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PUAF 740
May 13, 2001
Ecological Risks and Benefits of Agricultural Biotechnology

Introduction

Genetically engineered food and fiber crops are rapidly transforming the political, economic and ecological landscape of American agriculture. Since the first commercially grown transgenic crop (Calgene's Flavr Savr tomato) was approved by the USDA in 1992, the technology has been adopted by US farmers at an extraordinary pace. The power to transpose DNA from one species to another now allows researchers to engineer crops with traits such as pathogen resistance, longer shelf life, drought tolerance and other commercially and potentially environmentally valuable properties.

The rapid development and widespread use of transgenic crops may also pose significant and unforeseen risks to human health and the environment. This paper will address the ecological risks and benefits of the current generation of commercially grown transgenic plants. It will review the most recent data regarding changes in chemical pesticide and herbicide use that can be attributed to transgenic crops. It will also examine several case studies that attempt to illustrate the ecological issues posed by specific new biotech crops to researchers, farmers and regulators. Finally, this paper will assess the current regulatory scheme for overseeing the adoption of biotechnology in agriculture and identify important policy issues that will play an increasing role in the next decade.

The term "genetically modified" could legitimately be used to describe nearly any species of plant grown today for domestic agriculture. Indeed, farmers have engaged in the practice of selecting desirable traits and altering the genetic composition of crops for thousands of years. However, the term today is used by regulatory agencies to describe organisms engineered using recombinant DNA (rDNA) techniques that were first developed roughly twenty years ago. These techniques are distinct from conventional breeding in several key ways. First, they allow genetic material to be exchanged between two species that could never crossbreed naturally, such as a bacterium and a potato or a jellyfish and a strawberry. Secondly, the precision of this technology

means that the novel organism contains only the desired gene or set of genes from the other source. Conversely, conventional breeding techniques typically involve the transfer of large portions of DNA, some of which may actually reduce the fitness of the new organism. Finally, the technique itself utilizes DNA segments that act as genetic markers on either side of the desired gene or gene fraction. Some of these markers are also under scrutiny for their effects on food safety and the environment.

Genetically modified crops therefore pose a number of challenges for policy makers and regulators due to the extraordinarily rapid pace of their development and adoption and their potential impact on so many facets of health, trade and the economy and the environment. In adopting what it calls a “science-based approach” to biotechnology, US regulators have chosen to evaluate the product of each new genetic modification, rather than the process itself. For example, genetically engineered foods are “generally regarded as safe” (GRAS) by the Food and Drug Administration unless they contain known allergens or compounds not generally found in conventional foods. While this case-by-case approach is deemed appropriate by many in the scientific community, others fear it creates a possibility for significant Type II errors, the situation where something is judged safe when, in fact, it is harmful. At the conclusion of this paper I will review several recommendations for modifying the regulatory framework governing biotechnology in the US in order to better monitor and safeguard ecological systems from these types of errors.

The current scale of biotechnology in US agriculture

Since their introduction nearly a decade ago, transgenic crops have been widely adopted by growers on several continents. Globally, genetically engineered crops covered 100 million hectares in 1999, nearly eight percent of land devoted to major crops. The vast majority (81%) were grown in the US and Canada (BIO, 2000a). Approximately one quarter of the land used for the cultivation of major crops in the US was planted with transgenic species in 1999. Over half the cotton and soybeans and more than 1/3 the corn and canola grown in the US in 1999 was transgenic. Other commercially grown biotech crops include tomatoes, squash and papaya.

Crop	Approximate acreage (in millions)	Total US crop acreage (in millions)	Transgenic percentage of total acreage
Corn (US)	28	76	37
Soybean (US)	35	74	47
Cotton (US)	7	14	48
Canola (US and CA)	5	15	35
Potato (US and CA)	<1	---	---
Total	76	---	---

Source: BIO Member Survey (BIO, 2000a)

Data from the United States Department of Agriculture provides another lens into the degree of development and adoption of commercial transgenic crops in the US (National Research Council, 2000). Under a regulatory program begun in 1987, the USDA has issued 887 permits for growing genetically modified organisms; most were granted for limited field tests. The agency later relaxed its rules, requiring companies to notify, rather than seek a permit, as long as the transgenic organism met certain criteria. To date 4,400 notifications have been acknowledged by the USDA and 260 were denied or withdrawn. Finally, USDA rules provide a mechanism for companies to seek “nonregulated status” for genetically modified crops they wish to sell for commercial use. Of 69 petitions submitted, the USDA has deregulated 50 varieties of genetically engineered plants. (As will be discussed in this paper, it is possible that some forms of GMO’s do not fall under the regulatory scope of the USDA and would not be included in these counts.)

