, transgenic crops could reduce environmental stress in the United States and abroad. However, significant yield increases for transgenic crops have not yet materialized. The first generation of transgenic corn and soybeans, if these crops were to be adopted globally, would increase production by only an estimated 2 percent or less. The slight increase could be enhanced, but not without major changes to current agricultural research, according to experts. Early indications are that the next generation of transgenic crops will emphasize traits that are valuable to consumers, such as increases in particular nutrient levels, and not yield enhancement. Furthermore, it is doubtful that increased crop yields are, by themselves, sufficient to protect natural habitats.

If significant yield increases materialize through new research, then the world trading system will need to distribute the increased production to help meet global food needs. Unfortunately, trade in agricultural biotechnology is in a state of flux and uncertainty. Most important in this regard, the World Trade Organization (WTO) has not decided how to settle trade disputes involving agricultural biotechnology. Ultimately, the WTO will likely adopt dispute resolution rules similar to those used in its Sanitary and Phytosanitary Agreement (SPS). Signatory countries to the Cartagena Biosafety Protocol of the Convention on Biological Diversity (CBD), in contrast, will want to take a precautionary approach for screening the entry of genetically altered seeds, fish, and other organisms. The precautionary approach uses the most reliable scientific information available to inform decision-making, and requires sufficient evidence of no significant environmental risk before approving releases. The Cartagena Protocol does not require that bulk shipments of foods be subject to a precautionary review, just genetically modified seeds and other organisms that might threaten the environment. The WTO and Cartagena approaches will be untested for several years. It is not clear how “precautionary” decisions under the Cartagena Protocol will compare to those made under the SPS risk assessment criteria. Furthermore, if a trade dispute over biotechnology arises, the applicable dispute resolution process depends upon the countries’ standings as members of the WTO and/or the CBD. Therefore, the outcome is uncertain *a priori*.

The role of varying IPR regimens around the world and the uncertainty of implementing the Trade Related Intellectual Property (TRIPS) agreement after the 1999 Seattle WTO Ministerial Meeting add further uncertainty. The TRIPS agreement, among other provisions, defines the process through which countries can adopt IPR regimens that facilitate trade in agricultural biotechnology. Given the unsettled state of affairs, the diffusion and trade in transgenic crop seeds and products may proceed erratically for some time.

Chapter Four: Conclusion: Strengthening Public Research and Regulation

Given our small base of knowledge, we cannot expect to tap the full potential of transgenic crops to benefit the environment—or to adequately address the environmental risks they may pose. Equally important, we simply do not know how large either the benefits or risks will be, or how long they will last. If poor national or international oversight leads to a human or environmental health catastrophe, it could jeopardize the future of biotechnology and its considerable potential. In this context, it is well worth remembering that the U.S. nuclear power industry suffered a stunning blow from the 1979 accident at Three Mile Island—and that it never fully recovered.

Given the potential risks of transgenic crops to the environment—and to the biotechnology industry as a whole—a cautious approach to the use and dissemination of transgenic crops is appropriate. There are two key elements to this cautious approach:

1. *Increase investment in public research and development for agricultural biotechnology to ensure that the neglected environmental aspects of transgenic crops receive adequate attention, and to build a credible scientific knowledge base, including a comprehensive monitoring system, by which to evaluate these crops and their environmental impacts*.

Private firms have scant incentive to invest in the research necessary to understand the environmental impacts of transgenic crops or to investigate alternative farming systems. Their incentives are to increase profits, market share, and return to stockholders. Thus, there is a strong case to be made for improved public research and development to bring more information on transgenic plants and related technologies into the public arena, and to provide various publics with more information for informed oversight. Such an increased role will require increased funding, as the current dollars spent are inadequate to accomplish the task.

2. *Develop appropriate regulatory frameworks for transgenic crops, and reform the institutions and regimens, such as intellectual property rights, that control their development and diffusion*.

Also, many argue that the tripartite system used to regulate transgenic crops in the U.S—which consists of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA)—has a variety of demonstrable shortcomings. Many of these shortcomings are documented in a recent review from the National Research Council. Among other findings, the Council identified gaps in regulatory coverage of transgenic plants, and failure of the agencies to conduct comparably rigorous reviews with original scientific data. Clearly, there is a substantial need for data that environmental scientists can best supply, and they need to be better integrated into the regulatory system.

The ability of private firms to respond to the reformed regulations and to deliver innovative transgenic crops that reduce environmental risks is influenced by the degree of competition within the agricultural biotechnology industry. Currently, a few large companies control the vast majority of commercial technologies. The reasons are varied. According to the National Research Council report, overly costly regulatory requirements can inhibit the entry of small firms. Anti-competitive behavior also stymies entry and innovation. The current generation of transgenic crops follows a pest management model like that employed for chemical pesticides—through interventions that are toxic to pests. An alternative is for transgenic technologies to mimic ecological approaches to agriculture. These types of technologies would control pest populations through cultural or non-toxic means, such as integrated crop rotations. In addition to effective antitrust oversight, cost-effective biosafety regulations and public research on transgenic technologies that are ecologically and evolutionarily oriented will foster private efforts to find such alternatives.

Most of the commercially based institutions that protect and govern the development and distribution of transgenic crops—significantly, international trade agreements and IPR regimens—give only minimal attention to the environmental impacts of such crops. Indeed, it is not yet clear how today's international conservation and trade regimens will apply to disputes involving these crops. There is an urgent need for clarity, as well as for increased consensus, on how to deal with the emerging technologies on a national and global level, and within a business decision framework that incorporates all social values of environmental effects.

The small knowledge base about the environmental effects of transgenic plants holds risks for the environment and for the agricultural industry. More research and stronger regulatory regimens will help diminish the serious risks, and thereby ensure a better future for the developers, producers, marketers, and consumers of transgenic crops, while protecting valuable natural resources for current and future generations.

Introduction

Few issues have sparked such fierce debate as genetic engineering of the foods we eat. The knowledge that major crops such as corn and soybeans are being genetically altered and planted on a regular basis—and that the ultimate effects of those alterations are largely unknown—has received a tremendous amount of attention in trade publications, as well as the popular press and numerous public forums. For all the discussion on the topic, however, actual knowledge about the environmental effects of genetically modified crops remains scant at best. The simple fact is that development and commercialization of crop biotechnologies are in their early stages—indeed, some products have been on the market for only a few years. There have been few analytical studies beyond laboratory reports, few field studies, and virtually no broad monitoring to assess how the current profusion of such crops might affect our ecosystems. Coupled with the lack of scientific research are regulatory regimens in the United States and the European Union that are relatively new and still under revision. As we know so little about the crops themselves, we cannot know how effective these policies will be in dealing with their environmental impacts.

This report focuses specifically on the possible environmental effects of transgenic crops—that is, crops produced using recombinant DNA methods in which genes from other organisms are spliced into the plants to make them more tolerant of pesticides, toxic to certain pests, or more nutritious. Soybeans engineered to tolerate the herbicide glyphosate, for instance, are common transgenic plants. Although other biotechnological processes (such as tissue culture methods, or genetic manipulation without transfer to other species) exist, we have chosen to focus on transgenic plants because most commercialization and environmental exposure is occurring through them. Because the topic is so broad as to demand a separate report, we have chosen not to examine the potential effects that transgenic crops might have on human health.

In an earlier Wallace Center report, *Agricultural Biotechnology and the Environment: A Review of Research and Other Information for Policy*, we reviewed a wide range of literature on agricultural biotechnology and the environment (Ervin et al., 2000). This report expands on that base, first by looking at how transgenic crops are currently used, and then by examining what we currently know (and do not know) about their potential environmental risks and benefits. The report goes on to evaluate the regulatory regimens that govern these crops, both in the United States and in the European Union. It also provides a summary of the business side of crop biotechnologies: that is, what roles are played by intellectual property rights, global agricultural markets, and agricultural trade in regard to transgenic crops and their environmental effects. We conclude by presenting recommendations for government policies and actions aimed at ensuring that our continued use of transgenic crops is ultimately beneficial to the environment. Farmers, consumers, and the biotechnology industry itself all stand to gain from strong, coherent policies geared to this goal.

Our report is the result of a broad review of the scientific literature, as well as governmental and interest-group publications, about the environmental effects of transgenic crops. Budgetary and time constraints led us to select carefully from a wide array of sources. Inevitably, such a selection process leaves out important writings that could not be reviewed because of time and space limitations. Moreover, we cannot present all of the findings of the selected research in great depth because of the need to limit the scope of coverage. We feel, however, that we have done justice to the existing literature and its main themes.

For a subject area that crosses several disciplines and is undergoing rapid change, it is common for the terminology and language used by different groups to vary. Within agricultural biotechnology in particular, terms such as "biotechnology" and "genetic engineering" are used narrowly, and also more broadly. In reviewing the literature, we have attempted to use more specific terminology, when possible, to appropriately communicate our source material. It is impossible, however, to completely avoid ambiguity in our reporting, when such ambiguity exists within other sources. We have included a glossary (Appendix 1) to provide further definition of many of the more technical terms that are treated (sometimes only briefly) within the body of the report, and to point out more or less distinct usages.

CHAPTER ONE:
The Environmental Effects of Transgenic Crops: What We Know Now

A Brief Background

Transgenic crops—that is, crops into which scientists have inserted genes isolated from microbes, animals, or other plants—are the most popular and most widely used of all crop biotechnologies. To date, the main purpose for transgenic technology has been to improve crops by making them more resistant to insects or more tolerant of herbicides. Genetic modification can also enhance a crop's value as food by increasing its nutrient or mineral content. Although early transgenic crops have been designed primarily for pest management purposes, the next generation may shift to more nutritious and more appealing food products (Kalaitzandonakes and Maltsbarger, 1998). Few of the early transgenic crops were designed to produce significantly higher yields—and in fact, few do so even now.

The most popular transgenic crops currently grown by U.S. farmers are soybeans, corn, cotton, potatoes, and tomatoes (USDA APHIS, 2000a). Genetically modified commercial crops grown on a smaller scale include sweet corn, canola, peanuts, mini-peppers, squash, papaya, and sunflower (BIO, 1998). Many new transgenic crops, including sugar beets, chili peppers, flax, melons, bananas, rice, strawberries, raspberries, and pineapples, are being developed and tested, or are just now entering the market.

Different crops have different transgenic qualities. For example, corn, canola, cotton, and soybeans have been engineered to resist herbicides. Insect-resistant crops that contain *Bacillus thuringiensis* (Bt), a naturally occurring pesticide, include corn, cotton, and potatoes. Disease resistance has been introduced into corn, squash, and papaya. Certain corn varieties have been genetically modified to grow in high-pH (i.e., alkaline) soils; some tomatoes, for improved taste, color, and texture; and certain mini-peppers and cherry tomatoes, for greater sweetness (Appendix 2, Table 1).

The most comprehensive data on transgenic crops are published by organizations that promote the use of agricultural biotechnology, such as the Biotechnology Industry Organization (BIO). According to BIO, transgenic crops were planted on approximately 4.3 million acres in 1996, 27.5 million in 1997, 69.5 million in 1998, and 100 million in 1999, with the latest figure accounting for approximately 8 percent of the world acreage in the major crops. Of the 100 million acres devoted to transgenic plants in 1999, 81 percent were in the U.S. and Canada (BIO, 2000a). More than 40 different commercialized transgenic crops were planted in 12 countries in 1999, including 8 developed countries and 4 developing nations (James, 1999).

The U.S. devoted roughly 71 million acres to transgenic crops in 1999, approximately one-quarter of its total cropland planted to the major crops, and more than any other country (BIO, 2000a; James, 1999). Argentina followed with an estimated 17 million acres (mostly soybeans) and Canada with 10 million acres. Nine other countries have less than 1 million acres of land planted with transgenic crops, including China (approximately 750,000 acres), Australia and South Africa (approximately

250,000 acres each), and Mexico, Spain, France, Portugal, Romania, and Ukraine (less than 250,000 acres each). Portugal, Romania, and Ukraine planted their first transgenic crops in 1999 (James, 1999). Overall, developing nations accounted for 18 percent of the global acreage of transgenic crops in 1999, up from 16 percent in 1998.

Compared with other countries, the United States has introduced and adopted transgenic crops quite rapidly. Part of the reason is that, in the U.S., approving these crops takes about one-half the time and one-fifth to one-seventh the cost of approving a new chemical pesticide compound (Ollinger and Fernandez-Cornejo, 1995). The result: almost half of the cotton and soybeans and more than a third of the corn and canola planted in the U.S. in 1999 were transgenic (Appendix 2, Table 2). From 1998 to 1999, U.S. farmers increased the amount of land planted with transgenic crops at a far faster rate (8.2 percent) than did other countries such as Argentina (2.4 percent), Canada (1.2 percent), and China (0.2 percent). Other nations increased plantings by less than 0.1 percent from 1998 to 1999. Hence, the environmental benefits and risks of the first generation of transgenic crops likely will be most pronounced within the U.S.

Soybeans are leading the overall growth in transgenic crops with a 7.1 percent increase from 1998 to 1999, followed by corn at 2.8 percent and cotton at 1.2 percent. Other crops had growth rates of 1 percent or less for the period (James, 1999). In 1999, approximately 21 percent of the transgenic crops planted across the globe were soybeans. Corn made up 11 percent, and cotton and canola each constituted between 3 and 4 percent. Developing nations generally grow four kinds of transgenic crops for commercial purposes: cotton, corn, soybeans, and tomatoes (James and Krattiger, 1999).

Despite the extraordinary popularity of transgenic crops in the United States in recent years, some, but not all, of the nation’s farmers may be slowing their adoption of some of these crops this year. According to a June 2000 survey of a random sample of farmers, conducted by the USDA’s National Agricultural Statistics Service, the proportion of acres planted to transgenic upland cotton is estimated to rise to 61 percent nationwide in 2000, from 55 percent in the major cotton-producing states in 1999 (USDA NASS, 2000). From 1998 to 1999, the rise was from 46 to 55 percent in the five major cotton-producing states. (Note that for cotton, and for the soybean and corn cases to follow, NASS reported 1999 figures only for the “major” states producing these crops, whereas estimates for 2000 are made for the entire U.S.) In contrast, transgenic soybean acreage is estimated to decrease from 57 percent in 1999 to 54 percent in 2000. This expected decrease comes on the heels of a 15 percent increase in all transgenic soybean varieties in major states, from 42 percent to 57 percent from 1998 to 1999. The proportion of acreage planted with transgenic corn is estimated at 25 percent of all U.S. corn acres, down from 33 percent in 1999 in the five major corn-producing states. This projected decline follows an increase of 30 to 33 percent from 1998 to 1999. The nationwide changes comprise varying changes for different types of transgenic crops in different regions. The differing patterns of change illustrate the different economic conditions for different transgenic crops, and thus the potential for varying environmental effects.

Environmental Risks and Benefits

The potential environmental impacts of any transgenic crop will vary depending on the crop’s characteristics, the ecological system in which it grows, the skill with which it is managed, and the private and public rules governing its development and production. To understand these variables and how they interact, we must rely on the work of biophysical and social scientists who are trained specifically to study these processes—and who can truly function as neutral observers. Because the early phases of biotechnological development focused almost exclusively on how plants could be genetically modified, molecular biologists and genetic engineers played the dominant roles. Now that the environmental impacts of these technologies are receiving increasing scientific attention, environmental scientists must play a larger role to answer the questions raised. Unfortunately, ecologists have only recently begun research programs on the environmental impacts of transgenic plants, and these programs have not been well funded. The U.S. Department of Agriculture's biotechnology risk assessment program has awarded an average of $1.5 million dollars annually—only 1 percent of USDA biotechnology research spending—to fund risk assessment of agricultural biotechnology applications (USDA ARS, 2000). The USDA's Agricultural Research Service spends approximately $5.4 million annually on biotechnology risk assessment research (Radin, 2000). The total of approximately $7 million per year is approximately 4 percent of public agricultural research funding on biotechnology.

Research funding is only one of the myriad challenges confronting scientists when they attempt to analyze the effects of transgenic crops on the environment. To begin with, because the commercial use of transgenic plants has grown so rapidly, there has been little time to build essential baseline ecological data. (What, for example, would environmental conditions or ecosystem functions in a certain area have been like if transgenic crops had not been introduced into it?) The definition of an appropriate baseline is critical to assessing the potential future impacts of such gene-altered crops. Because these baselines do not exist, the studies reviewed here generally compare expected environmental changes with those resulting from current agricultural practices, such as conventional pesticide applications. Relying on the known effects of current systems is understandable, but researchers using these methods must be cautious about how they interpret and measure their results. For example, if farmers begin to use new, alternative production systems that require fewer toxic pesticides than their current practices, the estimated reductions in pesticide use that would have come from planting transgenic crops will themselves decrease. Further, most monitoring data on the potential environmental effects of transgenic crops are limited to known problems and are collected by the biotechnology industry itself. Another difficulty is that government agencies regulating genetically altered crops do not generally require data on the indirect, compound, and long-term environmental impacts of these crops. For each of these reasons, the environmental science of transgenic crops has been slow to develop. Nonetheless, there is a small but steadily growing body of laboratory and field science to draw upon.

Changes in Pesticide Use

A number of transgenic crops have been designed to repel or resist a range of pests, or to tolerate chemical pesticides that pose less environmental risk than some more toxic alternatives. Accordingly, many analysts initially expected that farmers who planted these crops would use fewer, less-toxic pesticides, which, in turn, would benefit the environment. The rapid spread of these crops indicates that some farmers are benefiting from them economically, at least in the short run. However, the long-term effects of transgenic plants on pesticide use are not clear-cut. For instance, planting crops that have been engineered to contain Bt, a natural toxin effective as an insecticide, obviates the need for chemical insecticides, but planting transgenic crops that are resistant to specific herbicides may actually increase the use of these herbicides. Taken together, transgenic crops can induce entirely new patterns and volumes of total pesticide use—which means that potential risks to environmental and human health will change as well. Unfortunately, at this early stage in crop biotechnology, the cumulative shifts in use of many pesticide compounds are mostly uncertain. Because of variables such as farmers' behavior, climate, pest infestation levels, pest resistance buildup, and crop prices and costs, each of which can change over time, a decade of carefully monitored field- and larger-scale results may be necessary to assess the transgenic crops' full potential for benefit or risk to the environment. Most of the data currently available pertain to Bt crops and Roundup Ready soybeans (since these are the most widely used transgenic crops) and come from sources at the national, regional, and local levels. The Agricultural Resource Management Study (ARMS), conducted by the USDA's Economic Research Service and National Agricultural Statistics Service, is the most comprehensive nationwide survey on the use of pesticides and other agricultural production technologies in the U.S. (USDA ERS, 1999a, 1999b).

In any study of pesticide use, there are a number of reasons why it is not enough to make simple comparisons of changes from one year to the next, or of differences between farmers who use or do not use transgenic crops. First, simply comparing data from year to year does not account for annual variations in weather or pest problems. Second, changing socioeconomic conditions, such as crop and fertilizer prices, may change how farmers use pesticides, regardless of whether the crops in question are transgenic or not. Third, farmers who plant transgenic crops may simply use pesticides differently than farmers who plant conventional crops. For example, farmers who are accustomed to using larger-than-average amounts of conventional pesticides may have a great incentive to lower their pesticide expenditures once they start using genetically altered crops. Farmers who adopt the technology later, and who used average amounts of pesticides in the first place, may not report the same level of pesticide reduction. Fourth, the findings may be influenced by whether the data on pesticide use are collected locally, regionally, or nationally. With more data per unit area (i.e., a higher sampling density), local data may be able to capture more of the variations in pesticide use. Perhaps for all of these reasons, the early research findings on changes in pesticide use related to transgenic crops are not consistent.

Ideally, data that assess the long-term effects of transgenic crops on pesticide use should reflect a full range of climate, pest, and economic conditions, with variables to control for the influences of farmers who use (or do not use) these crops. The use data should also be linked to the natural resource base to estimate changes in acute and chronic toxicity in a variety of regional ecological systems (Antle and Capalbo, 1998). The data available (reported below), for a variety of reasons, do not measure up to these standards. The reliability of pesticide use data for transgenic crops will likely improve, however, as long-term trends can be established.

The USDA's Economic Research Service recently determined that, on the whole, the introduction of transgenic crops has reduced farmers' use of pesticides nationwide (USDA ERS, 1999a, 1999b). ERS analysts estimated a reduction of 6.8 to 9 million pesticide acre-treatments (about 1.9 to 3 percent of the total) between 1997 and 1998, due to genetically altered crops (Heimlich et al., 2000). (An "acre-treatment" is defined as "the number of different active ingredients applied per acre times the number of repeat applications" [USDA ERS, 1999a].) The estimated reduction in pounds of active pesticide ingredients ranged from 0.3 to 7.9 million pounds (0.4 to 3.4 percent of the total applied), with 1.2 million pounds serving as an estimate of the most likely value between 1997 and 1998. This net decrease in applied pesticides is composed of increases for some crops in some situations and of decreases for others. For example, the adoption of Bt crops is likely to reduce insecticide use overall. However, based on the ERS analysis, an estimated 13.4 million pounds of glyphosate have been substituted on transgenic soybeans for 9.9 million pounds of other synthetic herbicides, such as imazethapyr, pendimethalin, and trifluralin, on conventional soybeans (Heimlich et al., 2000). That substitution can be a positive change, as glyphosate can be 3 to 16 times less toxic than the herbicides it has replaced, and 1.6 to 1.9 times less likely to persist in the environment (Heimlich et al., 2000).

Although the early changes in pesticide use indicate a slight overall lowering of environmental risk from pesticides, it is important to remember that these findings may be only shortlived. If, for instance, farmers begin to use some other practices that lead them to rely less on conventional pesticide substitutes, such as integrated pest management (IPM), then the early findings of reduced pesticide quantities and toxicity may not hold over the long run. Furthermore, the ERS' overall numbers need to be disaggregated into figures for individual crops, if we are to gain a more precise understanding of the potential short-term environmental impacts of transgenic crops.

Insecticide Use on Cotton

Results from recent surveys indicate that because U.S. cotton farmers are planting more Bt cotton crops (specifically engineered to resist certain insects), they are using fewer chemical insecticides (Carlson et al., 1998; Gianessi and Carpenter, 1999; Hubbell et al., 2000; USDA ERS, 1999a, 1999b). However, the estimated reductions differ from study to study. The amount of insecticide applied to Bt cotton crops in 1997 to control the bollworm, pink bollworm, and tobacco budworm was less than half the amount applied to non-Bt cotton (USDA ERS, 1999a). Gianessi and Carpenter (1999) report that a total of 2 million fewer pounds of insecticides (a 12 percent reduction) were used to control the bollworm and budworm between 1995 and 1998 in Arizona, Arkansas, Louisiana, Mississippi, and Texas. In addition, approximately 2.3 fewer insecticide applications were required for Bt cotton, compared to conventional cotton crops.

Because cotton has so many pests, however, the advent of insect-resistant varieties will not necessarily lead to a large and sustained reduction in the use of cotton pesticides (Hayenga, 1998). The USDA's ERS (1999a), for example, reports that the use of insecticides on Bt cotton to control pests other than the bollworm, pink bollworm, and tobacco budworm increased in 1997. Further, increased use of Bt cotton in the southeastern U.S. in 1997 did not result in any significant change in the use of organophosphate and pyrethroid insecticides (USDA ERS, 1999b). However, the ERS does note a significant decrease in aldicarb usage. In contrast, Hayenga (1998) reports that the introduction of Bt cotton has led to a 20 percent reduction in acreage treated with pyrethroid insecticides.

The different estimates of insecticide use changes related to Bt cotton are difficult to interpret. A closer look at one of the most detailed investigations (reported in Carlson et al. [1998] and Hubbell et al. [2000]) may explain one reason for the discrepancies. The authors surveyed 293 cotton growers in North Carolina, South Carolina, Georgia, and Alabama about their adoption of Bt cotton and how they used pesticides on acres planted with conventional cotton (i.e., non-Bt), as well as acres planted with Bt cotton, in 1996 (the first year the technology was commercialized). Overall, the survey responses showed that the farmers who had chosen to plant Bt cotton made an average of 0.8 insecticide applications on acres planted with this crop, in contrast to 2.8 insecticide applications on acres planted with non-Bt cotton. By comparing pesticide use on farmland managed by farmers who planted some Bt cotton and some conventional cotton, the authors avoided a potential bias that could have occurred in comparisons between farmers who chose to plant Bt cotton and those who did not (Hubbell, 2000). In general, farmers who plant Bt cotton are likely to have used higher levels of conventional insecticides in the first place, and so can save more money than farmers who have chosen not to plant Bt cotton. Indeed, Carlson et al. (1998) report that farmers who planted Bt cotton made an average of 2.8 applications in 1996 on their conventional cotton acres, compared with just under 2.4 applications for farmers who planted conventional cotton.

In contrast, the findings from the ARMS survey reflect the differences in pesticide usage between farmers who plant transgenic crops, and those who do not. Recall the reasoning that farmers who use less insecticide on average also have less incentive to adopt Bt varieties because they have less expense to save. Thus, we should expect farmers who plant only conventional cotton to have lower insecticide use on average, all other factors being equal. Hence, estimating the reduction in insecticide use from adopting Bt cotton, by comparing new use levels with those of non-adopters who plant only conventional cotton (and therefore have lower insecticide use), will show a smaller difference, than would comparing insecticide use levels on fields planted by farmers who use Bt and also conventional cotton. That is precisely what the two studies show.

Reports of changes in pesticide usage related to transgenic crops may differ due to differences in study regions and time periods. For example, Carlson et al. (1998) report that the average number of insecticide applications by U.S. farmers who adopted Bt cotton was 3.29 on their conventional acres in the upper South, but only 2.58 in the lower South. The difference likely reflects different insect conditions in the two regions. The pest conditions also vary over time, leading to different pesticide use figures within a specific year.

An understanding of the long-term effects of Bt cotton on insecticide use may require analyses of 10 or more years to cover the cycles of pest, climate, and economic variations. Whether the large initial reduction in insecticide use, as reported by Hubbell et al. (2000), will apply to farmers who begin using genetically engineered crops will depend on a number of factors, including changes in the prices of the technologies, relative changes in the resistance of conventional and Bt crops to pesticides, farmer knowledge, and whether a field is planted exclusively with Bt crops, or a combination of Bt and conventional crops. Moreover, the ultimate impact of Bt cotton on pesticide use, and so on the environment, can be determined only by comparing the fate, transport, and toxicity of the full array of insecticides available to farmers, and how they are used by farmers, whether they do or do not plant Bt crops.

Insecticide Use on Corn

Based on an ERS analysis of the ARMS data from selected areas of the United States, farmers who planted Bt corn in 1997 used fewer insecticide treatments than usual, on average, to control the European corn borer, a major corn pest. The use of insecticides to control all other corn pests remained approximately the same (USDA ERS, 1999a). Gianessi and Carpenter (1999) report that

Bt corn has likely led to a 2 to 3 percent drop in the use of several insecticides to control the European corn borer. More dramatically, Hayenga reports that from 1997 to 1998, corn acreage treated with insecticides to control this pest dropped by 30 percent. He also notes that the use of Bt insecticidal sprays dropped from 10 percent of total corn acreage in 1997 to almost zero in 1998 (Hayenga, 1998). Hayenga predicts that after 2000, the introduction of crops resistant to the corn rootworm will further reduce the use of insecticides on corn, assuming pests do not develop resistance to the Bt toxins they contain.

Insecticide Use on Potatoes

The use of transgenic potatoes apparently has little effect on rates of insecticide use (Gianessi and Carpenter, 1999). This result is not surprising, as potatoes comprise only 4 percent of all U.S. crops, and Bt potato growers continue to spray their crops to control other pests (Gianessi and Carpenter, 1999).

Herbicide Use on Soybeans

The ERS reports that increased use of herbicide-tolerant soybeans in the U.S. in 1997 led to an increase in the use of the herbicide glyphosate (USDA ERS, 1999b). However, simultaneous decreases in the use of other herbicides resulted in a net decrease in the total pounds of herbicide applied to soybeans. The ERS indicates that herbicides can be applied to herbicide-tolerant crops at reduced rates, and in less-toxic concentrations, than traditional pesticide applications (USDA ERS, 1999a). Hayenga reports that, in 1998, soybean acreage treated with the herbicide Roundup doubled, due primarily to the increased acreage of Roundup Ready soybeans, which are specifically engineered to tolerate this herbicide. (Roundup is one of a number of commercial pesticide formulations containing glyphosate as active ingredient.) Corresponding volume reductions occurred for other herbicides that compete with Roundup (Hayenga, 1998). Benbrook (1999) notes that, based on USDA survey data, acreage of herbicide-tolerant soybeans increased by almost 37 percent from 1996 to 1998, and based on the number of acres treated with herbicides, changes in total herbicide use have not been dramatic. He cautions that because Roundup Ready soybeans have not been used for very long, it is too soon to assess how they will affect herbicide use in the long run. For example, he notes that there have been reports that such glyphosate-based herbicides have become less effective in controlling velvetleaf and ragweed. Consequently, farmers may need to use more herbicides to control these and other weeds that develop resistance to commonly used herbicides.

Herbicide Use on Cotton

The ERS reports that in 1997, despite an increase in herbicide-tolerant cotton acreage, the quantity of herbicides applied to cotton did not change significantly (USDA ERS, 1999b). Hayenga (1998) predicts an increase in the use of cotton resistant to the herbicide bromoxynil (currently 8 percent of total cotton acreage in the U.S.), and a resulting increase in its use. Bromoxynil became available for this and other applications after a U.S. Environmental Protection Agency (EPA) decision to register the compound for commercial use in 1998. Gianessi and Carpenter (1999) expect, however, that as farmers increasingly adopt bromoxynil-resistant and Roundup Ready cotton, they will be able to reduce their use of herbicides on cotton crops, because bromoxynil and Roundup can be applied at lower rates than alternative compounds.

Herbicide Use on Corn

Based on the ARMS survey, U.S. farmers increased slightly their use of herbicides on herbicide-tolerant corn in 1997, from 1.9 to 2.2 acre-treatments. However, the increase was not considered statistically significant (USDA ERS, 1999a). Hayenga (1998) reports that 20 to 30 percent of seed corn will likely be herbicide-tolerant by 2005, although thus far, transgenic corn resistant to glyphosate has not significantly affected herbicide use.

Yield Changes

In addition to the potential for decreased pesticide use, another early promise of transgenic crops was that they could significantly increase crop yields. Some argue that if the yield increases in fact materialize, current pressure to put new land into production and to increase production intensity on existing cropland may wane. The logic continues that the production increases would then result in conservation of wild lands and the animals, plants, and other organisms that depend on them. This argument for conservation rests on several linked assumptions that are unlikely to hold (Batie and Ervin, forthcoming). Nonetheless, we analyze the potential for significant yield increases from transgenic crops, because if that potential for increased yields is unlikely to unfold, the argument is moot.

Because transgenic crops came into commercial use relatively recently, however, the literature assessing the technology's potential effects on yields is limited. It is extremely difficult to predict what changes in yield quantity and quality might occur, given a full range of weather, pest, and other conditions. Changes in yield depend on the type of technology used (that is, the types of new genetic traits incorporated into existing crops), as well as a host of other factors that interact with the technology. For example, Roundup Ready soybeans contain new genes designed to make them resistant to a certain chemical pesticide, and not to increase the inherent yield potential of the crop (Nelson et al., 1999). In contrast, Bt corn and cotton are engineered specifically to increase crop yields. Isolating and measuring yield increases or decreases for each crop are complicated by several factors: yields depend on the region where the crops are grown, weather and pest conditions, and the rate at which pests come to resist plants modified to repel them. Yields also depend on a farmer's ability to use the new technology proficiently. The ARMS survey findings (USDA ERS, 1999a) reviewed below illustrate this variability and uncertainty, although the accumulating evidence is helping researchers to form stronger hypotheses about the ultimate yield effects.

Herbicide-tolerant Soybeans, Corn, and Cotton

The physiological impacts of genetically transforming soybean plants to tolerate the herbicide glyphosate have initially caused a drag on yields. Benbrook (1999) has summarized 1998 university and seed company trial data in southern Wisconsin and southern and central Minnesota to measure this effect. On average, the experiments using Roundup Ready soybeans showed a 6 to 7 percent yield drag, or 4 bushel per acre loss, compared to top-yielding conventional varieties. A recent 2-year study at the University of Nebraska also found that Roundup Ready soybeans yielded 6 percent less than their closest relatives and 11 percent less than high-yielding varieties (Elmore et al., in review). These results are not a surprise: Carpenter and Gianessi (1999) have concluded that

Roundup Ready soybeans would be expected to have yields that are lower than or about the same as competing non-transgenic soybean varieties. However, these analysts pointed out earlier this year that there are two ways to look at yields: by examining variety trials or by analyzing weed-control trials. They argue that the variety trials—which are often designed to measure the inherent genetic potential to affect yield—do not always assess the cultural potential to manage pests better, and thus do not take into account beneficial weed control. They conclude from their review of weed control studies that "there seems to be no resounding yield advantage or disadvantage in Roundup Ready systems compared to conventional programs" (Gianessi and Carpenter, 2000, p. 65).

Klotz-Ingram et al. (1999) report that the estimated yields from 1996–98 ARMS data for herbicide-tolerant cotton were not significantly different from or lower than yields for conventional cotton. Similar early-yield patterns may hold for corn resistant to herbicides. Nonetheless, the long-term effects of crops tolerant to herbicides are uncertain. If sufficient private incentives exist to reward yield increases, or if public research agencies make crop yield increases a higher priority, scientists may be able to minimize yield reductions or even enhance potential yields.

Bt Corn and Cotton

In terms of yields, Bt corn and cotton behave differently than crops engineered to tolerate herbicides. Theoretically, because Bt engineering provides cost-effective protection against the European corn borer, pink bollworm, and other insect pests, yields of Bt crops should be higher than those of their conventional counterparts. However, the findings of recent survey data are not uniformly confirming. According to Carlson et al. (1998), U.S. farmers who planted Bt crops reported that their average 1996 yields were 13 percent higher on their Bt cotton acres than on their conventional cotton acreage in the lower South. Oddly, the survey did not reveal a similar significant yield increase in the upper South. In both regions, farmers who did not plant Bt cotton at all had significantly lower yields on their conventional cotton acres than did farmers who had planted at least some Bt cotton elsewhere. The authors characterize this result as "somewhat puzzling."

The ERS reports that Bt cotton and Bt corn are associated with significantly higher yields in "most years for some regions" (USDA ERS, 1999a). According to the ARMS survey, from 1996 to 1998 the average annual yields of Bt cotton in three regions of the U.S. outpaced yields of conventional cotton by 9 to 26 percent in four of nine cases studied, but were not significantly different in three cases (Klotz-Ingram et al., 1999). Yield increases for Bt corn were not as dramatic. The authors' cautious conclusion, that Bt cotton may increase yields and economic returns, stems from their inability to control for all factors that might affect yields, such as climate variation and the differing characteristics of farmers who did or did not plant the gene-modified crops. Even if all of these factors could be considered, yields could increase or decrease over time as a result of new transgenic crops or other factors unknown at present.

Reduced Soil Tillage and Water Use

Soil and water are natural resources critical to crop production. In this regard, transgenic crops could help conserve soil, primarily by alleviating farmers of the burden of tilling the soil to control weeds. Some crops could even be engineered to tolerate drought, and thus reduce the use of ground and surface waters for irrigation. There is virtually no empirical evidence, however, on how transgenic crops have affected soil tillage and water use. Scientific estimates of erosion changes based on shifts in tillage (and pesticide usage) are possible, but apparently have not been made. In the case of water, crops have not yet been developed specifically to address this concern. Arabiyat et al. (1999) simulated the possible water savings achieved by the use of bioengineered crops in the Texas High Plains, but the yield effects that are key to those savings are estimates, not data from actual harvests. Firm evidence on tillage and water effects must await further research and development of new transgenic varieties.

Transfer of Genes to Wild Relatives

Although the agricultural community has generally paid little attention to the flow of genetic material from crops—whether transgenic or conventional—to wild plants, there is little doubt in the scientific community that genes will, in fact, move from crops into the wild (Hails, 2000; NRC, 2000; Snow and Palma, 1997). The relevant concern is not whether the genes will move, but whether they will thrive in the wild and how they might significantly increase the “weediness” of particular wild plants, by conferring a fitness advantage that makes such plants more difficult (e.g., expensive) to control in areas where they are not desired (Hails, 2000; Keeler et al., 1996; NRC, 2000; Snow and Palma, 1997).

The answers to these questions depend on a number of factors, including the availability of wild relatives closely related to the transgenic crop, whether the crop is a self-pollinator or an outcrosser (outbreeder), and whether the modified wild plant realizes a physiological cost imposed by the novel traits (Hails, 2000; NRC, 2000; Snow and Palma, 1997). Generally, crops with wild relatives in close proximity to the areas where the crops are grown pose higher risk for gene flow to the wild plants. U.S. examples include sunflower and canola (Hails, 2000; Keeler et al., 1996; Snow and Palma, 1997). Gene transfer could become a problem if the transferred genes do not have deleterious effects on the crop-wild hybrids, but instead confer an ecological advantage (Hails, 2000; Snow and Palma, 1997).

Gene flow from classically bred crops to wild plants has been documented. The evidence available suggests that such crop-to-wild gene flow has, in fact, enhanced the weedy character of certain weedy species, creating so-called “superweeds.” For example, Johnson grass is an economically important weed that has gained fitness advantages via gene flow from cultivated sorghum (Hails, 2000; Keeler et al., 1996; NRC, 2000; Snow and Palma, 1997). Snow and Palma (1997) argue that increased weediness from gene flow from conventional crops to wild plants has been somewhat rare, though this question has not been thoroughly studied. Nonetheless, widespread cultivation of transgenic crops could enhance the fitness of sexually compatible wild relatives. Greater fitness might potentially occur because recombinant gene methods are more rapid, more precise, and allow access to a much greater array of desired genes than do traditional breeding methods. The precision and sophistication of bioengineering methods increase the likelihood, over conventional breeding methods, that crop-to-wild outcrossing of engineered traits will lead to the increased weediness of wild plants. Traditional breeding typically results in the inclusion of deleterious alleles (i.e., alternative forms of a gene) linked to the desired beneficial genes. The inclusion of harmful alleles decreases the likelihood that crop-to-wild outcrossing will result in enhanced weedy traits in the wild plants. Biotechnological methods enable solitary genes to be selected and transferred without including neutral or deleterious genes (Snow and Palma, 1997; see also NRC, 2000, p. 85).

Mikkelsen and colleagues (1996), employing field trials, found that genes expressing herbicide-resistant traits were transferred from transgenic canola to one of its wild relatives.[1] However, it is generally not expected that herbicide-resistant transgenes will result in increased weediness of wild relatives, as such genes tend to impose a cost, or are neutral, to the wild plants. Ecologists tend to be more concerned about potential fitness advantages of insect- and virus-resistant transgenes (Hails, 2000; see also the following section on virus resistance). Nonetheless, in situations where herbicides are typically employed to control weedy plants, herbicide resistance could confer a competitive advantage (Keeler et al., 1996). Also, it is often argued that engineered genes exhibiting particular traits useful in plant products, such as oilseed modification, will not pose ecological risks. However, Linder and Schmitt (1995), using a combination of field trials and greenhouse studies, found that genetically modifying seed-oil composition in oilseed rape could potentially confer fitness advantages to wild relatives of the bioengineered crops.

Limiting ecological risk from transgene flow can include a number of interventions. These include rotating crops, spatial isolation, harvesting crops before flowering, planting non-transgenic crops as pollen trap crops, and avoiding production of transgenic crops with available wild relatives, such as canola, oats, artichoke, sunflower, lettuce, rice, radish, and sorghum in the U.S. (Keeler et al., 1996). In this vein, a promising development is the finding that transforming a plant cell's chloroplast genome, instead of inserting a gene into the cell's nucleus, will delay, but not preclude, the movement of the transgene via pollen dispersal (Daniell et al., 1998; Hails, 2000; NRC, 2000, p. 90; Stewart and Prakesh, 1998). Although transgenes can also spread through seed dispersal, this finding could have significant implications for the risk assessment of crop biotechnologies regarding gene flow.