Potential environmental benefits of agricultural biotechnology

Agricultural biotechnology has the potential to generate a number of environmentally beneficial outcomes. Proponents of the technology predict that genetically engineered food and fiber crops will lead to the use of fewer, less toxic or less persistent chemical pesticides and herbicides. By developing crops that are herbicide resistant, biotechnology may also reduce the

need for soil tillage as a weed-control mechanism. It is possible this could result in greater retention of water and nutrients in the soil. Other possible ecological benefits include decreased water usage due to the development of drought resistant crops and increased crop yields, which in turn could prevent the need to cultivate marginal or ecologically sensitive lands.

To date the vast majority of commercially grown biotech crops are engineered for insect, virus or herbicide resistance. Thus it is not yet possible to assess the validity of several predicted benefits, including the possibility of protecting marginal lands or the impact of drought resistant crops. However, preliminary data is becoming available regarding the impact of transgenic crops on the use of chemical insecticides and pesticides.

Overall, the amount of chemical herbicides applied to cotton and soybeans has increased since the adoption of transgenic varieties, but the number of acre-applications and the toxicity of chemicals used has decreased substantially. This change reflects farmers' use of Roundup Ready varieties of corn, cotton and soybeans that are engineered to tolerate applications of glyphosate, a broad-spectrum herbicide manufactured by Monsanto. A USDA study reveals that more than 13 million pounds of glyphosate were substituted for ten million pounds of other synthetic herbicides by soybean farmers in 1999. This change may reflect environmental improvement, since glyphosate is considered 3 to 16 times less toxic than the herbicides it replaced and is less likely to persist in the environment (Ervin et al., 2000).

Chemical insecticides applied to corn, cotton and soybeans declined by 8.2 million pounds between 1997 and 1998. While one-time comparisons are flawed due to the number of factors affecting pesticide use in agriculture, statistical models estimate that a reduction of 2.5 million pounds can be attributed to the use of pest-resistant transgenic crops (Wolfenbarger and Phifer, 2000). According to the USDA's Economic Research Service, the amount of insecticide used on Bt cotton fields to control three major pests (bollworm, pink bollworm, and tobacco budworm) in 1997 was less than half the amount used on conventional cotton crops in the same year. Insecticide use on corn dropped only slightly, a predictable outcome due to the fact that the transgenic corn targets a pest that cannot be effectively treated with conventional chemicals.

The impact on crop yields has been small to date, in part due to the fact that the first generation of biotech crops were engineered for pest-resistance and ease of production rather than yield generation. And once again, yield estimates over a time period of one or two years provide inadequate data for valid comparisons due to the influence of other factors such as weather. On the whole, Gianessi and Carpenter conclude “there seems to be no resounding yield advantage or disadvantage in Roundup Ready systems compared to conventional programs.”

In contrast, studies indicate that corn yields increased by 66 million bushels in 1999 due to the adoption of genetically engineered corn varieties. Several strains of biotech corn have been engineered to contain an insecticidal protein produced by the bacterium *Bacillus thuringiensis* (Carpenter and Gianessi, 2001). The Bt protein works against caterpillar pests including the European Corn Borer which are not well managed with conventional pesticides. Thus the widespread cultivation of Bt corn can be linked to higher yields, but it has not resulted in significant reductions in chemical applications.

Potential environmental risks of agricultural biotechnology

The primary ecological risks associated with genetically engineered food and fiber crops include the potential loss of genetic biodiversity due to gene flow from biotech crops to wild relatives; the development of “superweeds” if crops or their relatives become more aggressive or ecologically successful due to genetic engineering; the emergence of insect or virus resistance to genetically engineered plant pesticides and anti-viral properties; adverse effects of plant pesticides on non-target species; and other unknown and cumulative effects of changes in the genetic composition of crops planted on such a large scale.

There is widespread agreement that gene transfer will occur among numerous varieties of biotech crops and wild plant relatives. Specific species and families of plants (including carrots, sunflowers, squash, rice, poplar trees, grasses, berries and oilseed rape) have demonstrated a strong tendency to crossbreed with wild relatives. Others, such as corn, soybean, tomatoes and cotton are less likely to transfer genes beyond cultivated boundaries. Some researchers have expressed concern over the possibility of altering the genetic composition, and hence the

biodiversity, of rare or locally rare plant populations. However, this problem in and of itself is not unique to genetically engineered crops.