Crops Bred for Increased Resistance

Transgenic crops bred to resist herbicides and damage from pests have the potential to dramatically change agricultural practices. However, these technologies have been used only for a short period of time. The lack of long-term studies poses a serious obstacle to performing an adequate assessment of their potential environmental effects. Nevertheless, there are a number of studies and review articles that address the potential environmental impacts of these crops.

Herbicide-resistant Crops

Transgenic crops that are resistant to herbicides could help farmers improve their management of weeds, as well as lead them to use less-toxic herbicides less often (Krimsky and Wrubel, 1996).

[1] Gene flow between crops can potentially cause management difficulties regarding crop "volunteerism." Hall and colleagues (2000) recently reported the presence in a Canadian farmer's field of volunteer canola resistant to three herbicides: glyphosate, imidazolinone, and glufosinate. The "triple-resistant" canola developed from gene flow among three canola varieties designed to resist each of the three herbicides, which were planted in close proximity to each other. For additional information, see Alberta Agriculture's Web site (Thomas, 2000).

However, the literature identifies a number of environmental concerns related to widespread reliance on these crops. One, of course, is that herbicide-tolerant crops and wild, weedy relatives could interbreed, making the latter more resistant to herbicides. To control these stronger hybrid plants, farmers might respond by increasing the amount or toxicity of herbicides they apply (Krimsky and Wrubel, 1996; Royal Society, 1998). Weedy relatives may be especially difficult to control if they become resistant, as well, to other pests, including bacteria, fungi, and other plant pathogens (Watrud and Seidler, 1998).

Weed populations that are resistant to herbicides can emerge also if farmers choose to use only a few herbicides on their farms. Susceptible populations can develop resistance, or weeds that can tolerate or "avoid" certain herbicides may simply take the place of weeds that cannot. Weed scientists find the latter development likely. In fact, Owen (1998) reports that in Iowa in 1997, "[c]ommon waterhemp (*Amaranthus rudis*) populations demonstrated delayed germination and have 'avoided' planned glyphosate applications. Velvetleaf (*Abutilon theophrasti*) demonstrates greater tolerance to glyphosate and farmers are reporting problems controlling this weed with the rates of glyphosate for which they are willing to pay." Such problems could lead to an increase in the use of more herbicides that are far more toxic than glyphosate.

Fortunately, early data suggest that nothing of this sort has yet happened. As noted earlier in this report, the ERS has determined that despite an increase in the U.S. acreage of herbicide-tolerant cotton since 1996, there has been no associated increase in use of cotton herbicides (USDA ERS, 1999b). However, the U.K.'s Royal Society (1998) cautions that as herbicide-tolerant crops have been used for only a limited time, it is too soon to accurately predict such effects.

Insect-resistant Crops

The potential benefits of planting insect-resistant transgenic crops include decreased insecticide use and reduced crop damage. However, the innate ability of insect populations to rapidly adapt to environmental pressures poses a serious threat to the long-term efficacy of insect-resistant biotechnologies. Adaptation by insects and other pests to pest protection mechanisms can have environmental and health impacts. For example, adaptation by insect populations to an environmentally benign pest control technique could result in the use of chemical pesticides with higher toxicity. Also, if an insect pest adapts to a transgenic pest-resistant crop, another gene-altered crop, with which scientists and farmers are less familiar in terms of its environmental or health impacts, could be introduced in its place (NRC, 2000). In addition, the insecticidal toxins in insect-resistant crops can affect non-target organisms (see the following section). Several studies document the evolution of insect resistance to genetically modified crops and note the importance of establishing refuge areas (refugia) to slow the rate of resistance. However, in general, the body of scientific literature is limited to laboratory studies of specific insect pests. As more research is performed, knowledge of the extent and evolutionary rate of resistance development will deepen considerably.

Tabashnik (1994) reported an increase in resistance to Bt toxin in laboratory studies of Lepidoptera (butterflies and moths), Coleoptera (beetles) and, to a lesser extent, Diptera (mosquitoes and flies). These findings could influence the development of resistance management policies if they are supported by field experiments. Huang et al. (1999) found that, at specific doses, the inheritance of resistance in the European corn borer to Bt toxin is incompletely dominant, rather than recessive, as was previously believed. Based on this finding, the European corn borer would likely develop resistance more quickly than previously predicted. Current resistance management strategies are based largely on the assumption that resistance to Bt will be slow to evolve since it was assumed to be a recessively inherited trait (Huang et al., 1999). This finding, if confirmed, could have a major impact on current strategies to manage resistance development, such as the size of refuge areas.

Two additional studies have relevance to both non-target organism impacts and pest resistance. Koskella and Stotzky (1997) found that certain Bt toxins, when bound in clay, did not readily break down, and thus retained their insecticidal activity for prolonged periods. The persistence of Bt toxins in clay soils may increase the risk of pest resistance (Koskella and Stotzky, 1997). These investigators imply that prior predictions may have underestimated the rate of evolution of Bt resistance in pest populations. Schuler et al. (1999) found that insect behavior and target pest resistance may influence how plants genetically engineered to express Bt toxin affect non-target organisms. In their study, Bt toxins present in Bt-resistant moth larvae did not harm wasp parasitoids of the diamondback moth, a lepidopteran normally susceptible to Bt. The authors suggest that the ability of the wasps to prey on Bt-resistant moth larvae could limit the development of Bt resistance in diamondback moth populations.

A preliminary report released recently by the U.S. EPA to its Scientific Advisory Panel (SAP)[2] assesses, among other things, current resistance management programs for Bt crops. The report concludes that the existing insect resistance management (IRM) plan for Bt potatoes is adequate to mitigate development of resistance in the Colorado potato beetle. It also concludes that the IRM plan for Bt corn is sufficient to diminish European corn borer resistance, but could require strengthening to limit development of resistance in stalk-borer pests, such as corn earworm. Regarding Bt cotton, the SAP concludes that current IRM plans may require strengthening in the areas of refuge size and “deployment” in order to combat resistance development in tobacco budworm, cotton bollworm, and pink bollworm (US EPA, 2000b).

Virus-resistant Crops

Although they have as yet produced only a small body of literature on the subject, scientists have voiced several key environmental concerns related to virus-resistant transgenic crops. First, these varieties may promote disease in neighboring plants by altering them so they become hosts for particular viruses, when such plants were not previously susceptible to infection by the viruses of concern (and thereby increasing the viruses’ host ranges). Second, virus-resistant transgenic crops may alter the processes through which plant viruses are transmitted (Rissler and Mellon, 1996; Royal Society, 1998). These changes could result in the development of stronger (i.e., more virulent) viruses (Hails, 2000; Rissler and Mellon, 1996; Royal Society, 1998). Unfortunately, scientific research on this potential risk has been minimal.

[2] The EPA document was released in September 2000, just prior to publication of this report. Therefore, we were not able to review it in-depth or to seek comments from our project advisors. An EPA spokesperson described the findings in the report as “tentative” and indicated that additional and important research results (e.g., field evidence) on the risks and benefits of Bt crops were forthcoming.

Scientists are also concerned that the DNA genome in virus-resistant crops may recombine with the viral genome during replication of RNA plant viruses (Rissler and Mellon, 1996; Royal Society, 1998). In one laboratory study, genetic recombination occurred between *Nicotiana benthamiana* plants and cowpea chlorotic mottle bromovirus. Researchers believe that such recombination could lead to genetically unique viruses that may be difficult to control (Greene and Allison, 1994).

Rissler and Mellon (1996) contend that, of the risks associated with virus-resistant transgenic crops, weediness is of greater concern than is the risk of increased viral host ranges, or of new, stronger viral strains. For its part, the National Research Council (NRC) found that the USDA's current assumption, that transgenic resistance to viruses engineered in cultivated squash will not result in enhanced weediness of wild squash through gene flow, needs verification through longer-term studies. The NRC also concluded that the USDA's assessment of the potential for virus-protective transgenes in cultivated squash to affect wild populations of squash "is not well supported by scientific studies," especially for transgenic squash engineered to be resistant to several viruses instead of three or fewer (NRC, 2000, p. 124).

In this vein, The Royal Society (1998) recommends a "case-by-case" assessment of the impacts of antiviral proteins. Should research on the effects of virus-resistant crops reveal undue risks, it would be reasonable to expect more regulation of these new strains.

Impacts on Non-target Organisms

While crops bred to resist pests may suffer less damage and lead farmers to use less insecticide, there is widespread concern that the toxins these plants produce may harm non-target organisms, including animals, plants, and microorganisms that are not pests (Royal Society, 1998; Watrud and Seidler, 1998). Insect predators, soil biota, and wildlife such as birds and invertebrates (which depend on healthy insect populations) could all be affected (Johnson, 1999).

Laboratory research confirms that transgenic insecticidal crops can have negative impacts on beneficial insect predators, including lacewings (Hilbeck et al., 1998a) and ladybird beetles (Birch et al., 1997); monarch butterfly larvae (Losey et al., 1999); and soil biota (Watrud and Seidler, 1998). Hilbeck et al. (1998a) found that 62 percent of lacewing larvae (predators of many agricultural insect pests) died after consuming prey fed with Bt corn, versus 37 percent mortality for those consuming prey fed on conventional corn (see also Hilbeck et al., 1998b). However, data presented to the EPA by Monsanto (which develops and markets Bt corn) found no difference in mortality associated with Bt treatment. In a review of the contradictory findings, the National Research Council concluded that the Monsanto study may have failed to sufficiently mimic natural conditions, since the Bt toxin was applied to the surface of the lepidopteran eggs. In general, lacewings feed only on the internal contents of its prey's eggs (NRC, 2000, p. 113).

The results of the studies by Hilbeck and colleagues were downplayed, however, in the previously mentioned preliminary report from the EPA to its Scientific Advisory Panel (US EPA, 2000b). The EPA report argued that the studies undertaken by Hilbeck's team did not mimic field conditions sufficiently to warrant concern for lacewings from Bt corn. For example, the EPA cited the lack of controls for a choice in diet for the lacewings utilized in the studies, as well as levels of Bt exposure unlikely to be found in field settings (US EPA, 2000b). Such conflicting findings and interpretations indicate that further knowledge generation in this area is critical, especially evidence from field and ecosystem conditions, to supplement laboratory studies.

Other research by Birch et al. (1997) found that transgenic potatoes expressing snowdrop lectin, a plant protein that reduces aphid infestation, caused reduced fecundity and increased numbers of unhatched and unfertilized eggs in ladybird beetles, natural enemies of aphids. In addition, Tabashnik (1994) asserts that reductions in pest populations due to transgenic crops may negatively affect available numbers of desirable natural predators. These findings indicate potential conflicts with conservation efforts and IPM strategies that may rely on healthy populations of natural predators. On the other hand, a field study done in Wisconsin found that populations of predators and parasites were higher in Bt potato fields than in conventional potato fields where conventional chemical insecticides were used. Non-chemical or less-intensive chemical treatments were not evaluated (Hoy et al., 1998, as cited in NRC, 2000). This finding points to the need to evaluate the impacts of insect-resistant transgenic crops relative to current alternative practices, whether they involve intensive use of chemicals, less-intensive use of chemicals, or non-chemical pest control techniques.

In the most publicized laboratory study of potential ecological impacts of crop biotechnology, Losey et al. (1999) found a 44 percent mortality rate in monarch butterfly larvae fed on milkweed leaves dusted with Bt corn pollen. No mortality occurred in monarchs fed on leaves with non-Bt corn pollen. The findings of Losey and colleagues have become the subject of heated debates and criticism. The intense focus on this study by both skeptics and proponents of biotechnology is symbolic of the division in viewpoints on the environmental effects of biotechnology and on the role of science in identifying impacts and shaping policy. The central finding is not surprising since Bt is known to be toxic to Lepidoptera, including monarch butterflies. It is still unclear, however, what degree of risk is posed to monarch butterfly populations in the field, because the research was conducted in a laboratory. Field conditions such as pollen drift and monarch migration patterns are key to whether the risk is high or low. In addition, concern has been raised that the Losey team's study failed to address pollen dilution effects—that is, as pollen containing Bt drifts from a corn field, there may not be sufficient amounts deposited on milkweed leaves to harm monarchs (Beringer, 1999). Also, it is important to note that not all Bt corn cultivars produce Bt toxin in their pollen (NRC, 2000, p. 76).

In a follow-up study, Hansen-Jesse and Obrycki (2000) found that monarch butterfly larvae feeding for 48 hours on milkweed leaves, which had been naturally dusted with pollen from Bt corn plants, exhibited higher rates of mortality compared to larvae feeding on leaves with non-Bt pollen or no pollen at all. These investigators concluded that Bt corn effects on non-target organisms can extend beyond field borders. The potential is greatest closer to the field, within 3 meters (9.8 feet), but can extend beyond that distance.

Recent findings by Wraight et al. (2000), that a common type of Bt corn had no deleterious effects on black swallowtail butterflies, exemplify the complexity of these issues. These researchers studied the effects of a different type of Bt corn on a different species of butterfly than was examined by Losey and colleagues. Further, the Wraight team combined field and laboratory studies, while the

Losey group's study was limited to the laboratory. These types of findings point to the need for further research and risk assessment on a case-by-case basis.

The EPA's recently released preliminary report (US EPA, 2000b) underscores the need for further research in this area. In the report to its Scientific Advisory Panel, the EPA contends that, among other pertinent information, the literature on monarch breeding patterns shows there is not substantial overlap between corn pollen shed and monarch breeding areas in the U.S. Corn Belt. The preliminary report concludes that ". . . the published preliminary monarch toxicity information is not sufficient to cause undue concern of widespread risks to monarch butterflies at this time." At the same time, however, the background report cautions that studies to assess the threat to monarchs from Bt corn pollen in field settings are still ongoing. The EPA has only recently become aware of the presence of monarch larvae on milkweed plants within corn fields. These milkweed plants would be exposed to the highest concentration of Bt pollen and, therefore, put monarch larvae at the highest risk (Yoon, 2000). The results from ongoing studies of these issues will, hopefully, provide insight into the nature and extent of the threat to monarchs in areas where monarch breeding areas overlap with periods of corn pollen shed.

If non-target insects are indeed affected by insect-resistant transgenic plants, then their predators may be affected as well. Johnson (1999), for instance, notes that more than 50 percent of farmland bird populations in Great Britain are in serious decline. He attributes the declines of several species, including the gray partridge and skylark, directly to the increased use of chemical pesticides. Based on these declines, and on the harm that insecticides and herbicides have wrought on European plant and insect populations over the past several decades, Johnson predicts that transgenic crops producing pesticidal toxins may damage food web connections between native species and crops. These links are vital to maintaining biodiversity (Johnson, 1999). The Royal Society also notes that recent decreases in biodiversity are likely influenced by "current agricultural practices." It emphasizes the need for more studies of the impacts of transgenic crops on birds, mammals, and soil biota (Royal Society, 1998). In its turn, the National Research Council asserts that the commercialization of crops containing diverse insecticidal toxins could harm some forms of wildlife by reducing their food supplies (NRC, 2000, p. 80). Conversely, it is conceivable that some bird populations may increase if farmers replace conventional pesticides, which have diminished the birds' food supply, with transgenic crops (NRC, 2000, p. 80).

Insects and other animals are not the only organisms potentially affected by transgenic crops. In their review of relevant studies on the impacts of transgenic crops on soil biota, EPA researchers Watrud and Seidler (1998) reported increased numbers of soil bacteria and fungi associated with Bt cotton, and increased nematodes and decomposers associated with transgenic insecticidal tobacco. They found no change in soil microbes associated with Bt potatoes. One line of transgenic fungus-resistant tobacco apparently led to impaired mycorrhizal fungus colonization. Colonization of plant roots by mycorrhizal fungi is often beneficial to plant growth. The environmental implications of these findings were inconclusive and require further research and explanation. It is clear that the EPA considers impacts on soil biota to be an important component of evaluating the environmental effects of transgenic crops. In fact, the agency's recent preliminary report to its Scientific Advisory Panel (US EPA, 2000b) cites the need to generate more data on the issue. The report concluded that, currently, evidence suggests that Bt crops are unlikely to have adverse impacts on soilborne organisms. The report notes, however, that it is important to continue research in this area, especially with regard to the levels of root expression of Bt proteins, in order to discern if higher than expected levels of root expression of such proteins are to be found.

Crop Genetic Diversity

The development and global spread of improved crop varieties through the Green Revolution has reduced genetic diversity in cropping systems (i.e., *in situ*), although not in germplasm maintained in seed banks (*ex situ*). This reduction (or genetic erosion) has occurred as modern varieties have replaced farmers' traditional landraces (NRC, 1993). However, the conservation of traditional landraces is recognized as essential, since they are often important sources for desirable breeding traits such as disease and pest resistance (NRC, 1993).

The issue of crop genetic diversity, and its relation to biotechnology, essentially divides into two lines of argument. One asserts a negative relationship between the development and introduction of transgenic crops (at least the current generation) and crop genetic diversity. Altieri (2000) argues that transgenic crops will continue the trend toward simplification of cropping systems. Such a trend started with the introduction of Green Revolution technologies and has become dominant in agriculture (NRC, 1993). According to this analyst, the integration of seed companies and biotechnology firms and the consolidation of the biotechnology industry into a few major players exacerbate cropping system simplification. The numbers and types of crops planted have greatly decreased as fewer and larger firms dominate the merging seed and biotechnology markets (Altieri, 2000). In addition, Altieri cites the intellectual property rights (IPR) associated with the advent of agri-biotechnological development for promoting the erosion of crop genetic diversity, by preventing farmers from saving seed. He believes that such seed-saving promotes genetic diversity as farmers cross commercial and local varieties and share seeds with, or sell seeds to, their neighbors. That is, continuous and localized experimentation (*in situ* conservation) results in increasing genetic diversity (Altieri, 2000). Crop varieties developed during the period that came to be known as the Green Revolution were not subject to the IPR restrictions applied to current agri-biotechnologies (Perseley, 1990; Smith et al., 1999) and, therefore, did not preclude seed-saving and experimentation (Hubbell and Welsh, 1998; Perseley, 1990).

In this vein, Gupta (1999) argues that the high cost of obtaining IPR inhibits grassroots innovators and undermines the conservation of biodiversity, a situation complicated by differing legal IPR structures in different countries (Lesser, 1997; OECD, 1999). Furthermore, King and Eyzaguirre (1999) argue that IPR are not necessarily adaptable to indigenous people's values or concepts of ownership. Lesser (1997), in particular, notes that IPR protection is not readily available for cooperative technologies—those produced by communities in accordance with age-old practices in plant breeding and conservation of landraces. Thus, IPR institutions may not suffice to support conservation of crop genetic resources through indigenous managers.

An alternative line of argument claims a potential positive relationship between crop biotechnology and crop genetic diversity. Hawtin (1997) provides a helpful example of this alternative argument. He contends that biotechnology applications have a critical role in conserving plant genetic resources, and thus crop genetic diversity, primarily by making seed bank storage (*ex situ* conservation) more efficient and efficacious. Hawtin asserts that molecular genetic techniques allow the tracking of genetic materials in seed banks more accurately. Such techniques are also useful for more accurately identifying disease-free plant material, which is crucial for effective collection and storage. Also, cryopreservation (a biotechnological method using low temperatures) could make very long-term storage possible, thus increasing the probability that more genetic material will be available when needed. Hawtin recognizes that *in situ* plant conservation also is necessary to maintain crop genetic diversity, although he criticizes this form of protection as not systematic and not well understood. He sees the combination of Geographic Information Systems (GIS) and genetic tracking of plant materials as a means of systematizing *in situ* conservation. Nonetheless, despite its limitations, *in situ* conservation may be an important element in ecosystem protection.

Findings

Transgenic crops have expanded in the U.S. at a rate unprecedented for new agricultural technologies, but at a slower pace in other countries. Their introduction promises a number of environmental benefits, but also poses a number of ecological risks. The scientific knowledge base for understanding both the potential benefits and the risks is small and often yields inconsistent results.