The larger debate among researchers and policy makers is the extent to which gene flow from genetically engineered crops may confer ecological advantages on wild species, possibly creating more noxious weeds. (Plants are considered weeds if they are unwanted in human dominated or natural habitats.) The development so-called “superweeds” which acquire resistance to major pests, viruses and herbicides from transgenic relatives is a significant ecological and commercial concern. However, a recent study by the National Research Council acknowledged that “we know very little about the extent to which insects and diseases limit wild, weedy populations that are sexually compatible with cultivated species.” The report concludes that inadequate funding and insufficient limitations on trial releases of transgenic crops have hobbled efforts to gather important data about the ecology of weeds before crops were released for commercialization (NRC, 2000). An article by Wolfenbarger and Phifer in *Science* magazine concurs, noting that “ecological consequences (of transgenic gene flow) in nonagricultural habitats and ecosystems largely remain unstudied.”

In considering the risks of increased weediness, it is reasonable to consider whether gene flow from genetically engineered crops poses any greater risk than from conventional plants. Certainly there is evidence of gene flow from traditional crops to wild relatives. Johnson grass, for example, is a weed with severe impacts on pasture-raised livestock that became more difficult to control after gene transfer with conventional sorghum. However, some research suggests that biotechnology does present a greater danger for several reasons. First, the technology allows specific desirable genes to be inserted into a new organism without bringing along a large quantity of unknown genetic material. In the past it was more likely that breeding techniques might increase a plant’s fitness in regard to one factor, while decreasing it in other ways (Snow and Palma, 1997). Secondly, genetic engineering makes it possible to create crops that are resistant to multiple viral and insect pests at once. For example, GE squash are now being developed with resistance to five major squash viruses. The cumulative effects of such properties may increase the likelihood that gene flow results in more successful weeds.

While more research is needed to better understand the potential for and implications of transgenetic gene flow, crop management techniques may be able to slow – although not eliminate – the process. The USDA considers gene transfer inevitable and recommends several strategies (depending on the particular crop, growing conditions and location) to reduce its impact. These include surrounding transgenetic fields with large reservoirs of conventional crops, planting border rows of conventional plants to reduce unwanted pollen spread, reducing the number of exposed field edges by planting large fields, and in some cases avoiding planting altogether near weedy relatives.

In addition, researchers are attempting to develop techniques for inserting additional traits that could slow gene transfer. For example, it may eventually be possible to develop transgenetic poplar trees that are sterile and thus unable to interbreed with wild populations. This technology is controversial, however, for other reasons and may or may not provide an adequate solution to the problem of gene flow. (Monsanto has promised not to exercise its patent on this so-called “Terminator” technology after worldwide outcry from farmers who feared it would give too much power to seed companies.)

Another ecological risk of transgenetic crops is the potential for adverse effects on non-target organisms. In other words, will plants that are engineered to produce internal pesticides be harmful to other non-pest species such as birds, butterflies, and soil dwellers and detritivores? At this time there is insufficient data to fully assess the ecological implications of pest-protected transgenetic crops or to compare those risks with the effects of conventional pesticides. Theoretically the effects could include local extinctions of specific herbivores and their specialized predators or parasites (Riggin-Bucci and Gould, 1997). Current evidence about direct and indirect effects on non-target organisms is summarized below.

Direct affects include harm done to non-pest organisms that ingest or come into contact with the plant or feed on plant detritus. In some cases, it has been found that plants were engineered to resist particular insect pests also harmed parasites and predators of that pest, thus reducing the potential for biological control. For example, structural changes in the leaves of

tobacco and tomato and potato plants were found to have detrimental effects on the natural enemies of the targeted pests (Farrar and Kennedy 1993 and Kashyap et al. 1991).

Perhaps the most well publicized studies found that Bt corn, which is engineered to protect the crop against harmful lepidopteran (butterfly) species, also affects the non-pest monarch butterfly. Monarch larvae feed exclusively on milkweed plants which frequently grow at the edges – and in the middle – of corn fields. A study by Losey et al. found that larvae died when fed on milkweed leaves dusted with high doses of Bt corn pollen. (1999). A follow-up study in which larvae were fed milkweed leaves collected from Bt corn fields found similar results (Hansen and Obrycki 1999). To date no field research has documented adverse affects on population densities of non-pest butterflies or other species. Based on initial laboratory evidence, however, researchers and policy makers need to take a closer look at the impacts of transgenic plant pesticides on non-target species, especially in crops such as corn, poplar and pine, all of which exhibit widespread pollen dispersal.

A few studies have attempted to compare the impacts of transgenic pest-protected crops with the use of conventional crops and synthetic pesticides. In the case of corn, this comparison is not appropriate, since Bt corn is engineered to protect against pests that are not well managed using chemical sprays. However, studies of Bt potato fields indicated that populations of predators (mostly birds and other insects) were 64% lower in conventional fields than in fields of transgenic Bt potatoes. In addition, aphid infestations are more frequent in conventional fields. These observations seem to indicate that conventional sprays are more harmful to ladybugs and other natural predators of crop pests than the transgenic plants are. (Hoy et al. 1998).

Currently, most pest-protected crops grown for commercial use are engineered to produce proteins of the Bt bacteria, toxins that specifically target butterfly and some beetle species. Most synthetic pesticide sprays, on the other hand, have broader effects on a wide range of insects. Thus, while initial comparisons the ecological impacts of engineered plant pesticides and conventional pesticides indicate healthier predator populations on transgenic crops, that advantage can be expected to diminish as additional plant-pesticides are developed. As a report from the National Research Commission cautions, “If in the future we continue to commercialize

pest-protected crops that constitutively express more diverse insect-specific toxins, we could inadvertently produce crops that lower general herbivore abundance. This could result in lower biodiversity of species at higher trophic levels that depend on herbivorous insects as food.”

I was unable to find any discussion in the literature regarding one additional issue related to impacts on non-target pest species. In order to reduce the likelihood of pesticide resistance developing among insects targeted by Bt crops, the EPA recommends that plants be engineered to produce a high dosage of the pesticide. If the plant generates levels of toxin well above the amount required to kill the targeted pests, there is a diminished chance that some individuals will survive and pass on their resistance to new generations. This important strategy may have the unintended consequence of making the crop more harmful to other non-target species as well.

Case studies:

Both proponents and opponents of agricultural biotechnology agree that ecological risks and benefits will vary widely depending on the particular species, climate, soil conditions, crop management methods, surrounding ecosystem, time span and other factors. This complexity is one reason why each side prefers contrasting regulatory approaches. Opponents of the technology argue that the full range of risks are unknowable and prefer that regulations err on the side of precaution. Proponents assert that a blanket prohibition or restriction on agricultural biotechnology would prevent many valuable and ecologically harmless (or even beneficial) transgenic crops from being developed.

The current position of US regulatory agencies supports the latter “science-based” approach. In theory this approach requires a case-by-case assessment of each new transgenic product and its diverse growing environments. In practice the available research and resources are often too thin to adequately predict and monitor the ecological impacts of newly developed trans-species.

It is instructive to examine several case studies to gain an understanding of the complex and unique research and policy issues that may arise with any new transgenic development.

The following examples are intended to illustrate just a few of the ecological issues that can arise. These cases cannot provide a comprehensive view; rather, they are offered to provide a greater appreciation for the challenge of implementing a “science-based” approach to regulation of biotechnology. To provide a full understanding it would be necessary to for this paper to review all fifty or more of the commercially grown transgenic crops *and* examine data regarding new products now in development.

Transgenic Squash

A recent report by the National Research Council (2000) provides a critical view of scientific data used to support the USDA’s decision to de-regulate (and thus approve for commercial use) several strains of virus-resistant squash. The case illustrates how little empirical research currently exists to evaluate ecological risks such as gene flow and increased weediness of wild relatives of transgenic crops.

Many types of squash (*Cucurbita pepo*), including zucchini, yellow summer squash and acorn squash are vulnerable to numerous viruses that are spread by aphids. As aphids are difficult to control using chemical pesticides, developing viral resistance within squash crops has been an early goal of biotechnology seed companies. In 1994 a transgenic variety of crookneck squash was developed by Upjohn/Asgrow and deregulated for commercial use by the USDA. Known as Freedom II, this squash demonstrated strong anti-viral protection against common viruses WMV2 and ZYMV (Fuchs and Consalves 1995).