An understanding of the impacts of transgenic crops on **pesticide use** is hindered by the few years of use data available since commercialization. In addition, the early findings from USDA national surveys and regional studies are often not comparable because of uneven data quality, varying weather and pest conditions, and different analytical methods. Nonetheless, each level of study has its value: for instance, regional studies that examine large groups of farmers can help us to understand regional pesticide use changes better than national surveys can. The key factors in farmers' decisions about pesticide use on transgenic crops are not always measured or estimated, including the influences of risk preferences and soil, water, and climatic variations. Virtually no research has traced the estimated pesticide use changes through to their effects on various environmental resources. Finally, the lack of monitoring data at ecosystem scales is a serious difficulty in assessing those processes and the ultimate toxicity effects of pesticide shifts.

Concerning **yield effects**, transgenic crop technologies have the potential to enhance yields. However, yield gains have been small to date. This finding should not be surprising. The most widely planted transgenic varieties, including Roundup Ready soybeans, have emphasized input-switching traits, and thus were not designed to achieve large yield increases. In contrast, Bt cotton and corn crops were developed to raise yields through more cost-effective pest control. Still, their record in doing so varies, with significant yield increases in most years for some U.S. regions, but insignificant increases in other areas. A full understanding of the long-term yield effects must await more experience over the normal range of climatic and pest conditions. Ruttan (1999) argues that higher levels of public support for basic research in functional genomics and other areas will be necessary to achieve significant yield increases. Advances in such basic science may attract more private funding for research into enhancing yields, thus leveraging the public investment.

The potential ecological impacts of **gene flow** vary considerably, depending on a number of factors including plant species and type of transgenic trait. Also, our current knowledge is limited with respect to the extent to which wild plant populations are affected by herbicides, insects, or viruses.

Therefore, it is difficult to predict whether, and to what degree, wild or weedy plant populations would benefit from resistance to these factors. In general, transgene spread will occur. However, we do not know if transgenes will persist in the wild or increase the weediness of wild plants. The latter is more likely to happen if transgenic crops are introduced into areas that are home also to their wild relatives. Also, some promising research in genetic engineering of the chloroplast genome might result in DNA-transfer techniques that hobble gene flow via pollen transfer. Institutions are needed that provide incentives to firms to develop transgenic crops, recombinant technologies, and management regimens that would make outcrossing of beneficial genes to wild relatives less likely. Such incentives, which do not currently exist, could include “fast-track” regulatory approval or tax breaks, among other interventions.

A key approach to improving our knowledge of the gene flow process and its effects is to substantially increase the USDA budget dedicated to risk assessment of transgenic crops. Traditionally, the amount available for risk assessment is $1 to 2 million per year. Indeed, the recently released National Research Council report on genetically modified pest-protected plants finds that the transfer of resistance traits from crops to their wild relatives has not been “adequately studied” (NRC, 2000, p. 93). Also, Hails (2000) argues that research should move from laboratory and limited field experiments to large-scale trials. Such trials will account for the fact that “. . . large pollen sources interact on a regional scale to increase estimates of gene flow” (Hails, 2000, p. 17). Altieri (2000) contends that ecological science has been left out of the biotechnology revolution, and therefore, it is not surprising that potential ecological impacts from agricultural biotechnologies have not been fully considered. He argues that this oversight should be corrected.

As for the environmental effects of **herbicide-, insect-, and virus-resistant crops**, increased risk assessment and, particularly, better monitoring systems could lead to more precise decisions on appropriate control measures. For example, as we saw earlier, setting aside refuge areas where healthy populations of susceptible pests are maintained is an important way to slow down the evolution of pest resistance (Gould, 1998). However, determining the appropriate size for such reserves can be quite complex. Gould believes that the recommended 4 percent refuge size is inadequate to maintain the effectiveness of pest-resistant crops. In fact, the EPA has published new requirements for year 2000 plantings: 20 percent of corn acreage in the Corn Belt and up to 50 percent of cotton acreage in the Cotton Belt should be set aside as refuge areas to maintain healthy populations of susceptible pests (US EPA, 1999). The EPA recently announced three new options for refuge requirements for 2001 Bt cotton plantings. These vary from 5 to 25 acres of non-Bt (refuge) cotton for every 100 acres of Bt cotton (95 acres in the case of embedded refuges), depending on the use of insecticides and proximity to Bt cotton fields (US EPA, 2000a). In addition to setting aside refuge acreage, reducing the amount of insecticidal toxin present in pest-resistant plants may help slow down the evolution of resistance (Gould, 1998; Royal Society, 1998). The development of transgenic crop varieties that produce toxins only in specific parts of the plant, or at critical times during a growing season, could also prove helpful (NRC, 2000).

The National Research Council recently criticized the EPA for not developing and implementing a general policy for designating situations that require transgenic crop resistance-management plans. The NRC went on to recommend that such resistance-management plans should be encouraged when “a pest protectant or its functional equivalent is providing effective pest control, and if growing a new transgenic pest-protected plant variety threatens the utility of existing uses of the pest protectant or its functional equivalent." However, the NRC intends for resistance management to apply to "all uses" of the pest protectant, not just its use within transgenic crops. Regarding Bt crops and resistance management, this recommendation would mean that resistance-management practices would also be encouraged for microbial Bt sprays, in addition to Bt crops (NRC, 2000, p. 103).

Future research on insect-resistant crops of all types could investigate the development of traits that make resistance development less likely. Such traits could include manifestation of tolerance to pest damage rather than pesticidal properties (Hubbell and Welsh, 1998), or the ability to delay symptoms and damage from pathogens until after the plant has produced its valuable seeds or fruits. Delayed damage would remove the need for treatment with chemicals or other environmentally disruptive agents. This type of trait would not interfere with the pathogens' ability to reproduce, and thus should not foster more aggressive pathogens, yet would allow farmers to realize the full economic benefits of their crop plantings (Krimsky and Wrubel, 1996). In this vein, the NRC recently cited the need for environmental research to develop pest-protected plants, including transgenic crops, which can be used in environmentally and evolutionarily sustainable approaches to agriculture (NRC, 2000). Institutions and incentives are needed to spur research in these areas, which will most likely originate in the public sector.

The effects that transgenic plants have on **non-target animals, plants, and other organisms** are, as we have seen, unclear. The intensity of debate and lack of clarity about the significance of the findings from work by Losey et al. and Hansen-Jesse and Obrycki affirm the central conclusion of this review. There has been insufficient research (especially field studies) on the environmental effects of transgenic crops, in this case the potential impacts on non-target organisms. The recent preliminary report from the EPA to its Scientific Advisory Panel (US EPA, 2000b) did not benefit from reviewing such evidence. This gap in knowledge is being filled slowly due to controversies such as those that surround the aforementioned studies. However, a larger, systematic research program on the ecological implications of crop biotechnology, including broad-scale monitoring, is needed to anticipate the full-range effects for sound policy design, and avoid such reactive debates.

In addition, it is important to make evaluations of transgenic insect-resistant crops relative to current agricultural practices (NRC, 2000, p. 80). As previously presented, chemically intensive practices potentially have more negative impacts on non-target organisms than do certain transgenic insect-resistant crops. However, the growing popularity of organic food and organic production systems points to the need to include alternative systems in such comparative evaluations. For example, Robinson (1991) argues that the reduced soil erosion, increased crop diversity, and dearth of synthetic pesticides associated with organic farming systems have significant positive impacts on wildlife.

Regarding **crop genetic diversity**, once seed material (and other germplasm) is in storage, genetic modification techniques seem useful for evaluating, enhancing, or preserving crop genetic diversity. However, our experience with Green Revolution technologies suggests that, in the field, it is likely that the large-scale introduction of transgenic crops will further diminish *in situ* plant genetic diversity. To halt the trend towards genetic uniformity, governments could offer tax credits or direct payments to biotechnology firms that allow farmers to save seeds and experiment with them (Hubbell and Welsh, 1998). Alternatively, or in addition, governments could issue plant or variety protection that mirrors 1978 UPOV Convention rules (i.e., the 1978 version of the Convention of the International Union for the Protection of New Varieties of Plants), instead of utility or invention patent protection, to biotechnology firms. This change would allow farmers to legally save seed, replant, and crossbreed, and thereby promote crop genetic diversity (Hubbell and Welsh, 1998; Paarlberg, forthcoming; RAFI, 1999). Dawkins (1999) argues that regulatory regimens should include ecosystem-specific testing and more attention to technologies that enhance genetic diversification on the farm. Gupta (1999) contends further that the World Trade Organization's TRIPS agreement should be reformed so that every patent applicant would be obliged to disclose whether a proposed intellectual property was obtained through informed consent, and whether its benefits would be shared with those who conserve biodiversity.

CHAPTER TWO: Biosafety Regulation

The U.S. regulatory system that currently governs biotechnological innovations uses the “best science” available on the environmental effects of transgenic plants. However, as we have already seen, that scientific knowledge base is still relatively undeveloped, and because biotechnology is such a new area for regulation, the system is still in need of some restructuring. Indeed, a recent report by the National Research Council offered a number of recommendations for strengthening parts of the system (NRC, 2000). The current U.S. system differs markedly from its EU counterpart, reflecting ideological differences that may have profound commercial and environmental implications in the future.

United States Regulations

In the United States, transgenic crops are subject to a tripartite regulatory system. The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture, the EPA, and the Food and Drug Administration (FDA) each play a part in this system, which focuses on determining the relative safety of biotechnology’s end products and uses, and not on the processes by which they are created (NRC, 1989). APHIS’ mandate is to ensure that transgenic plant varieties are as safe to grow as conventional varieties. The EPA’s primary responsibility is to ensure the environmental safety of new plant-pesticidal substances (a mandate that includes human health effects). The FDA’s regulatory process focuses on how foods made from transgenic crops might affect human health. (As our analysis centers on the environmental effects of transgenic crops, we have not reviewed the FDA role in detail.) The tripartite regulatory process initially conducted product-by-product reviews of transgenic varieties. Currently, the process may assess the possible risks from new transgenic products, based on the experience gained in reviewing earlier products. The implication is that some crops might be approved, or disapproved, without actual field testing.

U.S. Department of Agriculture/Animal and Plant Health Inspection Service

Under the authority of the 1957 Federal Plant Pest Act (FPPA), APHIS regulates the movement into and within the country of organisms that may pose a threat to U.S. agriculture (USDA APHIS, 1999). The agency’s objective is to prevent the introduction, dissemination, or establishment of such organisms in the environment. Since 1987, its mandate has included regulating transgenic crops.

APHIS does not focus on the origin of the modified genes in transgenic plants. Rather, it looks at how a plant that contains a modified gene behaves in comparison with its unmodified counterpart. Before 1993, a company needed to obtain a permit to introduce transgenic crops into a state or into the environment. The company was required to provide background information on the crops, including their origins; data on how and where it planned to test the crops; details on how the tests would be conducted; and a list of specific precautions that would be taken to prevent the escape of pollen, other parts of the crops, or the crops themselves from the test site. The company then was obliged to follow the experimental design requirements dictated by APHIS. The review process often took approximately 120 days.

In 1993, the APHIS permit requirements were modified so that companies needed to give only 30-day advance notification of their intention to introduce transgenic corn, cotton, tomatoes, potatoes, tobacco, or soybeans into the environment (USDA APHIS, 1993). In 1997, all crops, except pharmaceutical plants, plants containing toxins, and plants in which the function of the gene introduced was unknown, were placed on a "fast-track" regulatory process that requires advance notice prior to their release (USDA APHIS, 1997). As of 28 July 2000, APHIS had received 6,538 notifications and release permits, and had approved 5,755. Of the remainder, 291 received delayed approval, 233 were denied, 189 were withdrawn, 16 were void, and 49 were pending (USDA APHIS, 2000a, viewed at ISB, 2000). Since 1987, the approved releases and notifications have involved approximately 24,220 field test sites in the 49 mainland states, 3,405 in Hawaii, and 2,356 in Puerto Rico (USDA APHIS, 2000b, viewed at ISB, 2000). The tests have involved approximately 80 different regulated organisms, including corn, soybeans, and cotton, with nearly half of the approved releases for tests on herbicide resistance and insect resistance.

According to the new requirements, companies must provide APHIS with information on the types of transgenic crops they are planning to market, the genes they plan to introduce into each crop, and the crop's agronomic performance. They must also demonstrate that the new transgenic crop behaves like its conventional counterpart, exhibits no plant pathogen properties, is no more likely than comparable conventional varieties to become a weed, is not likely to increase the tendency for other plants to become weeds, causes no damage in processing, and does not harm insects that benefit agriculture, such as ladybeetles or honeybees. The companies may design their own experiments to develop the required information, or use information on the various performance requirements from acceptable data sources. Commentators have argued that the tests do not adequately capture the scale of potential ecological impacts and possible long-term effects, thus hampering sound ecological risk assessments (Krimsky and Wrubel, 1996; Lappé and Bailey, 1998). APHIS grants petitions once it has determined that the genetically modified plant poses no significant risk to other plants in the environment, and is as safe to use as more conventional varieties (USDA APHIS, 2000a). APHIS often relies on existing scientific literature to make these decisions, rather than requiring original experimental data from testing conducted by companies (NRC, 2000, p. 170). It is worth noting that fast-track procedures also stipulate that companies introducing a crop with an improved or truncated gene do not need to apply for a permit to market it, because the plant is deemed sufficiently similar to its previously approved version.

Fouldian (2000) estimates that 95 to 98 percent of field tests now take place under notification rather than permits. Field testing usually lasts two to three growing seasons. Once the final experimental data are submitted, APHIS can approve a transgenic crop for commercial release within 180 days. However, the process may take longer if APHIS requests additional information from companies. In that case, APHIS "stops the clock" until the company either provides the information or withdraws its application.

Once all the information on a particular transgenic crop is gathered, the non-confidential portions of it are posted in the *Federal Register* and the public is invited to comment within a period of 60 days. After completing the APHIS review process, companies can apply for deregulation, i.e., removing the organism from the regulatory process, usually a step toward commercialization. The EPA and/or the FDA may review the data as well, before allowing the crop to be released commercially. Before issuing a permit allowing a regulated transgenic plant to be released into the environment, APHIS must conduct an environmental assessment under the National Environmental Policy Act (NEPA). APHIS must also coordinate with the state(s) where the crops will be released to assure its safety in use. APHIS has approved 51 applications for deregulated status out of 75 submitted since 1987. Nineteen applications were withdrawn, three are pending, one was void, and one was incomplete during that period (USDA APHIS, 2000a). Over time, APHIS has increased the transparency of the approval process and now allows the public greater opportunity to respond to proposed regulation and deregulation decisions (USDA APHIS, 1999).

U.S. Environmental Protection Agency

The EPA regulates plant and microbial pesticides, new uses of existing pesticides, and new microorganisms that may pose risks to the environment or to human health. In carrying out its responsibilities, the EPA sets limits (known as "tolerance limits") for the amounts of pesticides that can be used on and in food and feed. The agency also exempts certain products from these tolerance limits if they are effectively regulated by other agencies.

In 1994, the EPA announced its intention to regulate the pesticides produced by transgenic crops that are engineered to protect themselves from pests. Examples include the Bt biological pest controls in Bt corn and Bt cotton. Note that the EPA did not indicate its intention to regulate the transgenic crops themselves, a common misconception (US EPA, 1994a, 1994b). The proposed regulation, based on the agency's statutory responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), establishes tolerance limits for herbicide residues on herbicide-tolerant crops, and regulates microorganisms intended for commercial use that contain or demonstrate new combinations of traits. Under FIFRA, the EPA assesses whether the pesticide produced by such transgenic crops poses "unreasonable adverse effects on the environment." Under the FFDCA, the EPA establishes residue levels for pesticides in or on raw agricultural commodities and for processed food and animal feed, based on a "reasonable certainty of no harm." Now, according to the U.S. Food Quality Protection Act (FQPA), which Congress passed in 1996, the EPA must apply a "safety-only" standard when examining the dietary risks caused by pesticide residues in food, such that risk minimization is the sole criterion for approval (Batie et al., 1999). Traditionally, under FIFRA, the EPA could assess the added risks against social, economic, and environmental gains in making a registration decision. A company may register a pesticide only after the EPA reviews the health and environmental test data it has submitted.

The EPA regulation process for transgenic pest-protected plants usually comprises three stages. First, companies that wish to conduct field tests on areas larger than 10 acres must apply for an experimental use permit under FIFRA (US Congress, 1947). Experiments on areas smaller than 10 acres are exempted unless the crop being tested will be used for food or feed products, or unless the experiment is not subject to oversight by a USDA plant pest program. Second, companies usually apply to the EPA for a registration that is limited to the production of propagative plant products, such as seeds, tubers, corms, and cuttings (US EPA, 1995). Finally, companies must apply for full commercialization of the pesticides produced by the crops in question. If the crops will be used for food or feed, the companies promoting them must also petition the EPA to (1) set pesticide tolerance limits for the crops, or (2) exempt the crops from the tolerance limit requirement. The EPA has already registered 10 pesticides expressed by transgenic corn, potato, and cotton plants and has determined that they do not need to meet any tolerance limits (NRC, 2000). An example of part of the EPA's regulatory process is the refuge requirement for Bt crops for insect resistance management.

European Union Regulations

The European Union's approach to regulating transgenic crops differs significantly from that of the United States. Indeed, whether the issue is human, environmental, or biotechnological, the EU has become increasingly sensitive to consumer concerns and now commonly adopts a "precautionary" approach. Simply put, this means that under the EU regulatory regimen, sufficient scientific evidence of "no excessive risk" must exist before a crop can be approved for commercial release. This approach centers on avoiding what is known as a "type II" statistical error—that is, the error of assuming that no significant environmental risk is present when, in fact, significant risks exist. In contrast, the U.S. process attempts to avoid what is known as a "type I" error—that is, the error of assuming that significant environmental risks exist, when they do not. In common language we might characterize the difference as: the EU approach is "guilty until proven innocent," while the U.S. approach is "innocent until proven guilty." The degree of confidence (i.e., the significance level) required by either the U.S. or the EU in avoiding the respective errors plays a crucial role in release decisions. It does not appear to be 100 percent in either case because some crop biotechnologies have been withdrawn from the U.S. biosafety approval process, and some have been approved in the EU. However, the burden of proof of no excessive risk before EU approval has had an influence. The EU market for crop biotechnologies is limited to Bt-based insecticides (Brouwer et al., 1999).

In 1990, when it was still the European Community, the European Union instituted an approval procedure for commercial releases of bioengineered organisms on the market.[3] However, only a limited number of bioengineered crops have entered the EU market as seeds. The EU regulatory authorization procedure is rather complex, as the approaches of different member countries must be reconciled and different regulatory structures integrated (House of Lords, 1998). The applicant must perform a full risk assessment. The competent authority in each country must audit this assessment with a view to whether potential risks to human health and the environment have been minimized.

By the end of 1995, the European Commission had authorized bioengineered rapeseed (also known as oilseed rape) from the company Plant Genetic Systems, but only for non-food seed (i.e., seed that would be used to grow feed for animals). This oilseed rape was genetically modified so that it would tolerate the herbicide glufosinate (trade name, Basta). Also, the EU authorized Bt corn from Novartis and Bt soybeans from Monsanto in 1996. The European Commission has also made several decisions enabling the appropriate authorities of member states to market products containing or consisting of genetically modified organisms (GMOs). According to industry sources, approximately 32,000 hectares (79,000 acres) of Bt corn were grown in European countries in 1999, including 30,000 hectares (74,000 acres) in Spain, and 1000 hectares (2,500 acres) each in France and Portugal (James, 1999). By the end of October 1998, some 30 bioengineered crops had been approved and were awaiting permission for commercial release in the European Union (House of Lords, 1998).

[3] Because this paper is focused primarily on the U.S. situation, a complete description of the EU biosafety regulatory system is not provided.

Despite all this activity, however, the commercial use of transgenic crops in EU countries has remained less than 0.1 per cent of total land used to grow the types of crops for which transgenic options are approved (House of Lords, 1998).

The regulatory approaches of EU member states may vary, to the extent of defining "adverse effects on human health and the environment." For instance, in the case of an herbicide-tolerant oilseed rape, the United Kingdom recommended approval while some other member states objected (Levidow and Carr, 1997). The EU's Nordic members are generally more cautious than those in central and southern Europe. In central or southern European countries, some disease or animal welfare problems associated with modern agricultural methods that are rejected by Nordic countries are considered acceptable. Some members energetically oppose transgenic crops: France, as an example, has recently issued a moratorium on planting them, and several other EU countries have prohibited growing such crops commercially until field trials examining crop safety have been completed. Austria and Luxembourg have banned Bt crops to protect their organic agriculture and have developed regulations for consumer food products (Cohen, 2000), despite being contrary to EU regulations (Lacy, in press).