The major environmental concern regarding transgenic squash is the great potential for gene flow to wild, weedy relatives. A wild variety of squash known as FLCP is an agricultural weed that grows among cotton and soybean crops throughout the southern United States. A study commissioned by the USDA concluded that FLCP is a significant pest that could theoretically gain ecological advantage from virus protection acquired through gene flow from transgenic varieties (Wilson 1993). Wilson’s review observed that hybridization between cultivated squash and FLCP is known to occur over distances as great as 1 km and that wild and cultivated varieties are vulnerable to the same viruses.

An important question, therefore, in the USDA's review of Asgrow's petition to deregulate the Freedom II, asked whether "genes for virus resistance (will be) beneficial enough to cause this weed to become more common?" To address this concern, Asgrow submitted data from a study of 14 FLCP patches in nine locations. Within this sample researchers found no cases of viral infection. However, according to the review of the data by the National Research Council, only one plant was sampled at each location (USDA 1994). In addition, the study made no mention of whether virus was present in the area among cultivated varieties at the time samples were taken from the wild.

Based on this study, the USDA concluded in 1994 that:

"Given the available knowledge, it is unlikely that resistance to ZYMV and WMV2 infection will confer a selective advantage or be maintained in FLCP populations. Surveys of natural FLCP populations for the incidence and severity of ZYMV and WMV2 infections suggest that resistance to these viruses will confer little, if any, selective advantage because disease caused by these viruses is apparently not among the factors important to the survival or reproductive success of FLCP."

The USDA also relied on this same study of nine locations to approve deregulation of other viral resistant squash varieties in 1995 and 1996. No other published studies have been conducted on the impact of acquiring virus resistance on the ecological success of FLCP. However, a conference report issued by researchers at Virginia Polytechnic Institute indicates that "recent experiments under cultivated field conditions have confirmed that transgenes for viral resistance will pass from transgenic hybrids into wild squash genotypes via natural pollen dispersal, and that viral resistance is advantageous to the wild material when this material is exposed to high viral pressure" (Traynor and Westwood, editors, 1999).

In its review of the empirical evidence and regulatory process, the National Research Council found many important flaws that could have led the agency to overlook important

ecological risks of the transgenic squash varieties. The initial sample size was very small and collected data for only one growing season. The study did not indicate whether squash viruses – which are known to be intermittent (Schultheis and Walters 1998) – were present in the area at the time samples were collected from wild plants. The USDA did not require original data for subsequent requests for de-regulation of new transgenic squash varieties. Finally, the USDA did not examine the potential for wild squash to gain advantage due to the cumulative effects of gene flow from new plants engineered to protect against increasing numbers of viruses.

The NRC report expresses concern about the precedent established by this example for the evaluation of environmental impacts of future transgenic crops. It concluded, “In cases when crucial scientific data are lacking about the potential impacts of gene flow on wild or weedy relatives, the committee recommends delaying approval of deregulation pending sufficient data (for example, surveys from several years over several regions), establishing a scientifically rigorous monitoring program in key areas to check for undesirable effects of resistance transgenes after the transgenic pest-protected plant is commercialized, or restricting the initial areas where the plants can be grown.”

Transgenic Poplar Trees

Unlike the previous example, the development of transgenic varieties of poplar trees is still in experimental stages. Research into genetically engineered trees has lagged behind research on food crops due to a number of factors. The genomic maps of tree species are less well documented than those of major food crops. Conifers have proven technically difficult to genetically modify using current rDNA methods. And the long life cycle of trees has made genetic research more costly and difficult.

However, a great deal of work is now underway to develop transgenic varieties of poplar endowed with numerous commercially valuable traits. According to a 1997 article in the *Journal of Forestry*, experimental plots of transgenic poplar trees are now being grown on more than 45,000 hectares in the northwestern and southeastern United States (Strauss et al 1997).

Most plots are currently being harvested before they flower for the first time (at around six years of age) in order to minimize gene flow from early transgenic varieties to wild populations.

The range of genetically engineered traits that may soon be found in commercially grown poplar trees gives some indication of the extraordinary power of the technology. Researchers are working to develop transgenic trees for herbicide resistance; pesticide resistance; bacterial, fungal and virus resistance; heavy metal resistance (in an effort to grow trees that can absorb soil pollutants); modified shape and rate of growth; flower sterility; frost and drought tolerance and modified wood content for ease of paper production (Charest 1995). Most of the current generation of genetically engineered trees being grown in the US is resistant to the herbicide glyphosate (Roundup).