Comparing U.S. and EU Regulatory Approaches

To reiterate, the European Union attempts to set the level of risk it is willing to accept, and then takes precautionary action to prevent the use of transgenic crops that exceed this level. In the United States, the so-called "science-based" risk approach is grounded on available information and expert opinion, and transgenic crops are accepted unless compelling proof of danger is provided. When some potential risks of commercializing transgenic crops emerged in the U.S., government officials chose to mitigate them by incorporating risk management plans into the regulatory process. In contrast, EU officials generally have considered the risks too excessive, without further research, to allow commercialization of these crops, even with mitigation (Levidow, 1999). The EU decision, in essence, bans or severely restricts the commercialization of transgenic crops until better information is available to complete risk assessments. Also, the EU submits all products developed with transgenic methods to its regulatory process, while the U.S. now considers that it has had enough experience to relax this approach and review only new gene-crop mixes. For instance, in the United States, bioengineered products must be labeled only if they are not "substantially equivalent" to existing products. At this writing, none have been placed in that category, and so none have been labeled. In contrast, the European Union requires labeling for products that contain at least 1 percent of one ingredient containing genetically engineered material. The label must state, "This product contains genetically modified organisms" (European Union, 1999).

Critics worry that the U.S. APHIS regulatory process for release of transgenic crops is simplified for crops with which the agency is familiar. However, some actions may be required by the agencies overseeing the reviews before release is approved. For example, the EPA allows commercialization of Bt crops only if an insect resistance management plan is in place. In Europe, at least two countries have banned the use of Bt crops because they were judged to pose a threat to organic agriculture. In the EU, some crop biotechnologies were not approved because of their antibiotic resistance markers, whereas the U.S. regulatory system has not judged that the marker genes cause excessive human health risk.

The differences between the U.S. and EU approaches to regulating biotechnology arise because of different initial cognitive frameworks, different levels of trust in government, and different agri-political situations. The dissimilar cognitive frameworks arise primarily because many Europeans appear to view the environment as a fragile ecosystem that may be easily unbalanced by transgenic crops (Levidow and Carr, 1997). The dominant view in the United States is of a resilient environment that can easily adapt. In the U.S., environmental scientists have not been widely involved in decision-making about transgenic crops, including releasing them into the environment. Instead, physical scientists, and later molecular biologists, have led biotechnology development (Regal, 1999). Some of these scientists have questioned the limitations of their disciplines in manipulating the hereditary materials in living organisms (Regal, 1999). Some U.S. interest groups that actively oppose transgenic crops appear to hold views similar to those prevalent in the European Union. They criticize the U.S. regulatory approach, arguing for a more cautious stance in approving transgenic crops, or even for outright bans.

To conduct their risk assessments, the U.S. regulatory agencies, and especially the USDA, rely on data from the companies that develop biotechnology products, and impose penalties (a $10,000 fine and 2 years in jail) if the companies fail to provide all available information. The EU system does not use industry data, nor do most Europeans trust government agencies. The U.S. citizenry generally appears to trust its government to make impartial risk assessments, and trusts its experts to provide unbiased "probabilities" of potential events. In contrast, the EU population appears to favor risk assessments conducted with publicly generated data and does not necessarily trust its experts, adding further uncertainty to the risk assessment.

The agri-political environmental situations also differ between the United States and European Union. Europeans, in general, view agriculture and the environment as an integrated whole, and they favor a diverse countryside. They also tend to believe that cultural diversity is a form of biodiversity, and are less inclined to prefer more uniform agricultural systems. In the U.S., farms generally are no longer viewed as tightly tied to their natural environments. Most U.S. farmers are oriented toward staying competitive internationally by producing more crops at lower prices. The political pressure not to infringe on biotechnology development has also been much stronger in the United States, where the majority of R&D investments have been made (Levidow and Carr, 1997).

Findings

In both the United States and the European Union, authorities recognize the need for improved regulatory structures based on reliable scientific data. To that end, the National Research Council (NRC) recently concluded that the overarching regulatory framework for transgenic plants resistant to pests must be completed as soon as possible. In the NRC's view, the diversity of bioengineered crops gaining commercial status, as well as the rates at which they are being adopted, argue strongly for immediate action (NRC, 2000). Four areas of improvement in the U.S. biosafety regulatory process emerge from the literature.

First, if environmental concerns are to be systematically addressed in the regulatory process, **larger roles for ecological and other environmental scientists are required**. Regal (1999) has proposed the wider use of multidisciplinary review teams, including environmental scientists. An increase in the U.S. budget dedicated to risk assessment of transgenic crops, now a meager $1 to 2 million annually, would make environmental scientists more effective contributors to the regulatory process (Snow and Palma, 1997). Possible subjects for more research include the effects of possible new virus strains; the effects of plant-pesticides on plants, animals, and other organisms that are not pests; and the ecotoxicity of plant pharmaceuticals—all of which would need to be examined within a framework or protocol specifically designed to evaluate risks (Rissler and Mellon, 1996; Royal Society, 1998). The relatively small public research base, particularly on the scale of biotechnology's potential environmental impacts and its long-term effects, means that scientists carrying out the regulatory review often need to rely on industry data, rather than independent sources (Krimsky and Wrubel, 1996; Lappé and Bailey, 1998). Other ways to better include environmental concerns are to collect environmental data early in the development of genetically modified crops (Krimsky and Wrubel, 1996; Royal Society, 1998), and to ensure that the ecological research moves from laboratory and limited field experiments to large-scale trials (Hails, 2000). Such trials could capture the movement of plant pollen across a regional scale, which increases the risk of unintended environmental impacts.

A second possible improvement in the biosafety regulatory framework is to **designate an environmental agency to lead the ecological assessment of transgenic plants** (Rissler and Mellon, 1996). Under the agency's leadership, all transgenic crops would be tested before release (Krimsky and Wrubel, 1996), at least for gene flow and weediness, using a three-tiered approach that would separate low- and high-risk crops early in the process (Rissler and Mellon, 1996). Designating a lead environmental body also may help to eliminate potential gaps in regulatory coverage identified by the National Research Council, including the categorical exemptions of transgenic pest-protectants derived from sexually compatible plants and from viral coat proteins expressed in transgenic plants (NRC, 2000). Conversely, a lead environmental agency might be in a better position to implement standards and rules that are flexible enough to limit restrictions on pest-protected plants that do not pose environmental risks (NRC, 2000). It might also reduce the concern by some that the USDA is simultaneously advocating the use of transgenic plants while trying to regulate their environmental risks. Similarly, a single lead agency might be able to exercise more comprehensive oversight of "revolving door" job switches among industry and government regulators (Regal, 1999). The concern about designating a lead agency with sufficient authority for effective regulation is not just a U.S. issue. In the U.K., a scientific review suggested that the government consider creating a body to oversee and regulate the broader impacts of transgenic crops on agronomic practices, and to look at the cumulative effects of such crops over time and space (Royal Society, 1998).

To build broad public trust, the lead agency would need to make its review process and data open and widely available to the public. This need to **improve public access to information** is a third biosafety reform. The NRC maintains that "[t]he quantity, quality and public accessibility of information on the regulation of transgenic pest-protected plant products should be expanded" (NRC, 2000, p. 15). The NRC found the USDA's database to be particularly useful and recommended it as a model. In contrast, it found the EPA's actions deficient in providing adequate information to the public about its biosafety process. In this light, the NRC notes that because biotechnology companies select the priority information to be submitted for review, federal agencies may not be able to obtain enough information to adequately inform the public about certain transgenic crops (NRC, 2000). This problem may be compounded by companies' tendencies to claim that much of their information is confidential.

Fourth, and finally, the regulatory process would be enhanced if it were to **incorporate greater consideration of social values**. A frequent criticism of the current regulatory systems is that socioeconomic values are not systematically considered in their decision processes. The consideration of ethical and socioeconomic factors, known collectively as the "fourth criterion," is inherent to risk assessment and social decision-making (Lacy, 2000). According to the "fourth criterion" reasoning, it is not justifiable simply to decide that risk assessments are science-based and so delegate decisions to experts alone. The selection of which type of error to control, type I or II, and the choice of confidence level are inherently social decisions reflecting the public's relative aversion to certain risks. Lacy (2000) argues that the development of future biotechnologies should be decided in a broad, participatory fashion. However, any public participation requirements would need to be designed carefully to control excessive transaction costs and to balance powerful lobbying groups that espouse narrow views. Such policy reforms could provide for more public involvement in decisions about public and private biotechnology R&D (Lacy, 2000). While these reforms depart from traditional biosafety approaches in the U.S., they will improve the public's confidence in transgenic plants over the long run.

CHAPTER THREE:
The Business of Biotechnology

Biosafety regulations in themselves cannot completely control the potential environmental impacts of transgenic crops. Moreover, the regulations may take effect only after these crops are researched and developed. The commercial forces that guide private R&D and indirectly affect public research systems—which include intellectual property rights, labeling policies, and international trade agreements—also play large roles, and can shape the evolution of new products. The long-term potential of transgenic crops to affect the environment cannot be assessed without examining these forces.

Intellectual Property Rights

The forces propelling transgenic crop development have altered traditional public and private research roles (Smith et al., 1999). Within the U.S., for much of the 20th century, universities and the federal government were the nation's leaders in basic agricultural science. Private industry focused largely on commercializing new technologies that had often been invented in public laboratories. Private firms had little incentive to undertake basic scientific research, because competing firms could use the results to develop products, without paying any compensation. However, patent laws eventually evolved to allow inventing firms to control access to research innovations or to charge fees for their use.

A profound shift in U.S. patent law occurred in 1980, when a narrow (5-4) Supreme Court ruling in Diamond vs. Chakrabarty made it possible for companies and individuals to obtain the strongest form of intellectual property protection possible—a utility patent—for newly created living organisms (Barton, 1999; King and Stabinsky, 1999). A utility (or invention) patent gives the inventor the right to exclude others from practicing the invention for a certain time period (usually 15 to 20 years) (Perseley, 1990, p. 90). This kind of patent stands in contrast to plant and variety protection patents, which provide plant breeders with some exclusionary rights but can, depending on the form of the certificate, allow farmers to save, replant, and even sell seeds for nonreproductive purposes (Paarlberg, forthcoming; Perseley, 1990). The prospect of obtaining patents with broad exclusions creates an incentive for private firms to increase their research investment in patentable technologies. Perhaps as a result of this development, total private agricultural research spending overtook total spending on agricultural research by the public sector in the early 1980s, and the gap has since widened (Smith et al., 1999).

In addition, public research institutions have entered some phases of commercialization traditionally left to the private sector. The motivating factor was the U.S. Bayh-Dole Patent Policy Act of 1980, which has allowed individuals and institutions to patent biological inventions and then grant licenses to the users of scientific results obtained through research conducted with federal funds. Hence, public-private alliances have become considerably more attractive. The cooperative research and development agreement (CRADA) exists to further such public-private collaborations. The CRADA institution was enabled by the U.S. Stevenson-Wydler Technology Innovation Act, which was, in turn, amended by the Federal Technology Transfer Act of 1986 to speed the transfer of technology from the public to private sectors (Klotz-Ingram and Day-Rubenstein, 1999).

Much has been written about intellectual property rights (IPR) regimens and agricultural biotechnology, but little literature addresses the relationship between IPR and environmental and biodiversity protection. Most general analysis focuses on the role that IPR regimens may play as barriers to agricultural trade or as incentives for innovation—or on the types of industries most dependent on IPR regimens for their profits. Mazzoleni and Nelson (1998), for example, explore the implications of and clarify the differences between theories of innovation regarding patent-based approaches and alternative approaches. They explain that virtually all empirical work has been guided by the theory that patents motivate invention and innovation. Therefore, most analysts conclude that patents are an important inducement to invention in industries that require substantial R&D. IPR regimens may also be an important factor in determining a country's competitive advantage (OECD, 1999). While other theories can lead to other conclusions, Mazzoleni and Nelson believe that there is little empirical evidence to answer whether, and in which cases, patents are a net benefit to society. Indeed, the most basic question of whether (and under what circumstances) patents stimulate or interfere with technical advance remains unanswered (Mazzoleni and Nelson, 1998).

IPR, Industry Structure and Competition

How the biotechnology industry is structured, the degree of competition within it, and market power of individual biotechnology firms are all factors that determine how many and what kinds of transgenic crops farmers ultimately plant in their fields. Following the Diamond vs. Chakrabarty decision of 1980, a few large firms and numerous smaller start-ups characterized the U.S. agricultural biotechnology industry. The larger firms had traditionally been involved in agriculture and contracted out much of their research to the smaller firms (Kalaitzandonakes and Bjornson, 1997). However, in the last decade, three developments have changed the industry significantly. First, the industry has consolidated through an increase in mergers and acquisitions. Second, the rate of product innovation has decreased (Kalaitzandonakes and Bjornson, 1997; Thayer, 1998). Third, large agri-chemical/ biotechnology firms have accelerated their acquisitions of seed firms (Hayenga, 1998; Ollinger and Pope, 1995; Thayer, 1999).

The implication of these changes is that process innovation, originating in the large firms, replaced product innovation as the firms concentrated on internalizing the technological capabilities related to agricultural biotechnology (Kalaitzandonakes and Bjornson, 1997). This course of events entailed the acquisition of seed firms, because seeds are the critical vehicles for delivering the new technologies (Hayenga, 1998; Thayer, 1998). Kalaitzandonakes and Bjornson (1997, p. 137) argue that no new major players in the agri-biotech industry are likely to emerge as "product innovation winds down and as complementary marketing and distribution assets are controlled by incumbent networks." The critical question raised, then, is whether changes in IPR regimens regarding agricultural biotechnology were instrumental in fostering industry consolidation and other related developments. Barton (1999) hypothesizes that the surge in mergers in the biotechnology industry was driven by the need to acquire IPR and reduce litigation over the ownership of IPR. That is, IPR issues have become so critical and central to the agricultural biotechnology industry (Smith et al., 1999) that the need to control them may have had significant structural impacts.

According to industry analysts, relatively few firms control nearly the entire transgenic crop market (Barton, 1999; RAFI[4], 2000). In addition, some agricultural biotechnology firms, such as Monsanto and DuPont, are major players in the global pesticide and seed markets (RAFI, 2000; Thayer, 1999). The increasing dominance of a few agricultural biotechnology firms and the emergence of a seed/chemical/biotechnology complex raise issues of market power and access (Hayenga, 1998; Smith et al., 1999; Thayer, 1998, 1999). For example, because most small agricultural biotechnology firms have already been bought up by major companies (Kalaitzandonakes and Bjornson, 1997; Thayer, 1998), those companies could conceivably limit access to critical and emerging technologies (Thayer, 1998). Increases in vertical integration within the biotech industry (e.g., chemical firms purchasing seed firms), combined with IPR restrictions and a consolidated industry structure, could limit competition within the industry (Smith et al., 1999).

In this context, it is important to ask how the relatively consolidated structure of the agricultural biotechnology industry might affect the potential environmental benefits and risks of transgenic crops. Some firms, for example, are marketing genetically modified seeds tied exclusively to their pesticides, such as Monsanto's Roundup Ready (herbicide-tolerant) products. DuPont has also moved in this direction, developing herbicide-tolerant crops intended to be used with its herbicide products (Hubbell and Welsh, 1998). These developments concern environmentalists who fear chemical complements will dominate crop biotechnologies, and lead to increased pesticide use.

Thayer (1998) argues that, as traditional agri-chemical firms move into biotechnology and the "life sciences," they shift away from strategies emphasizing low investment in R&D, and away from high-volume, low-margin products. Instead, these firms start to focus on products that require high investment in R&D and are low-volume and high-margin. At the outset, this kind of switch can cause some cash-flow problems. Agri-chemical firms have addressed these problems by developing biotechnologies that complement their agri-chemical products. Although such a strategy does not necessarily preclude the development of chemical substitutes (Ollinger and Pope, 1995), it likely ensures the continued development of chemical complements.

Observers have also voiced concerns that in this business environment, strict IPR regimens might impede and limit certain scientific efforts and undermine the ability of scientists around the globe to carry out their research. In addition, some fear that there might be a reduction in the free flow of ideas and information, and that most efforts will be directed towards research that can be privatized, or that results in profitable discoveries to the exclusion of so-called "orphan crops" (King and Stabinsky, 1999; Price, 1999). Orphan crops may help provide food security for many around the globe, but do not yield enough commercial returns to warrant private investment (Barton, 1999; Lesser, 1997; Paarlberg, 2000).

Market and Trade Developments

Apart from IPR issues, an immense commercial concern facing growers and processors of transgenic crops is the feasibility of marketing them abroad. In fact, a growing number of consumers in

[4] The Rural Advancement Foundation International (RAFI) is an agrarian civil society organization and biotechnology industry watchdog group, based in Canada and the U.S.

countries outside the U.S. are unwilling or reluctant to buy foods containing transgenic crops. Evidence on the causes of consumers' hesitancy, including human health, environmental, or ethical concerns, is sparse, despite the tremendous amount of press coverage this issue has received. This trend is most apparent in many EU countries, but is evident in Japan and Brazil as well.

It is not clear that U.S. consumers feel the same way. An early survey suggested a modest rise in concern, although most U.S. consumers appeared to be satisfied with foods made with ingredients from transgenic crops (Hoban, 1998). Indeed, other surveys found that up to 75 percent of U.S. consumers had positive attitudes toward biotechnologically enhanced foods (Hoban, 1998). A more recent survey found that the percentage of respondents who felt that biotechnology would provide benefits to them or their families decreased from 78 percent in 1997 to 59 percent in May 2000 (IFC, 2000). The proportion who felt that biotechnology would not provide benefits to them or their families rose over the same period from 14 percent to 25 percent (IFC, 2000). These surveys also suggest, however, that U.S. consumers know little about foods made with bioengineered crops. Hoban (1998) found that only one-third of his respondents had heard or read anything about biotechnology in general, while 55 percent of those responding to an International Food Information Council survey said that they had heard little or nothing about it, and 66 percent said they were not well informed (IFIC, 2000). The high percentages of poorly informed consumers suggest that their perceptions of risk may be quite susceptible to change until they are better informed.

In general, little scientific research exists on consumers' perceptions of the risks, environmental or other, that genetically modified foods might pose. Some basic questions are unanswered. Are consumers' perceptions of potential human health and environmental risks of foods with transgenic crop ingredients tied together to any extent, or are they separable concerns? Which consumer groups will respond to transgenic food products differentiated by their health attributes and/or environmental effects? How much extra will the consumers who are concerned about the perceived health and/or environmental effects of transgenic crops be willing to pay for "biotechnology-free" products?

As some governments (particularly in the European Union) have been unable to reassure their citizens that foods made with transgenic crop ingredients are safe to eat or safe for the environment, market forces may play a critical role in the near term. At present, these foods are marketed in the United States through the same channels of processing and distribution as used for conventional foods, which means that the U.S. marketing institutions for the two types of products are indistinguishable. If a marketing policy to segregate foods without transgenic ingredients (nonbiotech foods) is constructed, principally for foreign market demand at this point, costs will be incurred. However, according to a recent study by USDA analysts, "Although the costs are not small, they do not imply that disarray would occur in the grain marketing system if nonbiotech crops were handled on a larger scale" (Linn et al., 2000, p. 32).

Labeling

Consumers cannot say whether they are willing to accept any potential environmental (and human health) risks associated with genetically engineered foods unless they have accurate information about those risks. Product labels, like the ones used now to provide nutritional data, are an option. Indeed, U.S. marketing policy for genetically modified foods, as in many countries, has moved towards a discussion of labeling. Researchers often distinguish between mandatory and voluntary labeling policies in their analyses. Beyond that, several types of labels have been discussed in the literature. Caswell (1998) analyzed the idea of labeling foods that were or were not bioengineered, and determined that labeling a product was preferable to not labeling it at all. She did not conclude whether voluntary or mandatory labeling would be preferable. In a subsequent article, Caswell (2000) argues that governments should tailor their labeling policies to their own needs, depending on the benefits and costs of their situations. She believes that challenges to mandatory labeling are unlikely to be successful under current WTO rules.

Phillips and Isaac (1998) distinguished between bioengineering food processes, such as genetically modified enzymes used to produce high-fructose corn syrup, and genetically modified food products, such as tortilla chips made with Bt corn. They concluded that voluntary labeling would be preferable to mandatory labeling, and that the best labeling strategy would comprise voluntary labeling of “biotechnology-free” goods, and product-based labeling of goods with specific biotechnology traits. A policy of voluntary labeling would generally shift the costs of labeling (as well as the liability for failing to label products) to the producers, handlers, and suppliers of “biotech-free” foods.

Exactly what information a label should contain is very much a matter of national discretion. European countries that already label certain foods as “biotechnology-free,” for instance, have varying definitions of what “biotechnology-free” means. Some stipulate that foods must contain no more than 0.1 percent bioengineered substances to qualify as “biotechnology-free”; for others, the figure is as high as 1 percent. As we have seen in the case of organic and other foods sold with labels that describe the processes used to grow them or their ingredients (e.g., “sustainably produced” or “pesticide-free” foods), labeling can be an effective mechanism for conveying some information about how those foods may affect the environment and human health. Voluntary labeling of biotechnology-free foods could—by giving consumers a choice—allow them to demonstrate in the marketplace what their attitudes are toward the potential environmental and health consequences of using those products. Voluntary “biotechnology-free” labels also have the potential to create significant niche markets, as has occurred with the growth of markets for milk from cows not treated with recombinant bovine somatotropin (rBST), the genetically modified version of the naturally occurring bovine growth hormone (BST or BGH) (Runge and Jackson, 2000). A larger role for consumer preferences in the environmental management of agricultural biotechnology is consistent with the “fourth criterion”—that is, the inclusion of ethical and social values in biotechnology decision-making (Lacy, 2000).

Trade Issues

Although it was not controversial when it began, trade in agricultural biotechnology and in foods made with genetically modified ingredients has since generated many questions. The answers will affect where and how transgenic crops and foods made with them will participate in the global market, and their global environmental footprints. The three most pressing issues related to the environment are:

1. Do transgenic crops, and trade in these crops, truly help to meet rising global food requirements (and, possibly, help to protect natural habitats worldwide)?

2. What kinds of institutions will safeguard consumers and the environment from potentially adverse environmental effects of trading the transgenic crop technologies?

3. What role should IPR regimens play in the trade of transgenic crops?

Advocates have claimed that agri-biotechnology will significantly increase food production and trade to help meet rising global food demands. Some also argue that the increased production will significantly reduce pressure on the environment, by leading farmers to reduce their use of chemicals and stop converting wild lands to agricultural use. Batie and Ervin (forthcoming) argue that for transgenic crops to save valuable habitat, three linked assumptions must hold: (1) people are or will be hungry because of low agricultural yields and higher costs of food, (2) transgenic crops are necessary to adequately raise yields and lower food costs, and (3) as society meets its food needs with expanded acreage devoted to agriculture, more natural habitat will be lost—unless there are offsetting higher yields on existing cropland acreage. Their analysis casts doubts on the validity of each assumption as a general proposition. They conclude that the chain of logic embedded in the "increased-food-production-saves-habitat" argument oversimplifies complex situations.

Little empirical research exists to inform the yield-habitat debate. An exception is an analysis of the world food supply with and without biotechnology, which was prepared for the World Trade Organization (WTO) 2000 meetings (Nelson et al., 1999). The analysis uses the best scientific data available on yields, and on the costs of adopting Roundup Ready soybeans and Bt corn, to estimate the effects these transgenic crops would have on global production and prices. The central conclusion: full adoption of both crops worldwide would have only a slight impact on either production or prices. For corn, the analysis projects only a 1.9 percent increase in production and a 4.2 percent decline in price; for soybeans, a 0.5 percent increase in production and a 0.6 percent decline in price. Small benefits, if any, are estimated for farmers, and only negligible gains are expected for consumers. Theoretically, of course, it is still possible that new advances in biotechnology could significantly increase global production of certain crops, thus saving more habitat. However, large yield gains are not forecast for transgenic crops in the near future (Ruttan, 1999). Also, the first generation of crop biotechnologies has neglected so-called orphan crops that are important food plants in many developing countries in which critical natural habitat could be lost (Paarlberg, 2000).

The second issue is that international institutions to govern trade in transgenic crops are still unsettled. The WTO has not issued specific rules for settling trade disputes over transgenic crops. Nelson et al. (1999) explain that three WTO agreements may apply: the Sanitary and Phytosanitary agreement (SPS), the Technical Barriers to Trade (TBT) agreement, and the Trade Related Intellectual Property (TRIPS) agreement. The SPS agreement governs actions by member countries to protect "animal, plant, and human health." The TBT agreement covers all technical regulations and conformity procedures, such as labeling for product composition, except sanitary and phytosanitary measures. The TRIPS agreement requires WTO members to maintain at least a minimal set of national IPR standards. Whether and to what extent each agreement will pertain to transgenic crop trade, and related environmental impacts, likely will not be clear until several trade disputes are settled by the WTO. For example, Nelson et al. (1999, p. 66) state that the health and safety provisions of the SPS agreement do not cover environmental issues such as biodiversity and ecosystem effects, leaving open the possibility of conflict between the WTO and multilateral environmental agreements.

Indeed, with the recent formulation of the Cartagena Biosafety Protocol under the Convention on Biological Diversity (CBD), a new element of uncertainty was added (Gupta, 2000; Pollack, 2000). The final treaty, if approved by 50 CBD member countries, allows members to bar imports of genetically altered seeds, crops, microbes, and animals that they regard as threats to their nation's environment. The treaty's key requirement is that exporters must obtain advance permission from importing countries before they can begin to ship a particular living modified organism (LMO) meant for release into the environment, such as bioengineered seeds, microbes, and fish that might be released into rivers and lakes. Notably, the requirement is not imposed on foods made from plants grown with bioengineered seeds, for that would have meant greater intervention in trading mechanisms and larger costs. The treaty is a landmark agreement because it permits the application of the strongest form of the so-called "precautionary principle" to date: countries can ban genetically engineered seeds even if there is little scientific basis for determining that they are a danger to the environment. It also requires a label generally stating that "shipments may contain genetically modified organisms," rather than labels that identify specific varieties of genetically modified crops. The latter would require segregating genetically modified crops all the way along their journey from farmers to consumers. The labeling provision suggests that labeling of food that is "free" of genetically modified organisms will also be used. To be effective, however, the treaty must be enforced. In this regard, Gupta (2000) notes that the treaty sets up no mechanism for settling disputes among members, and that it does not have a strong liability and compensation clause.

How the Cartagena Protocol, if approved, will relate to the WTO rules for transgenic crop trade disputes is also unclear. A key uncertainty is the jurisdiction of the WTO or the CBD over trade disputes. Cors (1999) points out that the governing agreement on trade disputes will be the SPS agreement if one party is a WTO member and the other is a party to the CBD. He notes that if both countries are WTO members and parties to the CBD, the Cartagena Protocol rules would govern dispute settlement. The importance of this distinction is that the SPS does not recognize the precautionary principle. The United States is not a party to the CBD, and neither are other major exporters of genetically modified organisms, such as Australia and Argentina. However, support by the U.S. for the Cartagena Protocol indicates that it will honor the application of the treaty by CBD parties—even though it officially advocates the SPS approach to dispute resolution.

Differences in U.S. and EU policy further complicate disputes over whether the SPS or the Cartagena Protocol applies to trade in biotechnology. Although the United States favors the former, EU environment ministers prefer using the best scientific information available, but in the "precautionary principle" decision framework. Grant (2000) explains that the European Union's reluctance to accept transgenic crops is not based on a lack of public trust in food safety institutions due to mad cow disease (i.e., bovine spongiform encephalopathy or BSE, the degenerative brain disease affecting cattle) and other episodes. The European Union has readily accepted genetically engineered medicines, for instance. Rather, if the EU environment ministers endorse the SPS, their governments will face high political costs because of strong public sentiment against transgenic crops. He argues that the majority of Europeans see biotechnology through a different cultural lens, one that perceives the technology as a threat to valuable countryside amenities provided by current farming systems. They fear that use of bioengineered crops could result in "sterile food factories" or "green pavements." If Grant's analysis is accurate, regulatory reform and the use of "sound science" will not necessarily change their preferred policy approach.

The TRIPS agreement, with its focus on IPR, also has controversial implications for future trade in genetically modified crops. Tansey (1999) has examined this issue, and although his analysis pertains mostly to developing countries, it provides insight into the larger international trade forum. As Tansey notes, the TRIPS agreement's section 27.3(b) specifies that WTO members may exclude most forms of biotechnology from patent requirements if they prefer. However, they must provide some form of alternative intellectual property protection, such as plant variety protection via *sui generis* systems (i.e., designed to fit their particular needs and context). The United States likely prefers that all countries use patents or approximately equivalent *sui generis* systems. Many developing countries, however, are reluctant to adopt patent systems to protect IPR, for various reasons, such as the power that it grants to large foreign agribusiness firms. Section 27.3(b) was to be reviewed at the 1999 Seattle WTO meetings, but no action was taken, and the WTO Council has not specified further review of TRIPS. Tansey suggests that developing countries should delay decisions on adopting IPR regimens until they have further evidence on the effects of alternative approaches, such as one of the UPOV versions, and until technical assistance on alternatives can be provided. If they adopt this cautious approach, then trade in genetically modified seeds and crops likely will slow. In a similar vein, Barton (1999) argues that governments should comply with TRIPS in a way that benefits the whole of a country's agriculture, and not just adopt U.S. IPR regimens.

Findings

Numerous commercial aspects of biotechnology—ranging from IPR and marketing issues to labeling and international trade agreements—may ultimately have effects on farmers and their choices about what kinds of transgenic crops to plant. Those decisions, in turn, have significant import for the environments in which these crops grow. At this writing, however, many of these commercial aspects of transgenic crops are not covered sufficiently by existing legislation or international accords. As a result, it is difficult for us to project the likely environmental impacts of these new crop technologies.

Intellectual property rights issues dominate concerns that many have about biotechnological advances. Because they feel that too much information about biotechnology remains private, some experts are recommending setting up public information sites, as well as updating antitrust law, to prohibit "conceptual monopolies" from controlling ownership to particular fields of knowledge (Dodds, 1999; King and Stabinsky, 1999). King and Stabinsky (1999) recommend that the U.S. Congress amend existing patent laws to explicitly exclude life patents. Similarly, Dawkins (1999) argues for reconsideration of patent policy and inclusion of a precautionary principle into international law.

Other analysts (e.g., Merrigan, 1999; Welsh, 1999) acknowledge deep concerns, but call for creative legal research to reform intellectual property rights. Many argue for a wider dialogue with more stakeholders (King and Stabinsky, 1999; Tansey, 1999) and recognize the need for technical and legal assistance for many countries, with respect to IPR (Barton, 1999; Ives et al., 1999). Developing countries, in particular, would benefit greatly from an international effort by public and private organizations to build institutions to deal with IPR and environmental issues related to transgenic crops.

Labeling is another key issue, and agreement on labeling rules for bioengineered foods is critical. Economic theory and democratic principles suggest that consumers should be able to demonstrate their preferences for foods made with genetically modified ingredients and their related environmental benefits or risks. At this point, mandatory labeling of food and fiber products containing genetically engineered ingredients is authorized in the U.S. only in cases of documented human health risks. Thus, consumers can only express their preferences for desired environmental attributes through voluntary labeling schemes that identify "biotech-free" food and fiber products.

The policy governing **international trade in transgenic crops** is very unsettled and will likely remain so in the foreseeable future. The CBD's Cartagena Biosafety Protocol was a significant step, but it is not certain how effectively it can be applied to disputes over transgenic crops, including labeling disputes. The relationship between the Cartagena Protocol and the WTO—and how the WTO will choose to handle trade disputes involving transgenic crops—is key. How developing countries will create patent systems that fit their individual needs, including ensuring environmental protection, yet also permit participation in the global trade market under the TRIPS agreement, will be critical in determining the future global flow of transgenic crops.

CHAPTER FOUR:
Conclusion: Strengthening Public Research and Regulation

Biotechnology advances, enabled by changes in patent law, have profoundly changed the direction and communication of agricultural science and technology. The significant profit potential in transgenic crops has shifted both public and private R&D investments away from chemical-based "solutions" for crop protection, and likewise away from more systems-based approaches to pest management. In part because of U.S. patent law, U.S. private industry dominates the market in this new technology. As a result, there are considerable implications of widespread adoption of transgenic crops for world economies and the distribution of wealth. The domination by private industry also implies that environmental costs will tend to be neglected; this neglect is a classic example of "a missing market"—that is, where the normal workings of a private market exclude full consideration of important outcomes off the farm and in the future (Batie and Ervin, forthcoming).

The very speed of the development and release of diverse varieties of transgenic crops appears to have exceeded our ability to understand or to appropriately regulate them. The existing regulatory structure, both in the U.S. and in Europe, did not develop with transgenic crops in view. Many argue that the regulatory structure is currently inadequate to solve most "missing market" problems. One criticism, for example, is that, in the U.S., the industry controls access to most of the data from which reasoned, science-based arguments are to be fashioned. Environmental scientists and advocates have difficulty, therefore, providing the checks and balances that a well-designed regulatory system should maintain.

Furthermore, there is an exceptionally small base of knowledge about environmental impacts from the diffusion of transgenic crops. Yet, we cannot expect to tap the full potential of these crops to benefit the environment, or to adequately address the environmental risks they may pose, without such knowledge. Equally important, we simply do not know how large either the benefits or risks will be, or how long they will last. Given these uncertainties, it seems prudent, not only to our populations, but also to the biotechnology industry itself, to adopt a more cautious approach to the development and marketing of transgenic crops. If poor national or international oversight leads to an environmental catastrophe, it could jeopardize the entire future of biotechnology and its considerable potential. In this context, it may be worth remembering how the U.S. nuclear power industry never recovered from the stunning blow that came from the 1979 accident at Three Mile Island. This accident demonstrated to the public that the industry's assurances of safety were exaggerated.

We believe that there are two key elements to this cautious approach:

1. *Increase investment in public research and development for agricultural biotechnology to ensure that the neglected environmental aspects of transgenic crops receive adequate attention, and to build a credible scientific knowledge base, including a comprehensive monitoring system, by which to evaluate these crops and their environmental impacts*.

Private firms have scant incentive to invest in the research necessary to understand the environmental impacts of transgenic crops or to investigate alternative farming systems. Their incentives are to increase profits, market share, and return to shareholders. Yet, wise decisions about the development and diffusion of transgenic crops must begin with a sound understanding of their environmental effects (as well as their productivity, economics, and human health and social effects). Thus, there is a strong case to be made for improving public research and development in this area, and bringing more information on transgenic plants and related technologies into the public arena so that various publics can provide “informed oversight.”

However, a key issue is the lack of public funding for research. Only approximately $7 million, or 4 percent of the USDA’s research budget on biotechnology, is dedicated to assessing the potential environmental risks associated with transgenic crops. If we are to understand the full impact of transgenic crops, we must move beyond limited laboratory and field experiments to large-scale trials that can show us how these plants interact with the environments in which they grow. Public acceptance will best be garnered with third-party scientific experiments, rather than through industry-funded media assurances (Sandman, 1999).

Throughout this report, we have offered a detailed list of the types of research that might be done. However, the recommended research will require more funding. Such funding might come either from the general treasury or from taxes or fees from biotechnology firms. Currently, a consortium of biotechnology firms has organized a pro-biotechnology informational campaign through the Council for Biotechnology, which has $50 million earmarked for the first year of a three-to-five-year campaign (Hillyer, 2000), an amount that dwarfs the USDA’s $1 to 2 million of risk assessments. Whether biotechnology firms should bear the costs of their own regulation and/or provision of information on environmental impacts is, of course, a political decision. Without adequate funding, however, the public research and public monitoring activities will remain limited.

2. *Develop appropriate regulatory frameworks for transgenic crops, and reform the institutions and regimens, such as intellectual property rights, that control their development and diffusion*.

The tripartite system used to regulate transgenic crops in the U.S.—which consists of the USDA’s APHIS, the EPA, and the FDA—has a variety of demonstrable shortcomings. Many of these inadequacies are documented in a recent review from the National Research Council. Among other findings, the Council found gaps in regulatory coverage of transgenic plants, and failure of the agencies to conduct comparably rigorous reviews with original scientific data rather than existing information. Ecosystem-wide monitoring is generally not conducted to identify potential cumulative and synergistic effects of multiple transgenic crops. Clearly, there is a substantial need for data that environmental scientists can best supply, and they need to be better integrated into the regulatory system.

With regard to basic regulatory structure, the NRC has recommended that the USDA and the EPA reevaluate their procedures to ensure that the potential effects of transgenic plants on the environment are fully examined. To this end, the current system might benefit from the introduction of an environmental agency that would lead environmental assessments of transgenic plants. The lead agency could certainly eliminate potential gaps in regulatory coverage, as well as concerns about potential nepotism within agencies that deal closely with the business side of the biotechnology industry. If such a lead agency were established, it could also enhance public trust in biotechnology by making its review process and data open and widely available to the public. Such confidence would be more likely garnered with more transparency in the system, so that various groups could access and review data on environmental impacts. It could also bring to its task greater consideration of social values than is currently the case—which could further improve the public's confidence in transgenic plants in the long run.

A number of experts believe that a key problem is lack of information available to the public, a problem that they believe is related to strict IPR regimens. Agreements on labeling rules for transgenic crops and their products would be useful in this regard, but they would not be sufficient to provide the public with enough information about the potential risks and benefits of transgenic crops. Indeed, where there might be significant risks, the public would normally expect to be protected by regulation from those risks, and not need to take self-averting purchases. (To make this latter point clearer by analogy: no one would argue that the airline industry should be allowed to select the level of maintenance it desires for its planes, and that the public be informed of the risk level by labeling on airline tickets.) Within the section on IPR, this report has listed several suggestions for what shape these reforms might take. Some have even argued that the U.S. Congress should amend existing patent laws to explicitly exclude the patenting of life forms. They also advocate greater public access to information about patented transgenic crops, and technical and legal help for countries that are in the process of setting up their own IPR regimens. Despite these suggestions, however, IPR appears to be an area that would benefit from considerably more research and analysis so that the benefits and costs of existing and alternative patent laws can be better understood and balanced.

Relatively few firms control the vast majority of commercial transgenic crop technologies. These firms have strategically developed linkages among the biotechnology, seed, and agri-chemical sectors to capture as much market value as possible. However, the tightly controlled linkages of product sectors raise serious issues of market access, product innovation, and the flow of public benefits from transgenic crops. The current generation of transgenic crops follows the same pest management model that exists for chemical pesticides—through interventions that are toxic to pests. An alternative is for transgenic technologies to mimic ecological approaches to agriculture. These types of technologies would control pest populations through cultural or non-toxic means, such as integrated crop rotations. In addition to effective antitrust oversight, cost-effective biosafety regulations and public research on ecologically and evolutionarily oriented transgenic technologies will foster private efforts to find such alternatives (NRC, 2000).

Another complication is that most of the commercially based institutions that protect and govern the development and distribution of transgenic crops—significantly, international trade agreements and IPR regimens—give only minimal (if any) attention to the crops' environmental impacts. For instance, it is hardly clear at this writing whether such instruments as the Cartagena Biosafety Protocol will be applied successfully to trade and environment disputes involving transgenic crops. What is clear is that policy governing international trade in transgenic crops is likely to remain relatively incoherent into the near future. There is a great need for clarity, and for increased consensus, on how to deal with the emerging technologies on a national and global level, and within a business framework that accounts for legitimate social values. A clear statement by the WTO of the agreements and rules that will guide trade dispute panels in their deliberations over transgenic crop cases is a logical first step.

Using a cautious approach to the development, approval, and marketing of transgenic crops by no means entails a moratorium on all transgenic crops in all countries. As we have seen, some transgenic crops are fairly well researched and appear to pose little risk to the environment. However, the small knowledge base about the environmental effects of less-studied transgenic plants holds risks for the environment and for the agricultural industry. More research and stronger regulatory regimens could diminish these risks—and help to ensure a better future for the developers, producers, marketers, and consumers of transgenic crops, while protecting valuable natural resources for current and future generations.