The development of transgenic trees poses distinct challenges for those attempting to assess and regulate the ecological risks and benefits. As Canadian researcher Pierre Charest notes, “The main difference with short-lived crop plants in evaluating the risks is the potentially more profound effect of long living transgenic trees on the environment. This has a direct impact on increasing selective pressures on other organisms associated with transgenic trees.” In addition, tree species grown commercially are nearly genetically identical to wild populations, making gene flow from transgenic varieties a great concern. This phenomenon may be further complicated by the fact that some poplar species can hybridize within the same genus, making it possible for transgenic gene flow to impact several wild species.

The potential environmental benefits of transgenic poplars are significant. One current field of research is exploring ways to reduce the lignin content of wood. Lignin is a compound that essentially acts as glue or connective tissue in trees. It must be removed in the production of pulp and paper, a process that requires the use of large quantities of environmentally harmful chemicals. Engineering trees to produce less or more easily degraded lignin could result in substantial water quality improvements near paper mills.

Another potential benefit of current experiments could result from trees designed to absorb, tolerate, and store or expire heavy metals and solvents. Laboratory tests and a few highly

publicized field experiments have shown that transgenic poplar hybrids work at least as well as current soil remediation technologies and are far less expensive. Questions remain about whether the process simply transforms harmful pollutants from one medium to another or whether phytoremediation has lasting environmental benefits (AP report 1998).

An ecological benefit may also arise from the use of transgenic poplar that is resistant to glyphosate (Roundup), although the claim is controversial. Poplar trees are not strong competitors in their initial years of growth and large-scale plantations currently use heavy loads of herbicides to prepare the soil prior to planting. As trees are engineered to tolerate glyphosate, it is likely that larger quantities of this less toxic and less persistent herbicide will be used. Some studies suggest that the use of Roundup resistant trees will result in herbicide being used over larger areas of land, with less herbicide applied to each acre (Giaquinta 1992). It is also possible that herbicide resistant poplars will more durable buffers along the edges of agricultural fields, aiding in the retention of soil from wind and water erosion.

In the case of glyphosate resistant poplars, the primary ecological concerns are a) increased herbicide use, b) the potential for gene flow to wild populations and c) the development of pests that become resistant to a single, widely used herbicide. In addition, cottonwood trees themselves are considered weeds along right-of-ways, drainage ditches, and in perennial crop fields, as well as in commercially grown stands of conifers (Strauss et al, 1997). The spread of herbicide resistant genes may make management of unwanted pioneer trees more costly and chemically intensive. There is also some concern that the use of herbicide resistant poplars will cause growers to use more chemicals than necessary and to abandon other non-chemical forms of weed control.

Significant ecological concerns have also been raised about transgenic poplars engineered to produce Bt-toxins as protection against the cottonwood leaf beetle (CLB) and gypsy moth and tent caterpillars. These insect pests are significant obstacles to successful poplar plantations and are currently managed using synthetic pesticides. Research has demonstrated a high likelihood that insect strains will emerge that are resistant to Bt toxins if transgenic poplars are widely grown (Raffa et al. 1997). This is due to the opportunity for long-term

interactions between genetically engineered pesticides and target insect populations. The persistence of the same Bt toxin year after year in a transgenic poplar stand increases the chance that selective pressures will drive the emergence of pests resistant to the toxin.

Finally, it is important to note that the unique properties of trees, especially their long lifespan and genetic similarities to wild populations, create a number of challenges for researchers and policy makers. A working group on transgenic poplars convened by the Information Systems for Biotechnology of Virginia Polytechnic Institute concluded that it is very difficult to extrapolate from small trials to large-scale effects. This group noted that while the potential impact of transgenic poplars is large because of widespread pollen and seed dispersal, the current test trials will not provide sufficient data. The size of trees and the years needed to study their interactions with the ecosystem make it difficult to transpose research designs used to study transgenic food crops. Finally, the long lifespan of poplars, coupled with their tendency to reproduce vegetatively as well as sexually, complicates models of gene flow and hinders researchers' ability to assess future risks.

The current regulatory framework for transgenic food and fiber crops in the US

To date Congress has not passed legislation to address issues raised by biotechnology in agriculture. Rather, products generated using rDNA technologies are regulated under numerous existing statutes designed to protect food, agriculture and the environment. Since 1986, transgenic crops have been subject to review by three federal agencies under a document known as the Coordinated Framework for the Regulation of Biotechnology. This agreement was hammered out by the Office of Science and Technology Policy (OSTP) and continues to define the relevant roles, responsibilities and legislative mandates for three federal agencies with overlapping jurisdiction.