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Appendix 1: Glossary of Terms

(Cross-referenced terms are indicated in boldface type.)`

allele – One of two or more alternate forms of a gene occurring at the same position (locus) on a **chromosome**, which control the expression of the **gene** in different ways. A cell or organism is homozygous when it contains identical alleles at a given locus, or heterozygous when there are two different alleles present. A gene for height, for example, may exist in two allelic forms, one for short and one for tall.

antibiotic resistance (marker) gene – In some transgenic plants (and food products derived from them), a bacterial gene whose expression product (i.e., a **protein**) confers resistance to one or more antibiotics (such as ampicillin or kanamycin). The inserted gene may be an artifact of early stages of the **recombinant-DNA** process, or result from use of a **gene marker** to select for the efficiency of gene transfer (transformation) to the **genome** of recipient plant cells; neither leads to desirable traits in plants. Depending on the type of regulatory control, the gene's end product (including enzymes and other **proteins**) may or may not be expressed in the plant cells. Biosafety concerns include potential toxicity or allergenicity of the resulting protein, and possibility of horizontal gene transfer from food or animal feed products to microorganisms in the human or animal gut, or the environment, which may compromise the therapeutic efficiency of clinically useful antibiotics. (See also **genetic transformation**.)

***Bacillus thuringiensis* (Bt)** – A group of soil bacteria found worldwide, which produce a class of proteins highly toxic to the larvae (immature forms) of certain taxonomic groups of insects. Bacterial spores (resistant forms) containing the toxin are used as an environmentally benign commercial pesticide favored for its high specificity. Bt strains (over 20,000 known) produce "cry" (crystal) endotoxin **proteins** that disrupt digestive function and lead to death in moths, butterflies, and certain other insects, including corn borers, cabbage worms, cotton bollworms, and other agricultural **pests**. Since 1989 genes expressing the cry proteins have been introduced into plants (see **Bt crop**) to confer insect resistance. Bt also refers to the insecticidal toxins.

biodiversity – The total variability within and among **species** of living organisms and their habitats, first used in 1986 to denote biological diversity. Usually refers to all heritable variation at all levels, and is generally divided into 3 levels: genetic (**genes** within a local population or species), taxonomic (the species comprising all or part of a local community), and ecological (the communities that compose the living parts of ecosystems). According to E.O. Wilson, biodiversity is, in one sense, "everything." Human cultural diversity is sometimes viewed as a form of biodiversity. (See also **genetic erosion**; **genetic resource**.)

biosafety – The goal of ensuring that the development and use of **transgenic** plants and other **genetically engineered organisms** (and products of **biotechnology**, in general) do not negatively affect plant, animal, or human health**, genetic resources**, or the environment.

biotechnology – The scientific or industrial manipulation of life forms (organisms) to produce new products or improve upon existing organisms (plants, animals, or microbes), first coined to apply to the interaction of biology and human technology. In recent usage, refers to all parts of the industry that creates, develops, and markets a variety of products willfully manipulated on a molecular and/or cellular level. While gene splicing (see **recombinant DNA** technology) is a major technique, the term generally includes other areas such as plant tissue culture, plant meristem culture, embryo transfer, cell fusion, enzyme systems, fermentation, and immunology. (Bioengineering is generally synonymous, although some use this term more narrowly to mean **genetic engineering** or **recombinant DNA** technology.)

Bt crop – A crop plant genetically engineered to produce insecticidal toxins derived from the bacterium ***Bacillus thuringiensis***. Current commercial Bt crops include Bt cotton, Bt corn, and Bt soybeans. (See also **pest-protected plant**.)

canola – Particular plant varieties belonging to the mustard family (Brassicaceae or Cruciferae), whose members produce similar oils, some of which are used for human food (or animal feed) and industrial purposes. Canola is an improved oilseed rape (OSR, or rapeseed) variety developed by traditional plant breeding methods in Canada; canola varieties belong to either of two **species**, *Brassica napus* or *Brassica rapa*, and have improved agronomic traits and oil and meal qualities (i.e., low levels of particular anti-nutritional substances, erucic acid and glucosinolates). Canola has been grown commercially in North America since the mid-1980s; transgenic varieties developed more recently have improved nutritional value or herbicide resistance. (See also **herbicide-tolerant crop**.)

chloroplast genome – The genetic component contained in the chloroplasts, specialized chlorophyll-containing photosynthetic organelles (subcellular compartments) in plant cells. Chloroplast **genes** exist outside the cell nucleus and are not usually transferred in pollen grains. (See also **gene flow**; **genome**.)

chromosome – A discrete, highly compact, thread-like structure carrying thousands of **genes** arranged in linear sequence. In higher (nucleated) organisms, including plants and animals and excluding bacteria, chromosomes are arranged in pairs and are found in the nucleus of every cell.

coat protein (CP)-mediated resistance (or protection) – Resistance of a plant to virus infection, obtained by splicing into the plant **genome** a viral **gene** expressing the coat (capsid) **protein** from a (usually) related virus. The most widely used form of pathogen-derived resistance (PDR), shown to be effective across a number of crops and for a variety of **RNA viruses**, although the mechanism is poorly understood. With transformed plants containing virus-protective **transgenes**, which may be co-infected naturally by multiple viruses, **biosafety** concerns include creation of new viruses, expanded viral host ranges, or more severe viral diseases. (See also **viral coat protein**.)

DNA (deoxyribonucleic acid) – The basic genetic material found in all living cells (and some viruses), providing the blueprint for construction of **proteins**. When not actually being replicated (regenerated) within the cell, DNA exists as the so-called “double helix”: double-stranded, chain-like molecules composed of nucleotide base pairs (the specific carriers of genetic information) and condensed into compact structures known as **chromosomes**. (See also **gene**; **RNA virus**.)

***ex situ* plant conservation –** Literally, “out of place,” referring to the conservation of plants outside their original or natural habitats, including gene banks or **seed banks**. National and international gene banks worldwide hold millions of plant accessions (distinct samples) for short or long-term storage, for the purposes of study, distribution, or use. Most gene bank collections provide unrestricted access to *bona fide* users (e.g., plant breeders). (Compare ***in situ* plant conservation**.)

fitness – A relative measure of an organism’s reproductive efficiency (i.e., the relative probability of reproduction of a genotype), generally referring to Darwinian fitness. Components of fitness include survival, rate of development, mating success, and fertility, and pathogenicity in the case of microbes. Fitness is germane to hazard assessment of organisms engineered to contain foreign **genes**. Also called adaptive value. (See also **risk assessment**.)

GE crop (GM crop) – See **biotechnology**; **genetic engineering**; **GMO**; **transgenic**.

gene – The functional unit of heredity (the physical basis for the transmission of characteristics from parents to offspring), and the basic unit of biological diversity. A gene consists of a segment (locus) on a **chromosome** that corresponds, in most organisms, to a specific sequence of **DNA** subunits (nucleotide base pairs) and encodes for a specific product or has an assigned function. (In **RNA viruses**, the genes consist of RNA subunits.) Some genes direct the synthesis of one or more **proteins**, while others have regulatory functions (controlling the expression of other genes). (See also **allele**; **biodiversity**.)

gene flow – The exchange of genes (in one or both directions) at a low rate between different (usually) related and sexually compatible populations of organisms; gene exchange results from the dispersal of gametes (mature reproductive cells, also called sex cells). In plants, gene flow usually occurs via transfer of pollen (male gametes), and includes the natural transfer of **genes** from genetically modified plants to wild relatives. Gene flow may threaten the diversity of **landraces**. Also called gene migration. (Sometimes more loosely called gene transfer, but the latter term is more appropriately applied to transfer of genes via **genetic engineering** methods.) See also **chloroplast genome**; **non-target effect**; **transgene**; **transgenic**.

gene marker (or marker gene) – Any **DNA** segment that can be identified, or whose location on the **chromosome** is known, so it can be used as a reference point to map the location of other **genes**. A selectable marker gene produces an identifiable phenotype (i.e., observable characteristics) that can be used to track the presence or absence of other genes (e.g., genes of commercial interest) on the same piece of DNA transferred into a cell. (See also **antibiotic resistance marker gene**; **genetic transformation**.)

genetic engineering (genetic modification) – The selective, deliberate alteration of an organism's **genome** by human intervention, by introducing, modifying, or eliminating specific **genes** through molecular biology techniques. Includes alteration of the genetic material of an organism in order to produce endogenous (internal) **proteins** with properties different from the unmanipulated organism, or to produce entirely different (foreign) proteins, as well as changes accomplished by less direct, less precise methods, such as induced mutation by application of chemicals or radiation. Some use "genetic engineering" (and synonyms) to mean gene splicing and **recombinant DNA** technology, although in more precise usage these latter terms specifically refer to joining DNA from different sources or species (e.g., plants and microbes) and introducing nonnative DNA (**transgene**) into an organism. (See also **transgenic**.) Conversely, some use "genetic engineering" more broadly to include any human intervention, including classical, conventional breeding techniques for crop improvement and other means of artificial selection. (See also **biotechnology**; **GMO**; **LMO**.)

genetic erosion – For agricultural crops, the process that diminishes genetic diversity in the gene pool (all **genes** within a population) of a particular crop plant. Forces leading to genetic uniformity—a narrowing of crop **germplasm—**include the widespread replacement of local **landraces** with more uniform modern varieties grown in monoculture (see also **Green Revolution**), habitat destruction, and socioeconomic changes.

genetic resource – Genetic material serving as a resource for present and future human use. For plants, includes modern cultivars (varieties), **landraces**, and wild and weedy relatives of crop species. Plant breeders rely on a broad, diverse genetic base to enhance crop yields, quality, or adaptation to environmental extremes. (See also **biodiversity**; **DNA**; **germplasm**.)

genetic transformation – The process whereby free **DNA** (i.e., nonchromosomal and associated with a **vector**) from a donor organism is transferred directly into a competent (i.e., receptive) recipient cell to produce a **transgenic** organism. (See also **gene marker**; **recombinant DNA**.)

GMO (genetically modified organism) – The broad term used to identify organisms that have been manipulated by molecular genetic techniques to exhibit new traits. Also known as genetically engineered organism or GEO. (See also **genetic engineering**; **living modified organism**; **transgenic**.)

genome – The entire hereditary material of a cell or a virus, including the full complement of functional and nonfunctional **genes**. In higher organisms (including plants, animals, and humans) the genome comprises the entire set of **chromosomes** found within the cell nucleus. Sometimes refers to the complete (haploid) set of chromosomes carried by a gamete (sex cell). (See also **chloroplast genome**.)

genomics – The scientific field of study that seeks to understand the nature (i.e., **DNA** sequences) and specific function of **genes** in living organisms; in combination with bioinformatics, can be applied to development of **transgenic** crops and other biotechnologies. Includes mapping genes and genetic combinations.

germplasm – The total genetic variability available to a particular population of organisms, represented by the pool of germ cells (sex cells, the sperm or egg) or plant seeds. Also used to describe the plants, seeds, or other plant parts useful in crop breeding, research, and conservation efforts, when they are maintained for the purpose of studying, managing, or using the genetic information they possess (same as **genetic resources**). Also called germ plasm. (See also **biodiversity**.)

glyphosate – See **Roundup Ready soybean**.

Green Revolution – The technological advancements in developing-country agriculture after 1960, usually referring to the development and use of high-yielding modern varieties of grain crops (especially rice and wheat) and associated use of chemical pesticides, herbicides, and fertilizers, and irrigation technology. Sometimes used more generally to indicate a capital-intensive approach to agricultural development, along with innovations in hybrid-seed technology (and accompanying displacement of locally adapted **landraces**).

herbicide-tolerant crop – A crop able to survive the application of one or more synthetic chemical herbicides, many of which are toxic to both crops and weeds. Includes those naturally tolerant and those **genetically engineered** to contain genes that make them insensitive to or able to detoxify herbicides, as an approach to chemical weed control. Also called herbicide-resistant crop. (See also **Roundup Ready soybean**; **superweed**.)

hybridization – In crop science, the production of offspring (hybrids) from genetically unlike parents, by natural processes or by human intervention (i.e., artificial selection). In plant breeding, includes the process of cross-breeding two different varieties to produce hybrid plants. Hybrids may be less or more fit than either parent; the former condition is termed **outbreeding** depression, and the latter is called hybrid vigor (or heterosis). Hybrid offspring may result from pollen flow (**gene flow**) between **transgenic** crops and wild relatives. (In molecular biology, the term refers to fusing two unlike cells to produce monoclonal antibodies, and alternatively to the binding of complementary strands of **DNA** or RNA.) See also **fitness**.

***in situ* plant conservation** – Literally, "in its natural place," an approach to plant conservation using methods that include maintenance of wild plant **genetic resources** where they occur naturally, or maintenance of domesticated materials where they were originally selected and further developed. May include designating existing parks, wildlife refuges, or other protected areas as *in situ* reserves. Generally recognized as a strategy to complement ***ex situ* plant conservation**.

intellectual property rights (IPR) – The broad term applied to various rights granted by law or state authority for protection, essentially utilitarian, of economic investment in creative effort. The principle categories relevant to agricultural biotechnology are **patents**, plant variety rights (**plant breeders' rights**, PBRs), trademarks, and trade secrets. Various IPR forms differ with respect to the subject matter eligible for protection; the scope, duration, and specific attributes; and possible exemptions to exclusive rights. (See also **life patent**; ***sui generis***; **UPOV Convention**.)

landrace – A crop variety having a broad genetic base (highly heterozygous in genetic terms) and resulting from centuries of development and adaption to particular soil types and microclimates. Landraces have been improved by local farmers using traditional selection processes, rather than by professional plant breeding methods, and are an important source of diverse **genes** for plant breeders. (See also **allele**; **gene flow**; **genetic resource**.)

life patent – Patent law protection extended to living organisms altered by human intervention, and not applicable to naturally occurring living beings. For agricultural technologies, life **patents** were recognized after the 1980 U.S. Supreme Court decision, Diamond vs. Chakrabarty. (See also **intellectual property rights**.)

living modified organism (LMO) – As defined by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, any living organism possessing a novel combination of genetic material obtained through the use of modern **biotechnology** (i.e., here defined as *in vitro* nucleic acid techniques, including **recombinant DNA** methods, and cell fusion techniques that overcome natural reproductive barriers). Some may use term as synonym for genetically modified organism (**GMO**).

non-target effect – Generally, an ecological effect stemming from intentional introduction of plants, chemicals, or microbes to natural, agronomic, or forest ecosystems, and including various effects on non-target organisms (or **species**), the unintended recipients affected by an introduced product. Non-target effects may result from deliberate release of genetically engineered plants, microbes, or other life forms. (See also **gene flow**; **risk assessment**.)

oilseed rape (rapeseed) – See **canola**.

outbreeding – Sexual combination between distantly related members of the same **species**, in contrast to inbreeding, mating between closely related members. Same as outcrossing. In outbreeding plants, pollen and egg come from plants that are genetically different, permitting **gene flow** in and out. Breeding systems in plants occur along a continuum, from exclusive outbreeding to exclusive inbreeding (self-pollination), e.g., some plants are largely inbred but occasionally outcross at low rates. (See also **hybridization**.)

patent – Legal authority providing the right to exclude others from making, using, selling, or importing an invention that has been defined “new” by patent law, without authorization from the patent holder. Patents may be awarded for products and processes, and are limited to a fixed period (e.g., 20 years under the **TRIPS agreement**), after which the invention moves into the public domain and can be used by anyone. A patent grants temporary partial monopoly. (See also **intellectual property rights**; **life patent**.)

parasitoid – An insect that parasitizes and kills other insect or arthropod hosts; usually parasitic in its immature stages but free-living as an adult. Parasitoid species are often effective as biological control agents and are most prominent in the insect orders Hymenoptera (including wasps) and Diptera (true flies). (See also **pest**.)

pathogen – In general, a disease-causing agent, usually a microorganism. Economically important microbial pathogens of agricultural crops include bacteria, fungi, protozoa, mycoplasmas, and viruses. (See also **pest**; **resistance management**; **RNA virus**.)

pest – Any species that interferes with human activities, property, or health, or is otherwise objectionable. Economically important pests of agricultural crops include weeds, arthropods (including insects and mites), microbial plant **pathogen**s, and nematodes (roundworms), as well as higher animals (e.g., mammals and birds). (See also **resistance management**.)

pesticide – Any substance or agent employed to destroy a **pest** organism. Common pesticides include insecticides (to kill insects), acaricides (mites and ticks), herbicides (weeds), fungicides (fungi), and nematicides (nematodes). Pesticides are commonly classified as conventional chemical compounds and biopesticides (or biological pesticides) derived from natural materials. Biopesticides include microbial (i.e., living organisms), biochemical (e.g., pheromones), and plant-pesticides (e.g., **Bt crops**). (See also **pest-protected plant**.)

pest-protected plant – Any crop plant genetically engineered to contain **genes** that express a pesticidal trait, whether by conventional or transgenic technologies. **Bt crops** are currently the most widely used **transgenic** pest-protected plants. (See also **pest**; **pesticide**.)

plant breeders' right (PBR) – The form of **intellectual property rights** that is legally accorded to plant breeders by laws or treaties, and intended for cultivated plants. PBRs require distinctness, uniformity, and stability (DUS). Also know as plant variety right, and similar to **patent** law for inventors.

plant-pesticide – A term used by the U.S. Environmental Protection Agency to mean "a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant." (See also **pesticide**; **pest-protected plant**.)

protein – Any of a class of high-molecular weight polymer compounds, each the ultimate expression product of a **gene**. Proteins act in specific ways (as enzymes, regulators of gene activity, transporters, hormones), their specificity residing in characteristic three-dimensional shapes determined by their subunits, amino acids arranged in precise sequences and joined by peptide linkages. (See also **viral coat protein**.)

recombinant DNA (rDNA) – The product of **gene** splicing through **genetic engineering** techniques, joining together genes from different sources, and typically across **species** lines. (See also **recombination**; **transgenic**.)

recombination – The joining of **genes** (i.e., **DNA** segments), sets of genes, or parts of genes into new combinations, either biologically or through laboratory manipulation (e.g., **genetic engineering**). Genetic recombination is classified as intrageneric (within **species** of the same genus) or intergeneric (across species boundaries). In plants, recombination occurs naturally during sexual reproduction as the **chromosomes** form new associations.

refuge (*refugia*) – For **Bt crops**, an area within a field of a **transgenic** Bt crop, which is planted with a non-Bt variety of the same crop. Refugia are part of a strategy to delay the emergence of insects resistant to the Bt toxin, by providing areas for susceptible insects to mate with the resistant insects. (See also ***Bacillus thuringiensis***; **resistance management**.)

resistance management – Use of agronomic and integrated pest management (IPM) practices to delay the development of resistant individuals within a population of **pests** targeted for control by a **pesticide**; essential for proper use of chemical pesticides, as well as biological pest controls (biopesticides) such as microbial Bt formulations and **Bt crops**. (See also ***Bacillus thuringiensis***; **plant-pesticide**; **refuge**.)

risk assessment – For genetically engineered organisms, the process of predicting the behavior of the modified organism. For transgenic plants, refers to gauging the overall likelihood that their deliberate release into the environment will cause environmental harm, including adverse impacts on natural and agricultural ecosystems, or introduce new risks to public health. Harm may result from direct effect of a modified plant (e.g., enhanced weediness, or allergenicity), or from **gene flow** to unrelated plants and its consequences. (See also **superweed**.)

RNA virus – A group of **viruses** whose nucleic acid (the viral **genome**) consists of RNA (other viruses are composed of **DNA** molecules). Includes most plant pathogenic viruses. RNA viruses may serve as **vectors** (vehicles) for transporting **genes** from one cell to another. (See also **coat protein-mediated resistance**.)

Roundup Ready (RR) soybean – A soybean variety genetically engineered to tolerate direct application of glyphosate, a broad-spectrum, systemic, post-emergence herbicide manufactured and patented by Monsanto Company (trade name, Roundup). RR soybeans contain a slightly modified growth-regulating enzyme (a type of **protein**) that is resistant to or inactivates glyphosate, allowing the chemical to be applied directly to the crop. Also called GR (glyphosate-resistant) soybean.

seed bank – A term (often used loosely) to denote a collection of seed and other **germplasm** from a broad cross-section of plants; and serving as a form of ***ex situ*** **plant conservation**. Also called gene bank, although the latter term is more accurate in describing many plant collections that contain non-seed, propagative materials, as well as seeds. (Seed bank also refers to a store of dormant and viable seeds in the soil, which germinate when environmental conditions are favorable.) See also **genetic resource**.

species – A taxonomic category of life forms, usually consisting of organisms that are sexually compatible and may actually or potentially interbreed in nature. The scientific (or Latin) name of a species includes the genus name and species designation, with the genus placed first (e.g., *Bacillus thuringiensis*). (See also **biodiversity**.)

substantial equivalence – A regulatory concept emerging in the 1990s for genetically modified (GM) foods; if a GM food is shown to be substantially equivalent to its "natural" antecedent, it can be assumed to pose no new health or safety risks (thus requiring no additional biochemical or toxicologic testing) and hence is acceptable for commercial use. (See also **biosafety**; **genetic engineering**; **GMO**; **risk assessment**.)

sui generis – In referring to a system of **intellectual property rights**, an alternative, unique form of IPR protection designed to fit a particular context and needs. Literally, "of its own kind."

superweed – A weed plant with enhanced "weedy" traits (i.e., characteristics allowing it to invade, persist in, and disrupt ecosystems, including making it a nuisance in agronomic settings and reducing crop yields). Horizontal transfer of herbicide-resistance genes to weeds from genetically engineered crops may confer ecological advantage, potentially producing **superweeds** with greater **fitness** than the non-transgenic forms. Superior ecological performance in a **transgenic** crop may also enhance its potential for weediness. (See also **gene flow**; **herbicide-tolerant crop**; **hybridization**.)

transgene – A "package" of genetic material (**DNA**) that is inserted into the genome of a cell via gene splicing techniques, including genes moved across **species** lines into the **genome** of a host organism. Along with the genes of interest (i.e., those expressing a novel **protein**), a transgene may contain promoter, other regulatory, and marker genetic material. A transgene may consist of a gene (or genes) from a dissimilar organism (i.e., foreign DNA), or artificially constructed genes. (Compare **gene flow**; see also **gene marker**; **recombinant DNA**; **vector**.)

transgenic – An organism containing novel genetic material (**DNA**) derived from an organism other than the parents or in addition to the parental genetic material; includes the offspring of a genetically engineered organism. The foreign (nonnative) DNA is incorporated early in development and present in germ cells (reproductive cells, sperm or egg) and somatic cells, and is inherited by offspring in a Mendelian fashion. A transgenic plant usually contains DNA from at least one unrelated organism, including a virus, bacterium, animal, or other plant. (See also **genetic engineering**; **pest-protected plant**.)

TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement – Under the World Trade Organization (WTO), governs the patenting of biotechnological processes and certain resulting products, to ensure at least minimal national standards for intellectual property protection on traded goods. Article 27.3(b) is the clause under which member countries are permitted to exclude plant varieties from being patentable, provided other effective IPR protection is available (***sui generis*** system), such as **plant breeders' rights**. (See also **biotechnology**; **intellectual property rights**; **UPOV Convention**.)

UPOV Convention – The Convention of the International Union for the Protection of New Varieties of Plants (an intergovernmental membership organization based in Switzerland) whose aim is to "protect new varieties of plants by an intellectual property right," thus establishing **plant breeders' rights** (PBR), and serving as an example of a ***sui generis*** system for plant variety protection (PVP). The UPOV Convention aims to balance protection of the rights of farmers to replicate seeds on the farm, and the rights of plant breeders to use and develop plant **genetic resources** for commercial benefit. Initially adopted in 1961 and based on several European nations' PVP systems, the Convention was revised in 1978, and again in 1991. The 1978 version of UPOV protected farmers' traditional use of protected plant varieties for propagation activities on their own holdings. The 1991 version extends protection of the options and incentives of plant breeders to innovate, by extending breeders' IPRs to harvested materials (e.g., seeds), as well as propagating materials of protected varieties, while removing farmers' rights to replicate, exchange, or replant protected seed varieties. (See also **TRIPS agreement**.)

vector – A self-replicating agent used to carry new **genes** into cells to produce **recombinant DNA**. Includes plasmids (i.e., circular, nonchromosomal DNA found in bacteria), as well as viruses and other forms of **DNA**. (In plant pathology, a vector is an organism capable of transmitting a **pathogen** from one host to another, such as plant-feeding insects that transmit viruses.) See also **chromosome**; **transgene**.

virulence – The ability of a **pathogen** to infect other organisms and cause disease; the degree of pathogenicity.

viral coat protein – A **protein** covering (or capsid) that protects the viral nucleic acid core (RNA or DNA) from environmental degradation, which plays a role in viral transmission and replication. Transfer of the **gene** expressing coat proteins (capsid or CP gene) from a pathogenic virus to a crop plant has been used to confer **coat protein-mediated resistance** in order to prevent or diminish subsequent infection by (usually) related plant viruses. (See also **virus**.)

virus – A submicroscopic, nonliving, infectious particle that must invade living cells to reproduce, typically composed of a nucleic acid core (RNA or DNA) and **protein** coat (capsid). Typically causes disease in host organisms. Broadly grouped as **RNA viruses** (including most viruses infecting plants) and **DNA** viruses. (See also **pathogen**; **viral coat protein**.)

weed – In general, any unwanted plant that interferes with human activities (including agricultural systems) or natural habitats. The concept of a weed is fairly subjective; plants may be considered weeds for diverse reasons (e.g., rapid growth, persistence, invasiveness, toxicity to livestock). **Herbicide-resistant** crops intended for improved weed control may potentially contribute to weed severity. (See also **pest**; **superweed**.)

Appendix 2: Transgenic Crops in the U.S.

Table 1. Current transgenic crops on the U.S. market by crop and trait.[1]

Crop	Herbicide	Insecticide	Other
Corn	Liberty® Imidazolinone (2) Roundup Ultra™ Glufosinate Roundup® (2)	Bt (4)	Protein toxic to Lepidoptera High pH-tolerant Resistant to disease (gray leaf spot) Bt + Liberty + imidazolinone
Canola	Liberty® Imidazolinone (ODYSSEY®)		
Cotton	Protein Roundup®	Bt Stacked Bt	
Soybean	Roundup® (2)		High oleic acid Low linolenic acid Low saturated fat oil
Potato		Bt	
Tomato			Taste, texture, and shelf life of 30–40 days Increased pectin
Sweet mini-pepper			Taste, texture, and seedless
Cherry tomato			Taste, color, and texture
Sunflower			High oleic acid (2)
Peanut			High oleic acid (2)

[1] Number in parentheses beside a particular trait (herbicide, insecticide, or other) indicates the number of different commercialized products with that trait. NOTE that traits are combined here for presentation purposes only; each of the three trait categories exists independently of the others (e.g., for corn, 15 transgenic varieties are listed).

Source: BIO Member Survey (BIO, 2000b). Biotechnology Industry Organization represents more than 850 biotechnology companies, academic institutions, and state biotechnology centers in 46 states and 26 countries. BIO members are involved in research and development of health care, agricultural, and environmental biotechnology products.

Table 2. Acreage of transgenic and total crops grown in the United States and Canada in 1999.

Agricultural biotechnology products in 1999 U.S./Canada market

Crop	Approx. acreage (in millions)	Total U.S. crop acreage (in millions)	Transgenic percent of total acreage
Corn (U.S.)	28.3	76.2	37
Soybean (U.S.)	35	74.2	47
Cotton (U.S.)	7.0	14.6	48
Canola[1]	5.3	15	35
Potato[1]	0.06	—	—
Total	76.2	—	—

[1] For both U.S. and Canada. Canola is grown mainly in Canada.

Source: BIO Member Survey (BIO, 2000a).

Appendix 3: Public Information Quantity and Quality

Despite the small core of relevant scientific information on the environmental effects of agricultural biotechnology, voluminous public information about such effects has appeared. The profusion of information likely reflects the intense crosscurrents of public interest in the issues. Not surprisingly, there is a good deal of recycling of the small body of scientific findings.

There is a paucity of professional, peer-reviewed literature that evaluates the structure and operation of information institutions and non-governmental organizations dealing with agricultural biotechnology. To gain an appreciation for the range of public information sources, a search of Internet (World Wide Web) sites that provide information on agricultural biotechnology was conducted. The search revealed a central finding: institutions or mechanisms to ensure the quality of information on agri-biotechnology are missing, both in terms of authority and responsibility for quality assurance.

Diverse Information Sources

There appears to be a growing number of public and public-private information institutions that support crop biotechnology transfer and information dissemination. These information institutions are relatively young (formed within the last decade) and the information is available for free (e.g., Information Systems for Biotechnology) and less often, for a fee (e.g., AgBiotechNet), depending on the institution. These information institutions and services address a variety of different areas including agriculture, science, technology, industry, environment, and trade. The community of users of these information sources includes scientists, researchers, policymakers, commercial business, and citizens and consumers in both developed and developing countries.

Agricultural biotechnology information sources include the following categories:

- <u>Governmental and quasi-governmental entities</u>, such as the USDA/National Agricultural Library-Biotechnology Information Resource; the U.S. EPA Toxic Substances Control Act Biotechnology Program; the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition; the U.K. Department of the Environment, Advisory Committee on Releases to the Environment (ACRE); the Canadian Biotechnology Advisory Committee; the European Union's European Plant Biotechnology Network; Information Systems for Biotechnology (Virginia Tech); and the Organisation for Economic Co-operation and Development's BioTrack Online

- <u>Nonprofit biotechnology entities</u>, such as the National Agricultural Biotechnology Council (NABC); International Service for the Acquisition of Agri-Biotech Applications (ISAAA); and AgBiotechNet

- <u>Nonprofit consumer and environmental organizations</u>, such as Genetic Resources Action International (GRAIN); Greenpeace International; Rural Advancement Foundation International (RAFI); The Edmonds Institute; and Union of Concerned Scientists

- Industry trade associations and for-profit entities, such as the Biotechnology Industry Organization (BIO); American Crop Protection Association; and Council for Biotechnology Information

A listing of the Web site addresses of these organizations (and others) is given below to illustrate the large number of diverse organizations providing agri-biotechnology information on the Internet.

The number of public and public-private information institutions that support the environmentally responsible use of agricultural biotechnology products is significantly smaller than the entire set of information institutions, however. Information Systems for Biotechnology (ISB), funded by a grant from the USDA to Virginia Polytechnic Institute & State University, and involving other universities, appears to be one of the more balanced information sources on agri-biotechnology and the environment. Some non-governmental organizations (NGOs), including Greenpeace, for example, are providing information on agricultural biotechnology and the environment, but tend to focus on the costs and potential costs of biotechnology, to the exclusion of potential environmental benefits. The small number of information sources addressing the environmental effects of agricultural biotechnology, like the small science base, is likely a "public good" problem in need of policy initiatives.

A clearinghouse for the myriad existing information sources is needed to facilitate orderly searches by the general public and policy communities. Without such a clearinghouse, there is greater chance of an incomplete understanding of all effects by all interest groups. Furthermore, a quality filter for information is needed to ensure that readers can assess the veracity and completeness of the information. This quality-assurance role could be filled by a public entity apart from the regulating agencies, to remove potential conflicts of interest. Once the clearinghouse and quality-assurance institutions are in place, the need for institutions to apply the information to agricultural biotechnology and environmental issues emerges. The USDA's Cooperative Extension Service traditionally delivered this type of educational outreach and technology transfer to U.S. agriculture, but its capacity has diminished over time. An opportunity may exist for a new public-private partnership, including industry and NGOs in collaboration with Extension, to fill this gap. With such a diverse membership, this new educational and technology transfer institution would more likely consider the environmental and ecosystem effects of crop biotechnology.

Internet Sources of Agricultural Biotechnology Information

Governmental and Quasi-governmental Entities

Ag-West Biotech, funded by Saskatchewan's Department of Agriculture and Food: http://www.agwest.sk.ca/

- publishes *AgBiotech Bulletin*, http://www.agwest.sk.ca/bulletinonline.html

Australian Department of Health and Aged Care, Genetic Manipulation Advisory Committee (GMAC)

- Deliberate Release Information, http://www.health.gov.au/tga/gene/gmac/gmac.htm

Belgian Service of Biosafety and Biotechnology (SBB)

- Belgian Biosafety Server, http://biosafety.ihe.be/Server.html

Biosafety Information Network and Advisory Service (BINAS), a service of the United Nations Industrial Development Organization (UNIDO)

- BINAS Online, http://binas.unido.org/binas/index.php3

Biotechnology Australia: http://www.biotechnology.gov.au/

Canadian Biotechnology Advisory Committee, part of Industry Canada

- Canadian Biotechnology Strategy Online, http://strategis.ic.gc.ca/SSG/bh00127e.html

Canadian Food Inspection Agency (CFIA), part of Health Canada

- Office of Biotechnology, http://www.cfia-acia.agr.ca/english/ppc/biotech/bioteche.shtml
- Plant Health and Production Division, Plant Biosafety, http://www.cfia-acia.agr.ca/english/plaveg/pbo/pbobbve.shtml

Convention on Biological Diversity (CBD)

- Biosafety Clearing-House (BCH) http://www.biodiv.org/biosafe/protocol/BCH/Index.html

European Commission, Joint Research Centre (JRC): http://www.jrc.org/

Gene Technology Information Unit (GTIU) (Australia): http://geneinfo.hightide.net.au

International Centre for Genetic Engineering and Biotechnology (ICGEB)

- Biosafety Web Pages, http://www.icgeb.trieste.it/~bsafesrv/

Organisation for Economic Co-operation and Development (OECD)

- BioTrack Online (Biotechnology Regulatory Developments in OECD Member Countries), http://www.oecd.org/ehs/country.htm
- Database of Field Trials, http://www.olis.oecd.org/biotrack.nsf

U.K. Department of the Environment, Transport and the Regions, Advisory Committee on Releases to the Environment (ACRE): http://www.environment.detr.gov.uk/acre/index.htm

U.K. Department of Trade and Industry (DTI)

- BioGuide (guide to biotechnology support and regulations in the U.K.), http://dtiinfo1.dti.gov.uk/bioguide/bioguide.htm#contents

U.N. Environment Programme (UNEP), International Register on Biosafety (IRB): http://irptc.unep.ch/biodiv/

U.N. Food & Agriculture Organization, Technical Cooperation Network on Plant Biotechnology in Latin America and the Caribbean (REDBIO/FAO):
http://rlc.fao.org/redes/redbio/html/home.htm

U.S. Department of Agriculture (USDA), Cooperative State Research, Education, and Extension Service (CSREES), Agricultural Research Service (ARS)

- Biotechnology Risk Assessment Research Grants Program (BRARGP), http://www.reeusda.gov/crgam/biotechrisk/biotech.htm

U.S. Department of Agriculture (USDA), Cooperative State Research, Education, and Extension Service (CSREES), Agricultural Research Service (ARS), National Agricultural Library (NAL)

- Biotechnology Information Resource (BIC), http://www.nal.usda.gov/bic/

U.S. Department of Agriculture, Cooperative State Research, Education, and Extension (CSREES), Agricultural Research Service (ARS), Plant Genome Research Program

- GrainGenes (database for small grains and sugarcane), http://wheat.pw.usda.gov/indexframe.html

U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS)

- Agricultural Biotechnology information, http://www.aphis.usda.gov/biotechnology/
- United States Regulatory Oversight in Biotechnology, http://www.aphis.usda.gov/biotech/OECD/usregs.htm#epa

U.S. Department of Health and Human Services (HHS), National Institutes of Health (NIH)

- Bioethics Resources on the Web (including biotechnology), http://www.nih.gov/sigs/bioethics/
- Guidelines for Research Involving Recombinant DNA Molecules, http://www.nih.gov/od/orda/toc.htm

U.S. Department of State, Office of International Information Programs

- Biotechnology: Food Security and Safety (thematic issue of *Economic Perspectives* Vol. 4, No. 4, October 1999, http://www.usinfo.state.gov/journals/ites/1099/ijee/bio-toc.htm
- Global Issues: Biotechnology, http://www.usinfo.state.gov/topical/global/biotech

U.S. Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics

- Toxic Substances Control Act (TSCA) Biotechnology Program, http://www.epa.gov/opptintr/biotech/

U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN)

- Biotechnology information, http://vm.cfsan.fda.gov/~lrd/biotechm.html

Nonprofit Biotechnology Entities

AgBioTechNet (Online Service for Agricultural Biotechnology, from CABI Publishing, with support from Agricultural Biotechnology Support Project): http://www.agbiotechnet.com/
Agricultural Biotechnology Support Project (ABSP), formerly Agricultural Biotechnology for Sustainable Productivity project (USAID-funded project awarded to Michigan State University's Institute of International Agriculture): http://www.iia.msu.edu/absp/

Bioline International

- publishes *BioSafety Journal*, http://www.bioline.bdt.org.br/by

Consultative Group for International Agricultural Research (CGIAR) Research Centers: http://www.cgiar.org:80/centers.htm

European Federation of Biotechnology (EFB): http://efbweb.org/

- Agri-Biotechnology Section, http://www.agbiotech.org/pages/efb/home.html
- EFB Task Group on Public Perceptions of Biotechnology, http://www.kluyver.stm.tudelft.nl/efb/tgppb/main.htm

European Plant Biotechnology Network (EPBN), project funded by European Union: http://www.epbn.org

Illinois-Missouri Biotechnology Alliance (IMBA): http://www.ssu.missouri.edu/imba/

- publishes *AgBioForum* magazine, http://www.agbioforum.missouri.edu/

Information Systems for Biotechnology (ISB), part of the National Biological Impact Assessment Program (NBIAP) and administered by the USDA's CSREES

- International Field Test Sources, http://www.isb.vt.edu/cfdocs/globalfieldtests.cfm
- publishes *ISB News Report*, http://www.isb.vt.edu

International Food Information Council (IFIC)

- Food Biotechnology information, http://ificinfo.health.org/index14.htm

International Service for the Acquisition of Agri-Biotech Applications (ISAAA): http://www.isaaa.org

Information Service for National Agricultural Research (ISNAR)

- ISNAR Biotechnology Service (IBS), supported by Government of The Netherlands, Government of Switzerland, Government of Japan, and others, http://www.cgiar.org/isnar/ibs.htm

National Agricultural Biotechnology Council (NABC), a consortium of 30 leading agricultural research and teaching universities in the U.S. and Canada: http://www.cals.cornell.edu/extension/nabc/

National Biotechnology Information Facility (NBIF), based at New Mexico State University: http://www.nbif.org

University of Guelph, Department of Plant Agriculture (Canada)

- Food Safety Network, Genetically Engineered Food, http://www.plant.uoguelph.ca/safefood/

Nonprofit Consumer and Environmental Entities

Ag BioTech InfoNet (sponsored by a consortium of scientific, environmental, and consumer organizations): http://www.biotech-info.net

The Edmonds Institute: http://www.edmonds-institute.org

Genetic Resources Action International (GRAIN): http://www.grain.org/about.htm

Greenpeace International

- Genetic Engineering information, http://www.greenpeace.org/~geneng/gehome.htm

Rural Advancement Foundation International (RAFI): http://www.rafi.org/

Union of Concerned Scientists (UCS)

- Agriculture and Biotechnology Program, http://www.ucsusa.org/agriculture/agr-home.html
- publishes *FoodWeb* (formerly *Gene Exchange*), http://www.ucsusa.org/agriculture/foodweb.html

Industry Trade Associations and For-profit Entities

AgBioS (Agriculture & Biotechnology Strategies, Canada): http://www.agbios.com/

Agricultural Groups Concerned about Resources and the Environment (AGCare) (represents producer groups in Ontario, Canada): http://www.agcare.org

American Crop Protection Association (ACPA)

- Biotechnology information, http://www.acpa.org/public/issues/biotech/indexbiotech.html

BIOTECanada: http://www.biotech.ca/

Biotechnology Industry Organization (BIO): http://www.bio.org

Council for Biotechnology Information (CBI): http://www.whybiotech.com/en/default.asp

CSIRO Australia

- Gene Technology in Australia, http://genetech.csiro.au/

Food Biotechnology Communications Network (FBCN), from Canada: http://www.foodbiotech.org

Institute for Biotechnology Information (IBI): http://www.biotechinfo.com