The framework takes the position that crops produced through biotechnology are fundamentally similar to their conventional counterparts and asserts that existing laws provide for sufficient oversight of any risks. It identifies the USDA as the lead agency responsible for regulating transgenic food and fiber crops under the 1957 Federal Plant Pest Act (FPPA).

Additionally, the Food and Drug Administration has the responsibility to ensure that transgenic crops are safe for human consumption under the Federal Food, Drug and Cosmetic Act of 1958. The framework discusses, but did not resolve, the EPA's role and relationship to its sister agencies, as will be discussed.

Essentially, the USDA is responsible for determining if a crop is safe to grow for American agriculture. Beginning in 1987 the USDA established regulations requiring a permit before conducting field tests of transgenic crops. In the early 1990's the agency changed its rules to exempt many transgenic organisms from the permit process if the crop meets certain criteria. In these cases the USDA must simply be notified of plans to test the crop. In 1993 the agency established an additional process allowing transgenic varieties to be de-regulated and sold for commercial use. De-regulation by the USDA requires an environmental assessment to fulfill the requirements of the National Environmental Policy Act (NEPA).

The role of the US Environmental Protection Agency was not fully described in the initial coordinated framework, in part due to the fact that biotechnology had not developed to the point of creating plants such as Bt-crops that produce conventional pesticides. In 1994 the EPA announced its decision to regulate "plant-pesticides" based on provisions of the Federal Insecticide, Fungicide and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act. This proposal has never been finalized due to controversy about its scientific and legal grounding, but the agency has operated under its provisions since 1995.

For a pest-protected plant (such as Bt corn) to be grown commercially, the EPA must approve its registration as a pesticidal substance and establish a tolerance level for the amount that can be present in food crops. Three types of genetically modified pest-protected plants are excluded from EPA oversight. These include transgenic plants created using genetic material from sexually compatible relatives. (In other words, the use of biotechnology to create conventional hybrids.) Also excluded from EPA regulation are plants that are engineered to produce structural changes, rather than toxins, to ward off pests. Finally, the EPA exempts plants engineered with virus protection using viral coat proteins.

Weaknesses in the current regulatory approach to transgenic crops

The EPA's involvement in the oversight of transgenic crops has been subject to criticism on many fronts. Some environmental and consumer groups are seeking fewer exemptions and beefed up scientific reviews. They also point out that an approach limited to the regulation of plant-pesticides necessarily misses other important ecological risks. Biotech industry and agricultural interests warn that overlapping and cumbersome regulations place a high cost on seed developers and diminish the likelihood that smaller companies will be able to compete successfully. These groups also object to the term "plant-pesticides" as it creates the impression that the EPA is in the business of regulating plants themselves, rather than substances produced by the plants.

A recent review of the regulatory framework for transgenic crops by the National Research Council concluded that the coordination among these three agencies was largely effective. According to this report, current laws are adequate to "regulate products on the basis of risk and/or uncertainty and to exempt from regulation products believed to pose negligible risk." However, the NRC recommended the following policy changes to improve oversight of ecological risks posed by biotechnology:

First, the report urged immediate publication by the EPA of the final rules for pest-protected plants. In the process the NRC stated that the EPA should establish a clear process to "review its regulations on the basis of new information or changed circumstances" and then make decisions to expand or revoke exemptions given to certain types of plant-pesticides under FIFRA. The NRC report claims that the EPA's current blanket exemptions for genetically engineered structural changes and virus protection may be both too broad and too narrow. The exemptions may go too far, since scientific studies have demonstrated some negative ecological impacts as a result of these types of crops. For example, changing leaf glossiness or other plant structures can impact the natural enemies of insect pests as well as the targeted pests themselves (Bottrell and Barbosa 1998). At the same time, the current rules make no provision to exempt other specific plant-pesticides that have demonstrated low risk to the environment or human health.

Additionally, the NRC report urges the EPA to identify the most ecologically relevant test organisms and procedures in order to determine the impact on non-target organisms of pest protected biotech crops. The real impact of Bt corn on monarch butterflies, for example, cannot be adequately assessed without developing scientifically rigorous and consistently applied research protocols. The NRC criticizes the USDA for failing to require original data and relying on out-dated and weak studies regarding the risks of gene flow to weedy, wild relatives.

In addition, the report identifies a new challenge to the effective oversight of biotech crops by the USDA. Under current statutes, the only transgenic plants that fall under USDA regulations are those containing genetic material that meets the agency's definition of potential "plant pests." Until recently, this language encompassed most genetically modified plants, since a plant pathogen called *Agrobacterium tumefaciens* is the most commonly used vector for inserting new genetic material into plants. Thus nearly all transgenic organisms contained some DNA from *Agrobacterium* and could be regulated as a potential plant pest under FPPA. Recently, however, new techniques such as microprojectile guns allow researchers to transfer desired genes without the use of the plant pathogen. It is unknown how the USDA will address this growing gap in its ability to effectively safeguard against the ecological and agricultural risks of transgenic crops (National Research Council, 2000).

Major policy issues and recommendations

Recommendations proposed by Winrock International (a non-profit research institution funded heavily by the Rockefeller Foundation, a cautious proponent of agriculture biotechnology), provide a useful framework for policy makers wishing to embrace the potential benefits of transgenic crops and guard against the substantial and uncertain ecological risks. I draw heavily upon Winrock's environmental assessment of transgenic crops in reaching the following conclusions.

The fundamental weakness in the US approach to regulating biotech food and fiber crops is a stunning lack of science, especially regarding long-term and cumulative ecological impacts.

The extraordinarily rapid adoption of the new technology has preceded conclusive field studies regarding the effects on non-target organisms, gene flow, the development of widespread pest and herbicide resistance among other species and other unintended ecological impacts. More than 50 transgenic varieties have been de-regulated by the USDA and sold for commercial use with virtually no provisions for monitoring ecological impacts over time. In fact, the USDA's biotechnology risk assessment program has received an average of only \$1.5 million annually, about 1% of the agency's total spending on biotech research (USDA, ARS, 2000). Funding awarded to other programs within the USDA brings the total spent for biotech risk assessment research to only 4% of all public spending on agricultural biotechnology research.

The scarcity of large-scale, long-term research is particularly grievous given the commitment of federal agencies to a "science-based" approach to the regulation of genetically modified food and fiber. In the US, transgenic crops are generally regarded as safe unless firm evidence demonstrates harm to human health, agriculture or the environment. This case-by-case approach to regulation poses a substantial burden on federal agencies to identify, research and monitor potential risk factors. As the examples in this paper illustrate, the risk factors associated with transgenic crops vary widely depending on the natural history and reproductive strategies of the modified organism, the growing environment, and the existence of weedy relatives, as well as the specific engineered genetic material and resulting traits. Simply put, a meaningful science-based approach requires devoting significantly higher public and private resources to ecological monitoring and research.

Secondly, the framework for regulating the development and commercialization of biotech food and fiber crops fails to identify a single lead agency responsible for comprehensive, proactive oversight of the ecological risks posed by transgenic crops. The USDA's primary mandate is to ensure that such crops will not pose undue risks to American agriculture. The EPA only regulates pest-protected plants, about 40% of current transgenic crops. Neither agency is responsible for evaluating and monitoring the full ecological implications of the technology. The existing regulatory scheme also leads to fragmented and overlapping data and is riddled with other flaws. At this time, when the USDA's jurisdiction over "plant pests" encompasses fewer

and fewer genetically modified organisms, it is worth revisiting the framework and existing statutes in an effort to ensure a thoughtful, holistic approach to ecological concerns.

In addition to increasing investment in ecological research and designating a lead agency to assess the ecological implications of genetic engineering in agriculture, Winrock advocates increasing public information and transparency regarding regulatory decisions and incorporating ethical values and socioeconomic factors into decision-making. These latter points are clearly the most difficult for federal agencies to achieve, as they require the cultivation of meaningful public education and participation in decisions about agricultural biotechnology, an issue that is now completely out-of-view for most Americans.

The sheer difficulty of the task, however, does not obviate the importance of engaging American society in grappling with the many questions and tradeoffs raised by agricultural biotechnology. The ecological risks and benefits of transgenic crops can and must be better delineated through scientific research and analysis. The roles and functions of regulatory agencies must be reworked to reduce the gaps in oversight and provide for more thorough monitoring. Ultimately, however, the science emerging from these efforts must be used to inform the messy, slow and essential process of democratic decision-making.

Resources

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